**Blisovi™ Fe 1/20**

(norethindrone acetate and ethinyl estradiol tablets USP and ferrous fumarate tablets*)

1 mg/0.02 mg

*Ferrous fumarate tablets are not USP for dissolution

**Blisovi™ Fe 1/20**

Each yellow tablet contains 1 mg norethindrone acetate and 20 mcg ethinyl estradiol. Each brown tablet contains 75 mg ferrous fumarate.

Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

**DESCRIPTION**

Blisovi™ Fe 1/20 is a progestogen–estrogen combination.

Blisovi Fe 1/20 provides a continuous dosage regimen consisting of 21 oral contraceptive tablets and seven ferrous fumarate tablets. The ferrous fumarate tablets are present to facilitate ease of drug administration via a 28-day regimen, are non-hormonal, and do not serve any therapeutic purpose.

Each yellow tablet contains norethindrone acetate (17α-ethinyl-19-nortestosterone acetate), 1 mg; ethinyl estradiol (17α-ethinyl-1,3,5(10)-estratriene-3,17β-diol), 20 mcg.

Each brown tablet contains ferrous fumarate tablets, magnesium stearate, microcrystalline cellulose, povidone, sodium starch glycolate, and sucrose. The ferrous fumarate tablets do not serve any therapeutic purpose.

**CLINICAL PHARMACOLOGY**

Combination oral contraceptives act by suppression of gonadotropins. Although the primary mechanism of this action is inhibition of ovulation, other alterations include changes in the cervical mucus (which increase the difficulty of sperm entry into the uterus) and the endometrium (which reduce the likelihood of implantation).

**Pharmacokinetics**

The pharmacokinetics of Blisovi Fe 1/20 have not been characterized; however, the following pharmacokinetic information regarding norethindrone acetate and ethinyl estradiol is taken from the literature.

**Absorption**

Norethindrone acetate appears to be completely and rapidly deacetylated to norethindrone after oral administration, since the disposition of norethindrone acetate is indistinguishable from that of orally administered norethindrone (1). Norethindrone acetate and ethinyl estradiol are subject to first-pass metabolism after oral dosing, resulting in an absolute bioavailability of approximately 64% for norethindrone and 43% for ethinyl estradiol (1-3).

**Distribution**

Volume of distribution of norethindrone and ethinyl estradiol ranges from 2 to 4 L/kg (1-3). Plasma protein binding of both steroids is extensive (greater than 95%); norethindrone binds to both albumin and sex hormone binding globulin, whereas ethinyl estradiol binds only to albumin (4).

**Metabolism**

Norethindrone undergoes extensive biotransformation, primarily via reduction, followed by sulfate and glucuronide conjugation. The majority of metabolites in the circulation are sulfates, with glucuronides accounting for most of the urinary metabolites (5). A small amount of norethindrone acetate is metabolically converted to ethinyl estradiol. Ethinyl estradiol is also extensively metabolized, both by oxidation and by conjugation with sulfate and glucuronide. Sulfates are the major circulating conjugates of ethinyl estradiol and glucuronides predominate in urine. The primary oxidative metabolite is 2-hydroxy ethinyl estradiol, formed by the CYP2A4 isomerase of cytochrome P450. Part of the first-pass metabolism of ethinyl estradiol is believed to occur in gastrointestinal mucosa. Ethinyl estradiol may undergo enterohepatic circulation (6).

**Excretion**

Norethindrone and ethinyl estradiol are excreted in both urine and feces, primarily as metabolites (5,6). Plasma clearance values for norethindrone and ethinyl estradiol are similar (approximately 0.4 L/hr/kg) (1-3).
Special Population

Race

The effect of race on the disposition of Blisovi Fe 1/20 has not been evaluated.

Renal Insufficiency

The effect of renal disease on the disposition of Blisovi Fe 1/20 has not been evaluated. In premenopausal women with chronic renal failure undergoing peritoneal dialysis who received multiple doses of an oral contraceptive containing ethinyl estradiol and norethindrone, plasma ethinyl estradiol concentrations were higher and norethindrone concentrations were unchanged compared to concentrations in premenopausal women with normal renal function.

Hepatic Insufficiency

The effect of hepatic disease on the disposition of Blisovi Fe 1/20 has not been evaluated. However, ethinyl estradiol and norethindrone may be poorly metabolized in patients with impaired liver function.

Drug-Drug Interactions

Numerous drug-drug interactions have been reported for oral contraceptives. A summary of these is found under PRECAUTIONS, Drug Interactions.

INDICATIONS AND USAGE

Blisovi Fe 1/20 is indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.

Oral contraceptives are highly effective. Table I lists the typical accidental pregnancy rates for users of combination oral contraceptives and other methods of contraception. The efficacy of these contraceptive methods, except sterilization, depends upon the reliability with which they are used. Correct and consistent use of methods can result in lower failure rates.

<table>
<thead>
<tr>
<th>Method</th>
<th>Lowest Expected</th>
<th>Typical</th>
</tr>
</thead>
<tbody>
<tr>
<td>(No contraception)</td>
<td>(85)</td>
<td>(85)</td>
</tr>
<tr>
<td>Oral contraceptive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combined</td>
<td>0.1</td>
<td>N/A²</td>
</tr>
<tr>
<td>Progestin only</td>
<td>0.5</td>
<td>N/A²</td>
</tr>
<tr>
<td>Diaphragm with spermicidal cream or jelly</td>
<td>6</td>
<td>20</td>
</tr>
<tr>
<td>Spermicides alone (foam, creams, gels, vaginal suppositories, and vaginal film)</td>
<td>6</td>
<td>26</td>
</tr>
<tr>
<td>Vaginal Sponge</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nulliparous</td>
<td>9</td>
<td>20</td>
</tr>
<tr>
<td>Parous</td>
<td>20</td>
<td>40</td>
</tr>
<tr>
<td>Implant</td>
<td>0.05</td>
<td>0.05</td>
</tr>
<tr>
<td>Injection depot medroxyprogesterone acetate</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td>IUD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Progesterone T</td>
<td>1.5</td>
<td>2.0</td>
</tr>
<tr>
<td>Copper T 380A</td>
<td>0.6</td>
<td>0.8</td>
</tr>
<tr>
<td>LNG 20</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Condom without spermicides</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>5</td>
<td>21</td>
</tr>
<tr>
<td>Male</td>
<td>3</td>
<td>14</td>
</tr>
<tr>
<td>Cervical Cap with spermicidal cream of jelly</td>
<td>9</td>
<td>20</td>
</tr>
<tr>
<td>Nulliparous</td>
<td>26</td>
<td>40</td>
</tr>
<tr>
<td>Parous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Periodic abstinence (all methods)</td>
<td>1 to 9</td>
<td>25</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>4</td>
<td>19</td>
</tr>
<tr>
<td>Female sterilization</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Male sterilization</td>
<td>0.10</td>
<td>0.15</td>
</tr>
</tbody>
</table>

Adapted from RA Hatcher et al, Reference 7.

* The authors’ best guess of the percentage of women expected to experience an accidental pregnancy among couples who initiate a method (not necessarily for the first time) and who use it consistently and correctly during the first year if they do not stop for any other reason.

† This term represents “typical” couples who initiate use of a method (not necessarily for the first time), who experience an accidental pregnancy during the first year if they do not stop use for any other reason.

‡ N/A—Data not available.

CONTRAINDICATIONS

Oral contraceptives should not be used in women who currently have the following conditions:

- Thrombophlebitis or thromboembolic disorders
- A past history of deep vein thrombophlebitis or thromboembolic disorders
- Cerebral vascular or coronary artery disease
- Known or suspected carcinoma of the breast
- Carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia
- Undiagnosed abnormal genital bleeding
- Cholestatic jaundice of pregnancy or jaundice with prior pill use
- Hepatic adenomas or carcinomas
- Known or suspected pregnancy
- Are receiving Hepatitis C drug combinations containing ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, due to the potential for ALT elevations (see WARNINGS, RISK OF LIVER ENZYME ELEVATIONS WITH CONCOMITANT HEPATITIS C TREATMENT).

WARNINGS

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

The use of oral contraceptives is associated with increased risks of several serious conditions including myocardial infarction, thromboembolism, stroke, hepatic neoplasia, and gallbladder disease, although the risk of serious morbidity or mortality is very small in healthy women without underlying risk factors. The risk of morbidity and mortality increases significantly in the presence of other underlying risk factors such as hypertension, hyperlipidemias, obesity, and diabetes.
Practitioners prescribing oral contraceptives should be familiar with the following information relating to these risks.

