**DESCRIPTION**

PHILITH (Norethindrone and Ethinyl Estradiol Tablets, USP) provides a continuous regimen for oral contraception derived from 21 tan tablets composed of norethindrone and ethinyl estradiol to be followed by 7 white tablets of inert ingredients. The structural formulas are:

![Structural formula image]

**CLEAN PHARMAECOLOGY**

Combination oral contraceptives act by suppression of gonadotropin. 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 reduces the likelihood of implantation).

**INDICATIONS AND USAGE**

Oral contraceptives are indicated for the prevention of pregnancy in women who elect to use this product as a method of contraception. Oral contraceptives are highly effective. Table 1 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.

**WARNINGS**

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 current use today. The effect of long-term use of the oral contraceptives with lower formulations of both estrogen and progestogen remains to be determined.

**CONTRAINDICATIONS**

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

- Thrombophlebitis or thromboembolic disorders
- A past history of deep vein thrombophlebitis or thromboembolic disorders
- Cirrhosis of the liver or unconfirmed hepatic dysfunction
- Undiagnosed abnormal genital bleeding
- Prior history of liver disease
- Migraine headaches with aura
- Known or suspected carcinoma of the breast
- Known or suspected carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia
- Known or suspected pregnancy
- Hepatic adenomas or carcinomas
- Known or suspected porphyria
- Known or suspected hepatitis C drug combinations containing ribavirin (bevarabirin), with or without darunavir, due to the potential for ALT elevations (see WARNINGS, RISK OF LIVER ENZYME ELEVATIONS WITH CONCOMITANT HEPATITIS C TREATMENT).

**TABLE 1**

<table>
<thead>
<tr>
<th>Method</th>
<th>Lowest Expected</th>
<th>Typical**</th>
</tr>
</thead>
<tbody>
<tr>
<td>(No contraception)</td>
<td>(61)</td>
<td>(61)</td>
</tr>
<tr>
<td>Oral contraceptives</td>
<td></td>
<td></td>
</tr>
<tr>
<td>combined</td>
<td>0.1</td>
<td>0.01</td>
</tr>
<tr>
<td>progestin only</td>
<td>0.5</td>
<td>0.03***</td>
</tr>
<tr>
<td>sterilization with spermicidal cream or jelly</td>
<td>6</td>
<td>0.04</td>
</tr>
<tr>
<td>Spermicidal intravaginal cream or jelly</td>
<td>3</td>
<td>0.04</td>
</tr>
<tr>
<td>Vaginal sponge with spermicidal cream or jelly</td>
<td>11</td>
<td>0.03</td>
</tr>
<tr>
<td>IUD</td>
<td>0.8-2.0</td>
<td>0.03</td>
</tr>
<tr>
<td>Contraceptive ring without spermicides</td>
<td>2</td>
<td>0.04</td>
</tr>
<tr>
<td>Intrauterine device (all methods)</td>
<td>1-6</td>
<td>0.04</td>
</tr>
<tr>
<td>Intrauterine device (all methods)</td>
<td>0.3-0.4</td>
<td>0.04</td>
</tr>
<tr>
<td>Implant</td>
<td>0.04</td>
<td>0.04</td>
</tr>
<tr>
<td>IUD</td>
<td>0.03</td>
<td>0.03</td>
</tr>
<tr>
<td>Female sterilization</td>
<td>0.2</td>
<td>0.4</td>
</tr>
<tr>
<td>Male sterilization</td>
<td>0.1</td>
<td>0.15</td>
</tr>
</tbody>
</table>


**CONTRACEPTIVES**

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.

**WARNINGS**

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. 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 risk of several serious conditions, including myocardial infarction, thromboembolism, stroke, hepatic neoplasms, 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, hyperlipidemia, 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 estrogen and progestogen than those in current use today. The effect of long-term use of the oral contraceptives with lower formulations of both estrogen and progestogen 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 disease, namely, the ratio of the incidence of a disease among oral contraceptive users to that among menstruators. The relative risks do not provide information about 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 about the actual occurrence of a disease in the population.

- For further information, the reader is referred to a source in epidemiological methods.