The information contained in this package insert is principally based on studies carried out in patients who used oral contraceptives with higher formulations of estrogens and progestogens than those in common use today. The effect of long-term use of the oral contraceptives with lower formulations of both estrogens and progestogens remains to be determined.

Throughout this labeling, epidemiological studies reported are of two types: retrospective or case control studies and prospective or cohort studies. Case control studies provide a measure of the relative risk of a disease, namely, the ratio of the incidence of a disease among oral contraceptive users to that among nonusers. The relative risk does not provide information on the actual clinical occurrence of a disease. Cohort studies provide a measure of attributable risk, which is the difference in the incidence of disease between oral contraceptive users and nonusers. The attributable risk does provide information on the actual clinical occurrence of a disease in the population (adapted from References 8 and 9 with the author's permission). For further information, the reader is referred to a text on epidemiological methods.

1. **Thromboembolic Disorders and Other Vascular Problems**

   a. **Myocardial Infarction**

   An increased risk of myocardial infarction has been attributed to oral contraceptive use. This risk is primarily in smokers or women with other underlying risk factors for coronary artery disease such as hypertension, hypercholesterolemia, morbid obesity, and diabetes. The relative risk of heart attack for current oral contraceptive users has been estimated to be two to six (10-16). The risk is very low under the age of 30.

   Smoking in combination with oral contraceptive use has been shown to contribute substantially to the incidence of myocardial infarction in women in their mid-thirties or older with smoking accounting for the majority of excess cases (17). Mortality rates associated with circulatory disease have been shown to increase substantially in smokers over the age of 35 and non-smokers over the age of 40 (Table II) among women who use oral contraceptives.

   b. **Thromboembolism**

   An increased risk of thromboembolic and thrombotic disease associated with the use of oral contraceptives is well established. Case control studies have found the relative risk of users compared to non-users to be 3 for the first episode of superficial vein thrombosis, 4 to 11 for deep vein thrombosis or pulmonary embolism, and 1.5 to 6 for women with predisposing conditions for venous thromboembolic disease (9,10,25-30). Cohort studies have shown the relative risk to be somewhat lower, about 3 for new cases and about 4.5 for new cases requiring hospitalization (31). The risk of thromboembolic disease due to oral contraceptives is not related to length of use and disappears after pill use is stopped (8).

   A two- to four-fold increase in relative risk of postoperative thromboembolic complications has been reported with the use of oral contraceptives (15,32). The relative risk of venous thrombosis in women who have predisposing conditions is twice that of women without such medical conditions (15,32). If feasible, oral contraceptives should be discontinued at least four weeks prior to and for two weeks after elective surgery of a type associated with an increase in risk of thromboembolism and during and following prolonged immobilization. Since the immediate postpartum period is also associated with an increased risk of thromboembolism, oral contraceptives should be started no earlier than four to six weeks after delivery in women who elect not to breastfeed.

   c. **Cerebrovascular Disease**

   Oral contraceptives have been shown to increase both the relative and attributable risks of cerebrovascular events (thrombotic and hemorrhagic strokes), although, in general, the risk is greatest among older (greater than 35 years), hypertensive women who also smoke. Hypertension was found to be a risk factor for both users and nonusers, for both types of strokes, while smoking interacted to increase the risk for hemorrhagic strokes (33-35).

   In a large study, the relative risk of thrombotic strokes has been shown to range from 3 for normotensive users to 14 for users with severe hypertension (36). The relative risk of hemorrhagic stroke is reported to be 1.2 for non-smokers who used oral contraceptives, 2.6 for smokers who did not use oral contraceptives, 7.6 for smokers who used oral contraceptives, 1.8 for normotensive users, and 25.7 for users with severe hypertension (36). The attributable risk is also greater in older women (9).

   d. **Dose-Related Risk of Vascular Disease from Oral Contraceptives**

   A positive association has been observed between the amount of estrogen and progestogen in oral contraceptives and the risk of vascular disease (37-39). A decline in serum high-density lipoprotein (HDL) has been reported with many progestational agents (20-22). A decline in serum high-density lipoprotein has been associated with an increased incidence of ischemic heart disease. Because estrogen increase HDL cholesterol, the net effect of an oral contraceptive depends on a balance achieved between doses of estrogen and progestin and the nature of the progestin used in the
contraceptives. The amount and activity of both hormones should be considered in the choice of an oral contraceptive.

Minimizing exposure to estrogen and progestogen is in keeping with good principles of therapeutics. For any particular oral contraceptive, the dosage regimen prescribed should be one which contains the least amount of estrogen and progestogen that is compatible with the needs of the individual patient.

New acceptance of oral contraceptive agents should be started on preparations containing the lowest dose of estrogen which produces satisfactory results for the patient.

e. Persistence of Risk of Vascular Disease

There are two studies which have shown persistence of risk of vascular disease for ever-users of oral contraceptives. In a study in the United States, the risk of developing myocardial infarction after discontinuing oral contraceptives persisted for at least 9 years for women 40 to 49 years who had used oral contraceptives for 5 or more years, but this increased risk was not demonstrated in other age groups (14). In another study in Great Britain, the risk of developing cerebrovascular disease persisted for at least 6 years after discontinuation of oral contraceptives, although excess risk was very small (40). However, both studies were performed with oral contraceptive formulations containing 50 mcg or higher of estrogen.

2. Estimates of Mortality from Contraceptive Use

One study gathered data from a variety of sources which have estimated the mortality rate associated with different methods of contraception at different ages (Table III). These estimates include the combined risk of death associated with contraceptive methods plus the risk attributable to pregnancy in the event of method failure. Each method of contraception has its specific benefits and risks. The study concluded that with the exception of oral contraceptive users 35 and older who smoke and 40 and older who do not smoke, mortality associated with all methods of birth control is low and below that associated with childbirth. The observation of a possible increase in risk of mortality with age for oral contraceptive users is based on data gathered in the 1970s but not reported until 1983 (41). However, current clinical practice involves the use of lower estrogen dose formulations combined with careful restriction of oral contraceptive use to women who do not have the various risk factors listed in this labeling.

Because of these changes in practice and, also, because of some limited new data which suggest that the risk of cardiovascular disease with the use of oral contraceptives may now be less than previously observed (Porter JB, Hunter J, Jick H, et al. Oral contraceptives and nonfatal vascular disease. Obstet Gynecol 1985;66:1-4 and Porter JB, Hershel J, Walker AM. Mortality among oral contraceptive users. Obstet Gynecol 1987;70:26-32), the Fertility and Maternal Health Drugs Advisory Committee was asked to review the topic in 1989. The Committee concluded that although cardiovascular disease risks may be increased with oral contraceptive use after age 40 in healthy non-smoking women (even with the newer low-dose formulation), there are greater potential health risks associated with pregnancy in older women and with the alternative surgical and medical procedures which may be necessary if such women do not have access to effective and acceptable means of contraception.

Therefore, the Committee recommended that the benefits of oral contraceptive use by healthy non-smoking women over 40 may outweigh the possible risks. Of course, older women and all women who take oral contraceptives, should take the lowest possible dose formulation that is effective.

<table>
<thead>
<tr>
<th>Method of control and outcome</th>
<th>15 to 19</th>
<th>20 to 24</th>
<th>25 to 29</th>
<th>30 to 34</th>
<th>35 to 39</th>
<th>40 to 44</th>
</tr>
</thead>
<tbody>
<tr>
<td>No fertility control methods*</td>
<td>7.0</td>
<td>7.4</td>
<td>9.1</td>
<td>14.8</td>
<td>25.7</td>
<td>28.2</td>
</tr>
<tr>
<td>Oral contraceptives non-smoker†</td>
<td>0.3</td>
<td>0.5</td>
<td>0.9</td>
<td>1.9</td>
<td>13.8</td>
<td>31.6</td>
</tr>
<tr>
<td>Oral contraceptives smoker†</td>
<td>2.2</td>
<td>3.4</td>
<td>6.6</td>
<td>13.5</td>
<td>51.1</td>
<td>117.2</td>
</tr>
<tr>
<td>IUD†</td>
<td>0.8</td>
<td>0.8</td>
<td>1.0</td>
<td>1.0</td>
<td>1.4</td>
<td>1.4</td>
</tr>
<tr>
<td>Condom*</td>
<td>1.1</td>
<td>1.6</td>
<td>0.7</td>
<td>0.2</td>
<td>0.3</td>
<td>0.4</td>
</tr>
<tr>
<td>Diaphragm/spermicide*</td>
<td>1.9</td>
<td>1.2</td>
<td>1.2</td>
<td>1.3</td>
<td>2.2</td>
<td>2.8</td>
</tr>
<tr>
<td>Periodic abstinence*</td>
<td>2.5</td>
<td>1.6</td>
<td>1.6</td>
<td>1.7</td>
<td>2.9</td>
<td>3.6</td>
</tr>
</tbody>
</table>

Adapted from H.W. Ouy, Reference 41
* Deaths are birth related
† Deaths are method related

3. Carcinoma of the Reproductive Organs

Numerous epidemiological studies have been performed on the incidence of breast, endometrial, ovarian, and cervical cancer in women using oral contraceptives. Most of the studies on breast cancer and oral contraceptive use report that the use of oral contraceptives is not associated with an increase in the risk of developing breast cancer (42,44,49). Some studies have reported an increased risk of developing breast cancer in certain subgroups of oral contraceptive users, but the findings reported in these studies are not consistent (43,45-49,85-88). Some studies suggest that oral contraceptive use has been associated with an increase in the risk of cervical intraepithelial neoplasia in some populations of women (51-54). However, there continues to be controversy about the extent to which such findings may be due to differences in sexual behavior and other factors.

In spite of many studies of the relationship between oral contraceptive use and breast and cervical cancers, a cause and effect relationship has not been established.

4. Hepatic Neoplasia

Benign hepatic adenomas are associated with oral contraceptive use, although the incidence of benign tumors is rare in the United States. Indirect calculations have estimated the attributable risk to be in the range of 3.3 cases/100,000 for users, a risk that increases after four or more years of use (55). Rupture of rare, benign hepatic adenomas may cause death through intra-abdominal hemorrhage (56,57). Studies from Britain have shown an increased risk of developing hepatocellular carcinoma (58-60) in long-term (greater than 8 years) oral contraceptive users. However, these cancers are extremely rare in the U.S., and the attributable risk (the excess incidence) of liver cancers in oral contraceptive users approaches less than one per million users.

5. Risk of Liver Enzyme Elevations with Concomitant Hepatitis C Treatment

During clinical trials with the Hepatitis C combination drug regimen that contains ombitasvir/paritaprevir/ritonavir, with or without dasabuvir, ALT elevations greater than 5 times the upper limit of normal (ULN), including some cases greater than 20 times the ULN, were significantly more frequent in women using ethinyl estradiol-containing medications such as COCs. Discontinue Blisovi Fe 1/20 prior to starting therapy with the combination drug regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir [see CONTRAINDICATIONS (4)]. Blisovi Fe 1/20 can be restarted approximately 2 weeks following completion of treatment with the combination drug regimen.

6. Ocular Lesions
There have been clinical case reports of retinal thrombosis associated with the use of oral contraceptives. Oral contraceptives should be discontinued if there is unexplained partial or complete loss of vision; onset of proptosis or diplopia; papilledema; or retinal vascular lesions. Appropriate diagnostic and therapeutic measures should be undertaken immediately.

7. Oral Contraceptive Use Before and During Early Pregnancy
Extensive epidemiological studies have revealed no increased risk of birth defects in women who have used oral contraceptives prior to pregnancy (61-63). Such studies do not suggest a teratogenic effect, particularly insofar as cardiac anomalies and limb reduction defects are concerned (61,62,64,65), when taken inadvertently during early pregnancy.

The administration of oral contraceptives to induce withdrawal bleeding should not be used as a test for pregnancy. Oral contraceptives should not be used during pregnancy to treat threatened or habitual abortion.

It is recommended that for any patient who has missed two consecutive periods, pregnancy should be ruled out before continuing oral contraceptive use. If the patient has not adhered to the prescribed schedule, the possibility of pregnancy should be considered at the time of the first missed period. Oral contraceptive use should be discontinued if pregnancy is confirmed.

8. Gallbladder Disease
Earlier studies have reported an increased lifetime relative risk of gallbladder surgery in users of oral contraceptives and estrogens (66,67). More recent studies, however, have shown that the relative risk of developing gallbladder disease among oral contraceptive users may be minimal (68-70). The recent findings of minimal risk may be related to the use of oral contraceptive formulations containing lower hormonal doses of estrogen and progestogens.

9. Carbohydrate and Lipid Metabolic Effects
Oral contraceptives have been shown to cause glucose intolerance in a significant percentage of users (23). Oral contraceptives containing greater than 75 mcg of estrogen cause hyperinsulinism, while lower doses of estrogen cause less glucose intolerance (71). Progestogens increase insulin secretion and create insulin resistance; this effect varies with different progestational agents (22,72). However, in the non-diabetic woman, oral contraceptives appear to have no effect on fasting blood glucose (73). Because of these demonstrated effects, prediabetic and diabetic women should be carefully observed while taking oral contraceptives.

A small proportion of women will have persistent hypertriglyceridemia while on the pill. As discussed earlier (see WARNINGS, 1a. and 1d.), changes in triglycerides and lipoprotein levels have been reported in oral contraceptive users.

10. Elevated Blood Pressure
An increase in blood pressure has been reported in women taking oral contraceptives (74) and this increase is more likely in older oral contraceptive users (75) and with continued use (74). Data from the Royal College of General Practitioners (18) and subsequent randomized trials have shown that the incidence of hypertension increases with increasing concentrations of progestogens.

Women with a history of hypertension or hypertension-related diseases or renal disease (76) should be encouraged to use another method of contraception. If women elect to use oral contraceptives, they should be monitored closely, and if significant elevation of blood pressure occurs, oral contraceptives should be discontinued. For most women, elevated blood pressure will return to normal after stopping oral contraceptives (75), and there is no difference in the occurrence of hypertension among ever and never users (74,76,77).

11. Headache
The onset or exacerbation of migraine or development of headache with a new pattern which is recurrent, persistent, or severe requires discontinuation of oral contraceptives and evaluation of the cause.

12. Bleeding Irregularities
Breakthrough bleeding and spotting are sometimes encountered in patients on oral contraceptives, especially during the first three months of use. Non-hormonal causes should be considered, and adequate diagnostic measures taken to rule out malignancy or pregnancy in the event of breakthrough bleeding, as in the case of any abnormal vaginal bleeding, if pathology has been excluded, time or a change to another formulation may solve the problem. In the event of amenorrhea, pregnancy should be ruled out.

Some women may encounter post-pill amenorrhea or oligomenorrhea, especially when such a condition was preexistent.

PRECAUTIONS

1. Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

2. Physical Examination and Follow-Up
It is good medical practice for all women to have annual history and physical examination, including women using oral contraceptives. The physical examination, however, may be deferred until after initiation of oral contraceptives if requested by the woman and judged appropriate by the clinician. The physical examination should include special reference to blood pressure, breasts, abdomen and pelvic organs, including cervical cytology, and relevant laboratory tests. In case of undiagnosed persistent or recurrent abnormal vaginal bleeding, appropriate measures should be conducted to rule out malignancy.

Women with a strong family history of breast cancer or who have breast nodules should be monitored with particular care.

3. Lipid Disorders
Women who are being treated for hyperlipidemia should be followed closely if they elect to use oral contraceptives. Some progestogens may elevate LDL levels and may render the control of hyperlipidemia more difficult.

4. Liver Function
If jaundice develops in any woman receiving such drugs, the medication should be discontinued. Steroid hormones may be poorly metabolized in patients with impaired liver function.

5. Fluid Retention
Oral contraceptives may cause some degree of fluid retention. They should be prescribed with caution, and only with careful monitoring, in patients with conditions which might be aggravated by fluid retention.

6. Emotional Disorders
Women with a history of depression should be carefully observed and the drug discontinued if
There is evidence of an association between the following conditions and the use of oral contraceptives

An increased risk of the following serious adverse reactions has been associated with the use of oral contraceptives:

**ADVERSE REACTIONS**

See patient labeling printed below.

**INFORMATION FOR THE PATIENT**

See patient labeling printed below.