1. Thromboembolic Disorders and Other Vascular Problems:

The physician should be alert to the serious manifestations of thromboembolic disorders as discussed below. Should any of these occur or be suspected the drug should be discontinued immediately.

a. Myocardial Infarction:

An increased risk of myocardial infarction has been attributed to oral contraceptive use. This risk is primarily increased in women with other underlying risk factors for coronary artery disease such as hypertension, diabetes, hyperlipidemia, age and obesity. In particular, some progestogens are known to increase HDL cholesterol and cause glucose intolerance, while estrogens may cause a rise of hyperlipidemia. Oral contraceptives have been shown to increase blood pressure among users (see section 5. WARNINGS). Such increases in risk factors have been associated with an increased risk of heart disease and the risk increases with the number of risk factors present. Oral contraceptives must be used with caution in women with cardiovascular disease risk factors.

b. Thrombosis:

An increased risk of thrombotic and thrombembolic disease associated with the use of oral contraceptives in well established. Case-control studies have found the relative risk of users compared to non-users to be 3.5 for the first episode of superficial venous thrombosis, 4.1 for deep vein thrombosis or pulmonary embolism, and 1.5 to 6.0 for women with predisposing conditions for venous thromboembolism disease. Cohort studies have shown relative risks to be somewhat lower, about 1.3 for new cases and about 4.0 for new cases requiring hospitalization. The risk of thrombembolic disease due to oral contraceptives is not related to length of use and disappears after pill use is stopped.

A two- to four-fold increase in relative risk of postoperative thrombotic complications has been reported with the use of oral contraceptives. The relative risk of venous thrombosis in women who have predisposing conditions is twice that of women without such medical conditions. If feasible, oral contraceptives should be discontinued 6 to 8 weeks prior to and after surgery of a type associated with an increase in risk of thrombembolic events and following prolonged immobilization. Since the immediate postpartum period is also associated with an increased risk of thrombotic disease, oral contraceptives should be started no earlier than four to six weeks after delivery in women elect to breastfeed.

c. Cerebrovascular Diseases:

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

No large study, the relative risk of thrombotic strokes has been observed range from 2.3 to 2.4 for normotensive users to 4.4 for users with severe hypertension. The relative risk of hemorrhagic stroke is required to be 1.2 to 1.3 for normotensive users and 2.5 for users with severe hypertension. The attributable risk is also greater among smokers.

d. Disseminated Risk of Vascular Disease from Oral Contraceptives:

A positive association has been observed between the amount of estrogen and progestagens and vascular and cerebrovascular disease among oral contraceptive users. A decline in serum high density lipoprotein (HDL) has been reported with many progestagens and have been associated with an increased incidence of ischemic heart disease. Because estrogens increase HDL cholesterol, the effect on coronary heart disease is potentially beneficial. The amount of HDL cholesterol should be considered in the choice of oral contraceptive.

Minimizing exposure to estrogens and progestogens is in keeping with good principles of therapeutics. For any particular estrogen/progestogen combination, the dosage regimen prescribed should be that which contain the least amount of estrogen and progestogen that is compatible with a low failure rate and the needs of the individual patient. New acceptors of oral contraceptive agents should be started on preparation containing 0.05 mg or less 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 contraceptive use. Each method of contraception has its specific risk. The amount of both hormones should be considered in the choice of an oral contraceptive.

Oral contraceptives have been shown to increase blood pressure among users (see section 5. WARNINGS). Such increases in risk factors have been associated with an increased risk of heart disease and the risk increases with the number of risk factors present. Oral contraceptives must be used with caution in women with cardiovascular disease risk factors.

The physician should be alert to the earliest manifestations of thromboembolic disorders as discussed below. Should any of these occur or be suspected the drug should be discontinued immediately.

Estimates included the combined risk of death associated with contraceptive methods plus the relative risk attributable to pregnancy to the event of method failure. Each method of contraception has its specific benefit and risk. The study concluded that with the exception of oral contraceptives users 35 and older who smoke and 45 and older whether or not they are smokers, 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 1970’s but not reported until 1983. However, current clinical practice involves the use of lower estrogen dose formulations combined with careful restrictions of oral contraceptive use in women who do not have the various risk factors listed in this labeling.

2.1. Circulatory Disease Mortality Rates Per 100,000 Women Years by Age, Smoking Status and Oral Contraceptive Use

<table>
<thead>
<tr>
<th>Age</th>
<th>No Oral Contraceptives</th>
<th>Oral Contraceptives Nonsmoker*</th>
<th>Oral Contraceptives Smoker*</th>
</tr>
</thead>
<tbody>
<tr>
<td>15-19</td>
<td>1.9</td>
<td>0.9</td>
<td>0.9</td>
</tr>
<tr>
<td>20-24</td>
<td>4.6</td>
<td>2.2</td>
<td>2.1</td>
</tr>
<tr>
<td>25-29</td>
<td>7.6</td>
<td>3.2</td>
<td>3.2</td>
</tr>
<tr>
<td>30-34</td>
<td>10.0</td>
<td>4.5</td>
<td>4.3</td>
</tr>
<tr>
<td>35-39</td>
<td>28.2</td>
<td>12.8</td>
<td>12.6</td>
</tr>
<tr>
<td>40-44</td>
<td>50.1</td>
<td>23.0</td>
<td>22.8</td>
</tr>
</tbody>
</table>

*Deaths are method related.

These estimates included the combined risk of death associated with contraceptive methods plus the relative risk attributable to pregnancy to the event of method failure. Each method of contraception has its specific benefit and risk. The study concluded that with the exception of oral contraceptives users 35 and older who smoke and 45 and older whether or not they are smokers, 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 1970’s but not reported until 1983. However, current clinical practice involves the use of lower estrogen dose formulations combined with careful restrictions of oral contraceptive use in 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 be less than previously observed (Parker RB, Kizer JK, Jr., Kizer LR, et al. Oral contraceptives and nonfatal vascular disease. Obstet Gynecol 1982; 60:2:4 and Parker RB, Kizer KJ, Walker AM. Mortality among oral contraceptive users. Obstet Gynecol 1987;70:29-22), the Fertility and Maternal Health Drugs Advisory Committee was asked to review the topic in 1989. The Committee concluded that although cardiovascular disease risk may be
increased with oral contraceptive use after age 40 in healthy non-smoking women (even with the newer low-dose formulations); 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 who take oral contraceptives, should take the lowest possible dose formulation that is effective.

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. The overwhelming evidence in the literature suggests that use of oral contraceptives is not associated with an increase in the risk of developing breast cancer, regardless of the age and parity of first use or duration of the menstrual blood and drugs. The Cancer and Steroid Hormone (CASH) study also showed no marked effect on the risk of breast cancer for at least a decade following long-term use. A few studies have shown a slightly increased relative risk of developing breast cancer, although preclinical and modern methodologies of these studies, which included differences in examinations of tumors and patients differences in age at onset of use, have been questioned.

Some studies suggest that oral contraceptive use has been associated with an increased risk of cervical intraepithelial neoplasia in some populations of women. However, to be statistically significant, such a finding 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 cancer and cervical cancers, a cause-and-effect relationship has not been established.

4. Hepatic Vein Thrombosis/Budd-Chiari Syndrome:

Women who are being treated for hyperlipidemias should be followed closely if they elect to use oral contraceptives with particular care.

5. Oral Contraceptive Use Before or During Early Pregnancy:

The administration of oral contraceptives to induce withdrawal bleeding should not be used as a test for pregnancy. Oral contraceptives should be discontinued if pregnancy is confirmed.

6. Oral Contraceptive Use During Pregnancy:

Breakthrough bleeding and spotting are sometimes encountered in patients on oral contraceptives, especially during the first three months of use. Nonsteroidal agents 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 change to another formulation may solve the problem in the event of amenorrhea, pregnancy should be ruled out.

Women with a history of cholelithiasis or secondary amenorrhea or young women without regular cycles prior to taking oral contraceptives may again have irregular bleeding or amenorrhea after another formulation may solve the problem. In the event of amenorrhea, 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.

7. Gallbladder Disease:

Extensive epidemiological studies have revealed no increased risk of birth defects in women who have used oral contraceptives prior to pregnancy. Studies do not suggest a teratogenic effect, particularly in view of the fact that birth defects are concerned, when taken inadvertently during early pregnancy. The administration of oral contraceptives to induce withdrawal bleeding should be used as a test for pregnancy. Oral contraceptives should not be used during pregnancy to treat threatened or habitual abortions.

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 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. Elevated Blood Pressure:

Women with a history of hypertension or hypertension-related diseases, or renal disease 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. Oral contraceptives should be discontinued if pregnancy is confirmed.

9. Breakthrough Bleeding and Spotting:

The recent findings of minimal risk may be related to the use of oral contraceptive formulations containing lower hormonal doses of estrogen and progestogen.

6. Oral Contraceptive Use Before or During Early Pregnancy:

The recent findings of minimal risk may be related to the use of oral contraceptive formulations containing lower hormonal doses of estrogen and progestogen.

7. Gallbladder Disease:

The recent findings of minimal risk may be related to the use of oral contraceptive formulations containing lower hormonal doses of estrogen and progestogen.

8. Elevated Blood Pressure:

The recent findings of minimal risk may be related to the use of oral contraceptive formulations containing lower hormonal doses of estrogen and progestogen.

9. Breakthrough Bleeding and Spotting:

The recent findings of minimal risk may be related to the use of oral contraceptive formulations containing lower hormonal doses of estrogen and progestogen.

10. Headaches:

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.

11. Bleeding Irregularities:

Breakthrough bleeding and spotting are sometimes encountered in patients on oral contraceptives, especially during the first three months of use. Nonsteroidal agents 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 change to another formulation may solve the problem in the event of amenorrhea, pregnancy should be ruled out.

Women with a history of cholelithiasis or secondary amenorrhea or young women without regular cycles prior to taking oral contraceptives may again have irregular bleeding or amenorrhea after another formulation may solve the problem. In the event of amenorrhea, 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.