**ADVERSE REACTIONS**

An increased risk of the following serious adverse reactions has been associated with the use of oral contraceptives (see WARNINGS section):

- Thrombophlebitis
- Arterial thromboembolism
- Pulmonary embolism
- Myocardial infarction
- Cerebral hemorrhage
- Cerebral thrombosis
- Hyperension
- Gallbladder disease
- Hepatic adenomas or benign liver tumors

There is evidence of an association between the following conditions and the use of oral contraceptives, although additional confirmatory studies are needed:

- Mesenteric thrombosis
- Retinal thrombosis
The following adverse reactions have been reported in patients receiving oral contraceptives and are believed to be drug-related:

- Nausea
- Vomiting
- Gastrointestinal symptoms (such as abdominal cramps and bloating)
- Breakthrough bleeding
- Spotting
- Change in menstrual flow
- Amenorrhea
- Temporary infertility after discontinuation of treatment
- Edema
- Melasma which may persist
- Breast changes: tenderness, enlargement, secretion
- Change in weight (increase or decrease)
- Change in cervical erosion and secretion
- Diminution in lactation when given immediately postpartum
- Cholestatic jaundice
- Migraine
- Rash (allergic)
- Mental depression
- Reduced tolerance to carbohydrates
- Vaginal candidiasis
- Change in corneal curvature (steepening)
- Intolerance to contact lenses

The following adverse reactions have been reported in users of oral contraceptives and the association has been neither confirmed nor refuted:

- Pre-menstrual syndrome
- Cataracts
- Changes in appetite
- Cystitis-like syndrome
- Headache
- Nervousness
- Dizziness
- Hirsutism
- Loss of scalp hair
- Erythema multiforme
- Erythema nodosum
- Hemorrhagic eruption
- Vaginitis
- Porphyria
- Impaired renal function
- Hemolytic uremic syndrome
- Budd-Chiari syndrome
- Acne
- Changes in libido
- Colitis

OVERDOSE

Serious ill effects have not been reported following acute ingestion of large doses of oral contraceptives by young children. Overdosage may cause nausea, and withdrawal bleeding may occur in females.

NON-CONTRACEPTIVE HEALTH BENEFITS

The following non-contraceptive health benefits related to the use of oral contraceptives are supported by epidemiological studies which largely utilized oral contraceptive formulations containing estrogen doses exceeding 0.035 mg of ethinyl estradiol or 0.05 mg of mestranol (79-84).

Effects on menses:
- Increased menstrual cycle regularity
- Decreased blood loss and decreased incidence of iron deficiency anemia
- Decreased incidence of dysmenorrhea

Effects related to inhibition of ovulation:
- Decreased incidence of functional ovarian cysts
- Decreased incidence of ectopic pregnancies

Effects from long-term use:
- Decreased incidence of fibroadenomas and fibrocystic disease of the breast
- Decreased incidence of acute pelvic inflammatory disease
- Decreased incidence of endometrial cancer
- Decreased incidence of ovarian cancer

DOSAGE AND ADMINISTRATION

The blister has been designed to make oral contraceptive dosing as easy and as convenient as possible. The tablets are arranged in four rows of seven tablets each, with the days of the week appearing on the blister above the first row of tablets.

Note: Each blister has been preprinted with the days of the week, starting with Sunday, to facilitate a Sunday-Start regimen. Six different day label strips have been provided with the Detailed Patient & Brief Summary Patient Package Insert in order to accommodate a Day-1 Start regimen. If the patient is using the Day-1 Start regimen, she should place the self-adhesive day label strip that corresponds to her starting day over the preprinted days.

Important: The patient should be instructed to use an additional method of protection until after the first week of administration in the initial cycle when utilizing the Sunday-Start regimen.

The possibility of ovulation and conception prior to initiation of use should be considered.

Dosage and Administration for 28-Day Dosage Regimen

To achieve maximum contraceptive effectiveness, Blisovi Fe 1/20 should be taken exactly as directed and at intervals not exceeding 24 hours.

Blisovi Fe 1/20 provides a continuous administration regimen consisting of 21 yellow tablets of norethindrone acetate and ethinyl estradiol, 1 mg/0.02 mg and 7 brown non-hormone containing tablets of ferrous fumarate. The ferrous fumarate tablets are present to facilitate ease of drug administration via a 28-day regimen and do not serve any therapeutic purpose. There is no need for the patient to count days between cycles because there are no “off-tablet days.”

1. **Sunday-Start Regimen**: The patient begins taking the first yellow tablet from the top row of the
Each blister contains 28 tablets, as follows: (NDC 68180-865-71). Such three pouches are packaged in a carton (NDC 68180-865-73).

**HOW SUPPLIED**

Menstruation usually begins two or three days, but may begin as late as the fourth or fifth day, after the brown tablets have been started. In any event, the next course of tablets should be started without interruption. If spotting occurs while the patient is taking yellow tablets, continue medication without interruption.

If the patient forgets to take one or more yellow tablets, the following is suggested:

**One tablet is missed**
- take tablet as soon as remembered
- take next tablet at the regular time

**Two consecutive tablets are missed (week 1 or week 2)**
- take two tablets as soon as remembered
- take two tablets the next day
- use another birth control method for seven days following the missed tablets

**Two consecutive tablets are missed (week 3)**

**Sunday-Start Regimen:**
- take one tablet daily until Sunday
- discard remaining tablets
- start new pack of tablets immediately (Sunday)
- use another birth control method for seven days following the missed tablets

**Day-1 Start Regimen:**
- discard remaining tablets
- start new pack of tablets that same day
- use another birth control method for seven days following the missed tablets

**Three (or more) consecutive tablets are missed**

**Sunday-Start Regimen:**
- take one tablet daily until Sunday
- discard remaining tablets
- start new pack of tablets immediately (Sunday)
- use another birth control method for seven days following the missed tablets

**Day-1 Start Regimen:**
- discard remaining tablets
- start new pack of tablets that same day
- use another birth control method for seven days following the missed tablets

The possibility of ovulation occurring increases with each successive day that scheduled yellow tablets are missed. While there is little likelihood of ovulation occurring if only one yellow tablet is missed, the possibility of spotting or bleeding is increased. This is particularly likely to occur if two or more consecutive yellow tablets are missed.

If the patient forgets to take any of the seven brown tablets in week four, those brown tablets that were missed are discarded and one brown tablet is taken each day until the pack is empty. A back-up birth control method is not required during this time. A new pack of tablets should be started no later than the eighth day after the last yellow tablet was taken.

In the rare case of bleeding which resembles menstruation, the patient should be advised to discontinue medication and then begin tablets from a new blister on the next Sunday or the first day (Day-1), depending on her regimen. Persistent bleeding which is not controlled by this method indicates the need for reexamination of the patient, at which time nonfunctional causes should be considered.

**Use of Oral Contraceptives in the Event of a Missed Menstrual Period:**

1. If the patient has not adhered to the prescribed dosage regimen, the possibility of pregnancy should be considered after the first missed period and oral contraceptives should be withheld until pregnancy has been ruled out.
2. If the patient has adhered to the prescribed regimen and misses two consecutive periods, pregnancy should be ruled out before continuing the contraceptive regimen.

After several months on treatment, bleeding may be reduced to a point of virtual absence. This reduced flow may occur as a result of medication, in which event it is not indicative of pregnancy.

**HOW SUPPLIED**

Bikini Fe 1/20 (norethindrone acetate and ethinyl estradiol tablets USP, 1 mg/0.02 mg and ferrous fumarate tablets) are available in a blister (NDC 68180-865-71) containing 28 tablets packed in a pouch (NDC 68180-865-71). Such three pouches are packaged in a carton (NDC 68180-865-73).

Each blister contains 28 tablets, as follows:
- 21 yellow coloured, round flat face beveled edged tablets, each containing 1 mg norethindrone acetate and 0.02 mg ethinyl estradiol, debossed with “LU” on one side and “J23” on the other side.
- 7 brown mottled, round, flat face beveled edged tablets debossed with “LU” on one side and “M22” on the other side.
on the other side. Each brown tablet contains 75 mg ferrous fumarate. The ferrous fumarate tablets are present to facilitate ease of drug administration via a 28-day regimen, are non-hormonal, and do not serve any therapeutic purpose.

Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature].

REFERENCES


Manufactured by:
Lupin Pharmaceuticals, Inc.
Baltimore, Maryland 21202
United States

Distributed by:
Lupin Limited
Pithampur (M.P.) - 454 775
INDIA
Revised: April 2019

Bilnovi™ Fe 1/20 (noretindrone acetate and ethinyl estradiol tablets USP and ferrous fumarate tablets*)
1 mg/0.02 mg

*Ferrous fumarate tablets are not USP for dissolution

The patient labeling for oral contraceptive drug products is set forth below:

This brief summary patient package insert

Oral contraceptives, also known as “birth control pills” or “the pill,” are taken to prevent pregnancy and, when taken correctly, have a failure rate of about 1% per year when used without missing any pills. The typical failure rate of large numbers of pill users is less than 3% per year when who miss pills are included. For most women, oral contraceptives are also free of serious or unpleasant side effects. However, forgetting to take pills considerably increases the chances of pregnancy.

For the majority of women, oral contraceptives can be taken safely. But there are some women who are at high risk of developing certain serious diseases that can be life-threatening or may cause temporary or permanent disability. The risks associated with taking oral contraceptives increase significantly if you:

- Smoke
- Have high blood pressure, diabetes, high cholesterol
- Have or have had clotting disorders, heart attacks, stroke, angina pectoris, cancer of the breast or sex organs, jaundice, or malignant or benign liver tumors.

You should not take the pill if you suspect you are pregnant or have unexplained vaginal bleeding.

Most side effects of the pill are not serious. The most common side effects are nausea, vomiting, bleeding between menstrual periods, weight gain, breast tenderness, and difficulty wearing contact lenses. These side effects, especially nausea, vomiting, and breakthrough bleeding may subside within the first three months of use.

The serious side effects of the pill occur very infrequently, especially if you are in good health and are young. However, you should know that the following medical conditions have been associated with or made worse by the pill:

1. Blood clots in the legs (thrombophlebitis), lungs (pulmonary embolism), stoppage or rupture of a blood vessel in the brain (stroke), blockage of blood vessels in the heart (heart attack or angina pectoris) or other organ of the body. As mentioned above, smoking increases the risk of heart attacks and strokes and subsequent serious medical consequences.

2. Liver tumors, which may rupture and cause severe bleeding. A possible but not definite association has been found with the pill and liver cancer. However, liver cancers are extremely rare. The chance of developing liver cancer from using the pill is thus even rarer.

3. High blood pressure, although blood pressure usually returns to normal when the pill is stopped.

The symptoms associated with these serious side effects are discussed in the detailed leaflet given to you with your supply of pills. Notify your doctor or healthcare provider if you notice any unusual physical disturbances while taking the pill. In addition, drugs such as rifampin, as well as some anticonvulsants and some antibiotics, may decrease oral contraceptive effectiveness.

Most of the studies to date on breast cancer and pill use have found no increase in the risk of developing breast cancer, although some studies have reported an increased risk of developing breast cancer in certain groups of women. However, some studies have found an increase in the risk of developing cancer of the cervix in women taking the pill, but this finding may be related to differences in sexual behavior or other factors not related to use of the pill. Therefore, there is insufficient evidence to rule out the possibility that the pill may cause cancer of the breast or cervix.

Taking the pill provides some important non-contraceptive benefits. These include less painful menstruation, less menstrual blood loss and anemia, fewer pelvic infections, and fewer cancers of the ovary and the lining of the uterus.

Be sure to discuss any medical condition you may have with your healthcare provider. Your healthcare provider will take a medical and family history and examine you before prescribing oral contraceptives.

The physical examination may be delayed to another time if you request it and your healthcare provider believes that it is a good medical practice to postpone it. You should be reexamined at least once a year while taking oral contraceptives. The detailed patient information leaflet gives you further information
which you should read and discuss with your healthcare provider.

This product (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against transmission of HIV (AIDS) and other sexually transmitted diseases such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B and syphilis.

INSTRUCTIONS TO PATIENT

Blister

The Blisovi Fe 1/20 blister has been designed to make oral contraceptive dosing as easy and as convenient as possible. The tablets are arranged in four rows of seven tablets each, with the days of the week appearing on the blister above the first row of tablets.

Each blister contains 21 yellow tablets and 7 brown tablets.

Each yellow tablet contains 1 mg norethindrone acetate and 20 mcg ethinyl estradiol.

Each brown tablet contains 75 mg ferrous fumarate, and is intended to help you remember to take the tablets correctly. These brown tablets are not intended to have any health benefit.

DIRECTIONS

To remove a tablet, press down on it with your thumb or finger. The tablet will drop through the back of the blister. Do not press on the tablet with your thumbnail, fingernail, or any other sharp object.

HOW TO TAKE THE PILL

IMPORTANT POINTS TO REMEMBER

BEFORE YOU START TAKING YOUR PILLS:

1. BE SURE TO READ THESE DIRECTIONS:
   • Before you start taking your pills
   • Anytime you are not sure what to do

2. THE RIGHT WAY TO TAKE THE PILL IS TO TAKE ONE PILL EVERY DAY AT THE SAME TIME. If you miss pills you could get pregnant. This includes starting the pack late. The more pills you miss, the more likely you are to get pregnant.

3. MANY WOMEN HAVE SPOTTING OR LIGHT BLEEDING, OR MAY FEEL SICK TO THEIR STOMACH, DURING THE FIRST 1-3 PACKS OF PILLS. If you do have spotting or light bleeding or feel sick to your stomach, do not stop taking the pill. The problem will usually go away. If it doesn’t go away, check with your doctor or clinic.

4. MISSING PILLS CAN ALSO CAUSE SPOTTING OR LIGHT BLEEDING, even when you make up these missed pills. On the days you take 2 pills to make up for missed pills, you could also feel a little sick to your stomach.

5. IF YOU HAVE VOMITING OR DIARRHEA, for any reason, or IF YOU TAKE SOME MEDICINES, including some antibiotics, your birth control pills may not work as well. Use a back-up birth control method (such as condom or foam) until you check with your doctor or clinic.

6. IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL, talk to your doctor or clinic about how to make pill-taking easier or about using another method of birth control.

7. IF YOU HAVE ANY QUESTIONS OR ARE UNSURE ABOUT THE INFORMATION IN THIS LEAFLET, call your doctor or clinic.

BEFORE YOU START TAKING YOUR PILLS

1. DECIDE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILL. It is important to take it at about the same time every day.

2. LOOK AT YOUR PILL PACK TO SEE IF IT HAS 28 PILLS:

   The 28-Day pill pack has 21 “active” yellow pills (with hormones) to take for 3 weeks, followed by 1 week of reminder brown pills (without hormones).

3. ALSO FIND:
   1) where on the pack to start taking pills,
   2) in what order to take the pills (follow the arrows), and
   3) the week numbers as shown in the following picture:

   For use of day labels, see WHEN TO START THE FIRST PACK OF PILLS below.

4. BE SURE YOU HAVE READY AT ALL TIMES:

   ANOTHER KIND OF BIRTH CONTROL (such as condom or foam) to use as a back-up in case you miss pills.

   An EXTRA, FULL PILL PACK.

WHEN TO START THE FIRST PACK OF PILLS

You have a choice of which day to start taking your first pack of pills. Decide with your doctor or
DAY 1 START:

1. Pick the day label strip that starts with the first day of your period. (This is the day you start bleeding or spotting, even if it is almost midnight when the bleeding begins.)
2. Place this day label strip on the blister over the area that has the days of the week (starting with Sunday) printed on the blister.
3. Take the first “active” yellow pill of the first pack during the first 24 hours of your period.
4. You will not need to use a back-up method of birth control, since you are starting the pill at the beginning of your period.

SUNDAY START:

1. Take the first “active” yellow pill of the first pack on the Sunday after your period starts, even if you are still bleeding. If your period begins on Sunday, start the pack that same day.
2. Use another method of birth control as a back-up method if you have sex anytime from the Sunday you start your first pack until the next Sunday (7 days). Condoms or foam are good back-up methods of birth control.

WHAT TO DO DURING THE MONTH

1. **TAKE ONE PILL AT THE SAME TIME EVERY DAY UNTIL THE PACK IS EMPTY.**
   Do not skip pills even if you are spotting or bleeding between monthly periods or feel sick to your stomach (nausea).
   Do not skip pills even if you do not have sex very often.
2. **WHEN YOU FINISH A PACK OR SWITCH YOUR BRAND OF PILLS:**
   Start the next pack on the day after your last “reminder” pill. Do not wait any days between packs.

WHAT TO DO IF YOU MISS PILLS

If you **MISS 1** yellow “active” pill:
1. Take it as soon as you remember. Take the next pill at your regular time. This means you may take 2 pills in 1 day.
2. You do not need to use a back-up birth control method if you have sex.

If you **MISS 2** yellow “active” pills in a row in **WEEK 1 OR WEEK 2** of your pack:
1. Take 2 pills on the day you remember and 2 pills the next day.
2. Then take 1 pill a day until you finish the pack.
3. You **COULD GET PREGNANT** if you have sex in the **7 days** after you miss pills. You MUST use another birth control method (such as condoms or foam) as a back-up method of birth control until you have taken a yellow “active” pill every day for **7 days**.

If you **MISS 2** yellow “active” pills in a row in **THE 3RD WEEK**:
1. **If you are a Day-1 Starter:**
   THROW OUT the rest of the pill pack and start a new pack that same day.

If you are a **Sunday Starter:**
Keep taking 1 pill every day until Sunday. On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.
2. You may not have your period this month, but this is expected. However, if you miss your period 2 months in a row, call your doctor or clinic because you might be pregnant.
3. You **COULD GET PREGNANT** if you have sex in the **7 days** after you miss pills. You MUST use another birth control method (such as condoms or foam) as a back-up method of birth control until you have taken a yellow “active” pill every day for **7 days**.

If you **MISS 3 OR MORE** yellow “active” pills in a row (during the first 3 weeks):
1. **If you are a Day-1 Starter:**
   THROW OUT the rest of the pill pack and start a new pack that same day.

If you are a **Sunday Starter.**
Keep taking 1 pill every day until Sunday. On Sunday, THROW OUT the rest of the pack and start a new pack of pills that same day.
2. You may not have your period this month, but this is expected. However, if you miss your period 2 months in a row, call your doctor or clinic because you might be pregnant.
3. You **COULD GET PREGNANT** if you have sex in the **7 days** after you miss pills. You MUST use another birth control method (such as condoms or foam) as a back-up method of birth control until you have taken a yellow “active” pill every day for **7 days**.

A REMINDER FOR THOSE ON 28-DAY PACKS:

**IF YOU FORGET ANY OF THE 7 BROWN “REMEMBER” PILLS IN WEEK 4:**

**THROW AWAY THE PILLS YOU MISSED.**

**KEEP TAKING 1 PILL EACH DAY UNTIL THE PACK IS EMPTY.**

**YOU DO NOT NEED A BACK-UP METHOD.**

FINALLY, IF YOU ARE STILL NOT SURE WHAT TO DO ABOUT THE PILLS YOU HAVE MISSED:

Use a **BACK-UP METHOD** anytime you have sex.

**KEEP TAKING ONE YELLOW “ACTIVE” PILL EACH DAY** until you can reach your doctor or clinic.

Based on his or her assessment of your medical needs, your doctor or healthcare provider has prescribed this drug for you. Do not give this drug to anyone else.

Keep this and all drugs out of the reach of children.

**Rx only**

*Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature]*
Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives are strongly advised not to smoke.

This product (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

DETAILED PATIENT PACKAGE INSERT
What You Should Know About Oral Contraceptives

Any woman who considers using oral contraceptives (the "birth control pill" or "the pill") should understand the benefits and risks of using this form of birth control. This leaflet will give you much of the information you will need to make this decision and will also help you determine if you are at risk of developing any of the serious side effects of the pill. It will tell you how to use the pill properly so that it will be as effective as possible. However, this leaflet is not a replacement for a careful discussion between you and your healthcare provider. You should discuss the information provided in this leaflet with him or her, both when you first start taking the pill and during your revisits. You should also follow your healthcare provider's advice with regard to regular check-ups while you are on the pill.

EFFECTIVENESS OF ORAL CONTRACEPTIVES

Oral contraceptives or "birth control pills" or "the pill" are used to prevent pregnancy and are more effective than other non-surgical methods of birth control. When they are taken correctly, the chance of becoming pregnant is less than 1% (1 pregnancy per 100 women per year of use) when used perfectly, without missing any pills. Typical failure rates are actually 3% per year. The chance of becoming pregnant increases with each missed pill during a menstrual cycle.

In comparison, typical failure rates for other methods of birth control during the first year of use are as follows:

<table>
<thead>
<tr>
<th>Method</th>
<th>Typical Failure Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Injection</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>IUD</td>
<td>&lt;1% to 2%</td>
</tr>
<tr>
<td>Diaphragm with spermicides</td>
<td>20%</td>
</tr>
<tr>
<td>Spermicides alone</td>
<td>26%</td>
</tr>
<tr>
<td>Vaginal Sponge</td>
<td>20 to 40%</td>
</tr>
<tr>
<td>Female sterilization</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Cervical Cap</td>
<td>20 to 40%</td>
</tr>
<tr>
<td>Condom alone (male)</td>
<td>14%</td>
</tr>
<tr>
<td>Condom alone (female)</td>
<td>21%</td>
</tr>
<tr>
<td>Periodic abstinence</td>
<td>25%</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>19%</td>
</tr>
<tr>
<td>No method</td>
<td>85%</td>
</tr>
</tbody>
</table>

WHO SHOULD NOT TAKE ORAL CONTRACEPTIVES

Some women should not use the pill. For example, you should not take the pill if you are pregnant or think you may be pregnant. You should also not use the pill if you have any of the following conditions

- A history of heart attack or stroke
- Blood clots in the legs (thrombophlebitis), lungs (pulmonary embolism), or eyes
- A history of blood clots in the deep veins of your legs
- Chest pain (angina pectoris)
- Known or suspected breast cancer or cancer of the lining of the uterus, cervix, or vagina
- Unexplained vaginal bleeding (until a diagnosis is reached by your doctor)
- Yellowing of the whites of the eyes or of the skin (jaundice) during pregnancy or during previous use of the pill
- Liver tumor (benign or cancerous)
- Take any Hepatitis C drug combination containing daclatasvir/paritaprevir/ritonavir, with or without dasabuvir. This may increase levels of the liver enzyme "alanine aminotransferase" (ALT) in the blood.
- Known or suspected pregnancy

Tell your healthcare provider if you have ever had any of these conditions. Your healthcare provider can recommend a safer method of birth control.

OTHER CONSIDERATIONS BEFORE TAKING ORAL CONTRACEPTIVES

Tell your healthcare provider if you have:

- Breast nodules, fibrocystic disease of the breast, an abnormal breast x-ray or mammogram
- Diabetes
- Elevated cholesterol or triglycerides
- High blood pressure
- Migraine or other headaches or epilepsy
- Mental depression
- Gallbladder, heart or kidney disease
- History of scanty or irregular menstrual periods

Women with any of these conditions should be checked often by their healthcare provider if they choose to use oral contraceptives.

Also, be sure to inform your doctor or healthcare provider if you smoke or are on any medication.

RISKS OF TAKING ORAL CONTRACEPTIVES

1. Risk of Developing Blood Clots

Blood clots and blockage of blood vessels are the most serious side effects of taking oral contraceptives; in particular, a clot in the legs can cause thrombophlebitis, and a clot that travels to the lungs can cause a sudden blockage of the vessel carrying blood to the lungs. Rarely, clots occur in the blood vessels of the eye and may cause blindness, double vision, or impaired vision.

If you take oral contraceptives and need elective surgery, need to stay in bed for a prolonged illness, or have recently delivered a baby, you may be at risk of developing blood clot. You should consult your doctor about stopping oral contraceptives three to four weeks before surgery and not taking oral contraceptives for two weeks after surgery or during bed rest. You should also not take oral contraceptives soon after delivery of a baby. It is advisable to wait for at least four weeks after delivery.
if you are not breastfeeding. If you are breastfeeding, you should wait until you have weaned your child before using the pill. (See also the section on Breastfeeding in GENERAL PRECAUTIONS.)

2.  Heart Attacks and Strokes

Oral contraceptives may increase the tendency to develop strokes (stoppage or rupture of blood vessels in the brain) and angina pectoris and heart attacks (blockage of blood vessels in the heart). Any of these conditions can cause death or disability.

Smoking greatly increases the possibility of suffering heart attacks and strokes. Furthermore, smoking and the use of oral contraceptives greatly increase the chances of developing and dying of heart disease.

3.  Gallbladder Disease

Oral contraceptive users probably have a greater risk than nonusers of having gallbladder disease, although this risk may be related to pills containing high doses of estrogen.

4.  Liver Tumors

In rare cases, oral contraceptives can cause benign but dangerous liver tumors. These benign liver tumors can rupture and cause fatal internal bleeding. In addition, a possible but not definite association has been found with the pill and liver cancers in two studies, in which a few women who developed these very rare cancers were found to have used oral contraceptives for long periods. However, liver cancers are extremely rare. The chance of developing liver cancer from using the pill is thus even rarer.

5.  Cancer of the Reproductive Organs and Breasts

There is, at present, no confirmed evidence that oral contraceptive use increases the risk of developing cancer of the reproductive organs. Studies to date of women taking the pill have reported conflicting findings on whether pill use increases the risk of developing cancer of the breast or cervix. Most of the studies on breast cancer and pill use have found no overall increase in the risk of developing breast cancer, although some studies have reported an increased risk of developing breast cancer in certain groups of women. Women who use oral contraceptives and have a strong family history of breast cancer or who have breast nodules or abnormal mammograms should be closely followed by their doctors.

Some studies have found an increase in the incidence of cancer of the cervix in women who use oral contraceptives. However, this finding may be related to factors other than the use of oral contraceptives.

ESTIMATED RISK OF DEATH FROM A BIRTH CONTROL METHOD OR PREGNANCY

All methods of birth control and pregnancy are associated with a risk of developing certain diseases which may lead to disability or death. An estimate of the number of deaths associated with different methods of birth control and pregnancy has been calculated and is shown in the following table.

### Annual Number of Birth-Related or Method-Related Deaths Associated with Control of Fertility Per 100,000 Nonsterile Women, by Fertility Control Method According to Age

<table>
<thead>
<tr>
<th>Method of control and outcome</th>
<th>15 to 19</th>
<th>20 to 24</th>
<th>25 to 29</th>
<th>30 to 34</th>
<th>35 to 39</th>
<th>40 to 44</th>
</tr>
</thead>
<tbody>
<tr>
<td>No fertility control method*</td>
<td>7.0</td>
<td>7.4</td>
<td>9.1</td>
<td>14.8</td>
<td>25.7</td>
<td>28.2</td>
</tr>
<tr>
<td>Oral contraceptives-smoker†</td>
<td>0.3</td>
<td>0.5</td>
<td>0.9</td>
<td>1.9</td>
<td>13.8</td>
<td>31.6</td>
</tr>
<tr>
<td>Oral contraceptives-smoker†</td>
<td>2.2</td>
<td>3.4</td>
<td>6.6</td>
<td>13.5</td>
<td>51.1</td>
<td>117.2</td>
</tr>
<tr>
<td>IUD†</td>
<td>0.8</td>
<td>0.6</td>
<td>1.0</td>
<td>1.0</td>
<td>1.4</td>
<td>1.4</td>
</tr>
<tr>
<td>Condom*</td>
<td>1.1</td>
<td>1.6</td>
<td>0.7</td>
<td>0.2</td>
<td>0.3</td>
<td>0.4</td>
</tr>
<tr>
<td>Diaphragm/spermicide*</td>
<td>1.9</td>
<td>1.2</td>
<td>1.2</td>
<td>1.3</td>
<td>2.2</td>
<td>2.6</td>
</tr>
<tr>
<td>Periodic abstinence*</td>
<td>2.5</td>
<td>1.6</td>
<td>1.6</td>
<td>1.7</td>
<td>2.9</td>
<td>3.6</td>
</tr>
</tbody>
</table>

* Deaths are birth related.
† Deaths are method related.

In the above table, the risk of death from any birth control method is less than the risk of childbirth, except for oral contraceptive users over the age of 35 who smoke and pill users over the age of 40 even if they do not smoke. It can be seen in the table that for women aged 15 to 39, the risk of death was highest with pregnancy (7 to 26 deaths per 100,000 women, depending on age). Among pill users who do not smoke, the risk of death was always lower than that associated with pregnancy for any age group, although over the age of 40, the risk increases to 32 deaths per 100,000 women, compared to 28 associated with pregnancy at that age. However, for pill users who smoke and are over the age of 35, the estimated number of deaths exceeds those for other methods of birth control. If a woman is over the age of 40 and smokes, her estimated risk of death is four times higher (117/100,000 women) than the estimated risk associated with pregnancy (28/100,000 women) in that age group.

The suggestion that women over 40 who don't smoke should not take oral contraceptives is based on information from older higher dose pills and on less selective use of pills than is practiced today. An Advisory Committee of the FDA discussed this issue in 1989 and recommended that the benefits of oral contraceptive use by healthy, non-smoking women over 40 years of age may outweigh the possible risks. However, all women, especially older women, are cautioned to use the lowest dose pill that is effective.

**WARNING SIGNALS**

If any of these adverse effects occur while you are taking oral contraceptives, call your doctor immediately:

- Sharp chest pain, coughing of blood, or sudden shortness of breath (indicating a possible clot in the lung)
- Pain in the calf (indicating a possible clot in the leg)
- Crushing chest pain or heaviness in the chest (indicating a possible heart attack)
- Sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness, or numbness in an arm or leg (indicating a possible stroke)
- Sudden partial or complete loss of vision (indicating a possible clot in the eye)
- Breast lumps (indicating possible breast cancer or fibrocystic disease of the breast; ask your doctor or healthcare provider to show you how to examine your breast)
- Severe pain or tenderness in the stomach area (indicating a possibly ruptured liver tumor)
- Difficulty in sleeping, weakness, lack of energy, fatigue, or change in mood (possibly indicating severe depression)
- Jaundice or a yellowing of the skin or eyeballs, accompanied frequently by fever, fatigue, loss of appetite, dark colored urine, or light colored bowel movements (indicating possible liver problems)

**SIDE EFFECTS OF ORAL CONTRACEPTIVES**

1. **Vaginal Bleeding**
Irregular vaginal bleeding or spotting may occur while you are taking the pills. Irregular bleeding may vary from slight staining between menstrual periods to breakthrough bleeding which is a flow much like a regular period. Irregular bleeding occurs most often during the first few months of oral contraceptive use, but may also occur after you have been taking the pill for some time. Such bleeding may be temporary and usually does not indicate serious problems. It is important to continue taking your pills on schedule. If the bleeding occurs in more than one cycle or lasts for more than a few days, talk to your doctor or healthcare provider.

2. Contact Lenses
If you wear contact lenses and notice a change in vision or an inability to wear your lenses, contact your doctor or healthcare provider.

3. Fluid Retention
Oral contraceptives may cause edema (fluid retention) with swelling of the fingers or ankles and may raise your blood pressure. If you experience fluid retention, contact your doctor or healthcare provider.

4. Melasma
A spotty darkening of the skin is possible, particularly of the face.

5. Other Side Effects
Other side effects may include change in appetite, headache, nervousness, depression, dizziness, loss of scalp hair, rash, and vaginal infections.

If any of these side effects bother you, call your doctor or healthcare provider.

GENERAL PRECAUTIONS
1. Missed Periods and Use of Oral Contraceptives Before or During Early Pregnancy
There may be times when you may not menstruate regularly after you have completed taking a cycle of pills. If you have taken your pills regularly and miss one menstrual period, continue taking your pills for the next cycle but be sure to inform your healthcare provider before doing so. If you have not taken the pills daily as instructed and missed a menstrual period, or if you missed two consecutive menstrual periods, you may be pregnant. Check with your healthcare provider immediately to determine whether you are pregnant. Do not continue to take oral contraceptives until you are sure you are not pregnant, but continue to use another method of contraception. There is no conclusive evidence that oral contraceptive use is associated with an increase in birth defects, when taken inadvertently during early pregnancy. Previously, a few studies had reported that oral contraceptives might be associated with birth defects, but these studies have not been confirmed. Nevertheless, oral contraceptives or any other drugs should not be used during pregnancy unless clearly necessary and prescribed by your doctor. You should check with your doctor about risks to your unborn child of any medication taken during pregnancy.

2. While Breastfeeding
If you are breastfeeding, consult your doctor before starting oral contraceptives. Some of the drug will be passed on to the child in the milk. A few adverse effects on the child have been reported, including yellowing of the skin (jaundice) and breast enlargement. In addition, oral contraceptives may decrease the amount and quality of your milk. If possible, do not use oral contraceptives while breastfeeding. You should use another method of contraception since breastfeeding provides only partial protection from becoming pregnant, and this partial protection decreases significantly as you breastfeed for longer periods of time. You should consider starting oral contraceptives only after you have weaned your child completely.

3. Laboratory Tests
If you are scheduled for any laboratory tests, tell your doctor you are taking birth control pills. Certain blood tests may be affected by birth control pills.

4. Drug Interactions
Certain drugs may interact with birth control pills to make them less effective in preventing pregnancy or cause an increase in breakthrough bleeding. Such drugs include rifampin; drugs used for epilepsy such as carbamazepine, barbiturates (for example, phenobarbital), carbamazepine, and phenytoin (Dilantin® is one brand of this drug); tolbutamide; phenobarbital; and possibly certain antibiotics. You may need to use additional contraception when you take drugs which can make oral contraceptives less effective.

Birth control pills interact with certain drugs. These drugs include acetaminophen, clofibrate acid, cyclosporine, morphone, prednisolone, salicylic acid, theophylline. You should tell your doctor if you are taking any of these medications.

5. This product (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against transmission of HIV (AIDS) and other sexually transmitted diseases such as chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.

INSTRUCTIONS TO PATIENT
Blister
The Blisovi Fe 1/20 blister has been designed to make oral contraceptive dosing as easy and as convenient as possible. The tablets are arranged in four rows of seven tablets each, with the days of the week appearing on the blister above the first row of tablets.

Each blister contains 21 yellow tablets and 7 brown tablets.
Each yellow tablet contains 1 mg norethindrone acetate and 20 mcg ethinyl estradiol.
Each brown tablet contains 75 mg ferrous fumarate, and is intended to help you remember to take the tablets correctly. These brown tablets are not intended to have any health benefit.

DIRECTIONS
To remove a tablet, press down on it with your thumb or finger. The tablet will drop through the back of the blister. Do not press on the tablet with your thumbnail, fingernail, or any other sharp object.

HOW TO TAKE THE PILL

IMPORTANT POINTS TO REMEMBER

BEFORE YOU START TAKING YOUR PILLS:

1. BE SURE TO READ THESE DIRECTIONS:
   • Before you start taking your pills
   • Anytime you are not sure what to do

2. THE RIGHT WAY TO TAKE THE PILL IS TO TAKE ONE PILL EVERY DAY AT THE SAME TIME. If you miss pills you could get pregnant. This includes starting the pack late. The more pills you miss, the more likely you are to get pregnant.

3. MANY WOMEN HAVE SPOTTING OR LIGHT BLEEDING, OR MAY FEEL SICK TO THEIR
STOMACH DURING THE FIRST 1-3 PACKS OF PILLS. If you do have spotting or light bleeding or feel sick in your stomach, do not stop taking the pill. The problem will usually go away. If it doesn’t go away, check with your doctor or clinic.

4. MISSING PILLS CAN ALSO CAUSE SPOTTING OR LIGHT BLEEDING, even when you make up these missed pills. On the days you take 2 pills to make up for missed pills, you could also feel a little sick to your stomach.

5. IF YOU HAVE VOMITING OR DIARRHEA, for any reason, or IF YOU TAKE SOME MEDICINES, including some antibiotics, your birth control pills may not work as well. Use a back-up birth control method (such as condoms or foam) until you check with your doctor or clinic.

6. IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL, talk to your doctor or clinic about how to make pill-taking easier or about using another method of birth control.

7. IF YOU HAVE ANY QUESTIONS OR ARE UNSURE ABOUT THE INFORMATION IN THIS LEAFLET, call your doctor or clinic.

BEFORE YOU START TAKING YOUR PILLS

1. DECIDE WHAT TIME OF DAY YOU WANT TO TAKE YOUR PILL. It is important to take it at about the same time every day.

2. LOOK AT YOUR PILL PACK TO SEE IF IT HAS 28 PILLS:

   The 28-Day pill pack has 21 “active” yellow pills (with hormones) to take for 3 weeks, followed by 1 week of reminder brown pills (without hormones).

3. ALSO FIND:
   1) where on the pack to start taking pills,
   2) in what order to take the pills (follow the arrows), and
   3) the week numbers as shown in the following picture:

   ![Diagram of pill pack]

   For use of day labels, see WHEN TO START THE FIRST PACK OF PILLS below.

4. BE SURE YOU HAVE READY AT ALL TIMES:
   ANOTHER KIND OF BIRTH CONTROL (such as condoms or foam) to use as a back-up in case you miss pills.
   An EXTRA, FULL PILL PACK.

WHEN TO START THE FIRST PACK OF PILLS

You have a choice of which day to start taking your first pack of pills. Decide with your doctor or clinic which is the best day for you. Pick a time of day which will be easy to remember.

**DAY-1 START:**

1. Pick the day label strip that starts with the first day of your period. (This is the day you start bleeding or spotting, even if it is almost midnight when the bleeding begins.)
2. Place this day label strip on the blister over the area that has the days of the week (starting with Sunday) printed on the blister.
3. Take the first “active” yellow pill of the first pack during the first 24 hours of your period.
4. You will not need to use a back-up method of birth control, since you are starting the pill at the beginning of your period.

**SUNDAY START:**

1. Take the first “active” yellow pill of the first pack on the Sunday after your period starts, even if you are still bleeding. If your period begins on Sunday, start the pack that same day.
2. Use another method of birth control as a back-up method if you have sex anytime from the Sunday you start your first pack until the next Sunday (7 days). Condoms or foam are good back-up methods of birth control.

WHAT TO DO DURING THE MONTH

1. TAKE ONE PILL AT THE SAME TIME EVERY DAY UNTIL THE PACK IS EMPTY.
   Do not skip pills even if you are spotting or bleeding between monthly periods or feel sick in your stomach (nausea).
   Do not skip pills even if you do not have sex very often.

2. WHEN YOU FINISH A PACK OR SWITCH YOUR BRAND OF PILLS:
   Start the next pack on the day after your last “reminder” pill. Do not wait any days between packs.

WHAT TO DO IF YOU MISS PILLS

If you MISS 1 yellow “active” pill:

1. Take it as soon as you remember. Take the next pill at your regular time. This means you may
If you want more information about birth control pills, ask your doctor or pharmacist. They have a more
technical leaflet called the "Physician Insert", which you may wish to read.

HEALTH BENEFITS FROM ORAL CONTRACEPTIVES

In addition to preventing pregnancy, use of oral contraceptives may provide certain benefits. They are:

- Menstrual cycles may become more regular
- Blood flow during menstruation may be lighter and less iron may be lost. Therefore, anemia due to iron deficiency is less likely to occur
- Pain or other symptoms during menstruation may be encountered less frequently
- Ectopic (tubal) pregnancy may occur less frequently
- Noncancerous cysts or lumps in the breast may occur less frequently
- Acute pelvic inflammatory disease may occur less frequently
- Oral contraceptive use may provide some protection against developing two forms of cancer: cancer of the ovaries and cancer of the lining of the uterus.

If you want more information about birth control pills, ask your doctor or pharmacist. They have a more technical leaflet called the "Physician Insert", which you may wish to read.
Remembering to take tablets according to schedule is stressed because of its importance in providing you the greatest degree of protection.

MISSED MENSTRUAL PERIODS FOR BOTH DOSAGE REGIMENS
At times there may be no menstrual period after a cycle of pills. Therefore, if you miss one menstrual period but have taken the pills exactly as you were supposed to, continue as usual into the next cycle. If you have not taken the pills correctly and miss a menstrual period, you may be pregnant and should stop taking oral contraceptives until your doctor or healthcare provider determines whether or not you are pregnant. Until you can get to your doctor or healthcare provider, use another form of contraception. If two consecutive menstrual periods are missed, you should stop taking pills until it is determined whether or not you are pregnant. Although there does not appear to be any increase in birth defects in newborn babies if you become pregnant while using oral contraceptives, you should discuss the situation with your doctor or healthcare provider.

Periodic Examination
Your doctor or healthcare provider will take a complete medical and family history before prescribing oral contraceptives. At that time and about once a year thereafter, he or she will generally examine your blood pressure, breasts, abdomen, and pelvic organs (including a Papanicolaou smear, i.e., test for cancer).

Keep this and all drugs out of the reach of children.
Rx only
Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature].

Blisovi™ Fe 1/20 is a trademark of Lupin Pharmaceuticals, Inc.
The other brands listed are trademarks of their respective owners and are not trademarks of Lupin Pharmaceuticals, Inc. The makers of these brands are not affiliated with and do not endorse Lupin Pharmaceuticals, Inc. or its products.
Distributed by:
Lupin Pharmaceuticals, Inc.
Baltimore, Maryland 21202
United States
Manufactured by:
Lupin Limited
Pithampur (M.P.) - 454 775
INDIA
Revised: April 2019
ID#:259560

Blisovi™ Fe 1/20
(norethindrone acetate and ethinyl estradiol tablets USP and ferrous fumarate tablets*)
1 mg/0.02 mg
NDC: 68180-865-71
Blister Pack: 28 Tablets
Blisovi™ Fe 1/20
(norethindrone acetate and ethinyl estradiol tablets USP and ferrous fumarate tablets*)
1 mg/0.02 mg
NDC: 68180-865-71
Pouch Pack: 1 Blister of 28 Tablets Each
Blisovi™ Fe 1/20
(norethindrone acetate and ethinyl estradiol tablets USP and ferrous fumarate tablets*)
1 mg/0.02 mg
NDC: 68180-865-73
Carton: 3 Blister of 28 Tablets Each

Product Information
Product Type: HUMAN PRESCRIPTION DRUG
Item Code (Source): NDC:68180-865

Packaging

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Quantity of Parts

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Part 1 of 2

BLISOVI FE 1/20
norethindrone acetate and ethinyl estradiol tablet

Product Information
Route of Administration: ORAL

Active Ingredient/Active Moiety

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<th>Basis of Strength</th>
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<tr>
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Inactive Ingredients

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<td>LACTOSE MONOHYDRATE (UNII: 1MQ27Q0IQX)</td>
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### Lupin Pharmaceuticals, Inc.

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<tr>
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### Product Characteristics

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<td>04/01/2019</td>
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### Part 2 of 2

**BLISOVI FE 1/20**

inert tablet

### Product Information

**Route of Administration**: ORAL

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### Labeler

- **Lupin Pharmaceuticals, Inc.**

### Registrant

- **LUPIN LIMITED**

### Establishment

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Revised: 4/2019

Lupin Pharmaceuticals, Inc.