PRECAUTIONS

1. Sexually-Transmitted Diseases:

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 pelvic examination. The physical examination, however, may be deferred until 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 pelvic cytology, and relevant laboratory tests. In case of undiagnosed, persistent or recurrent abnormal vaginal bleeding, appropriate measures should be taken 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 hyperlipidemias should be followed closely if they elect to use oral contraceptives. Some progesterone may elevate LDL levels and may render the control of hyperlipidemia more difficult.

4. Liver Function:

If jaundice develops in any women 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 depression recurs to a serious degree.

Patients becoming significantly depressed while taking oral contraceptives should stop the medication and use an alternate method of contraception in an attempt to determine whether the symptom is drug related.

7. Contact Lenses:
Contact lens wearers who develop visual changes or changes in lens tolerance should be assessed by an ophthalmologist.

8. Drug Interactions:
Reduced efficacy and increased incidents of breakthrough bleeding and menstrual irregularities have been associated with concomitant use of rifampin. A similar association, though less marked, has been suggested with barbiturates, phenytoin sodium, and possibly with griseofulvin, ampicillin, and tetracyclines.

Concomitant Use with HCV Combination Therapy – Liver Enzyme Elevation
Do not co-administer PHILITH™ with HCV drug combinations containing boceprevir or telaprevir (participates in CYP3A metabolism) due to potential for ALT elevations (see Warnings, RISK OF LIVER ENZYME ELEVATIONS WITH CONCOMITANT HEPATITIS C TREATMENT).

9. Interactions with Laboratory Tests:
Certain endocrine and liver function tests and blood components may be affected by oral contraceptives:
   a. Increased prothrombin and factors VII, VIII, IX, and X; decreased antithrombin III; increased nonapeptide-induced platelet aggregability.
   b. Increased thyroid-binding globulin (TBG) leading to increased circulating thyroid hormone, as measured by protein-bound iodine (PBI), T4 by column or radioimmunoassay. Free T3 resin uptake is decreased, reflecting the elevated TBG: free T4 concentration is unaffected.
   c. Other binding proteins may be elevated in serum.
   d. Sex-binding globulins are increased and result in increased levels of adrenal androgens and estrogens; however, free or biologically active levels remain unchanged.
   e. Triglycerides may be increased.
   f. Glucose tolerance may be decreased.
   g. Serum folate levels may be depressed by oral contraceptive therapy. This may be of clinical significance if a woman becomes pregnant shortly after discontinuing oral contraceptives.

10. Carcinogenesis:
See WARNINGS section.

11. Pregnancy:
Pregnancy Category X: See CONTRAINDICATIONS and WARNINGS section.

12. Nursing Mothers:
Small amounts of oral contraceptive steroids may be identified in the milk of nursing mothers and a few adverse effects on the child have been reported, including jaundice and breast enlargement. In addition, oral contraceptives given in the postpartum period may interfere with lactation by decreasing the quantity and quality of breast milk. If possible, the nursing mother should be advised not to use oral contraceptives but to use other forms of contraception until she has completely weaned her child.

13. Vomiting and/or Diarrhea:
Although a cause-and-effect relationship has not been clearly established, several cases of oral contraceptive failure have been reported in association with vomiting and/or diarrhea. If significant gastrointestinal disturbance occurs in women receiving contraceptive steroids, the use of a back-up method of contraception for the remainder of that cycle is recommended.

14. Pediatrie Use:
Safety and efficacy of norethindrone and ethinyl estradiol tablets have been established in women of reproductive age. Safety and efficacy are expected to be the same in postpubertal adolescents under the age of 16 years and in users ages 16 years and older. Use of this product before menarche is not indicated.

INFORMATION FOR PATIENTS
See patient labeling printed below.

ADVERSE REACTIONS
To report SUSPECTED ADVERSE REACTIONS, contact Northstar Rx LLC. Toll-Free at 1-800-206-7821 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

An increased risk of the following serious adverse reactions has been associated with the use of oral contraceptives (see WARNINGS section):
- Thromboembolism
- Venous thromboembolism
- Pulmonary embolism
- Myocardial infarction
- Central venous catheter
- Central nervous system
- Hypertension
- 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:
- Malignant tumors
- Mental depression
- Change in weight (increase or decrease)
- Breast changes: tenderness, enlargement, and secretion
- Change in menstrual flow
- Spotting
- Breakthrough bleeding
- Gastrointestinal symptoms (such as abdominal cramps and bloating)
- Vomiting
- Nausea
- Edema
- Vaginal candidiasis
- Melasma which may persist
- Amenorrhea
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlargement, and secretion
- Menstrual changes: amenorrhea, enlarge...
• Have high blood pressure, diabetes, high cholesterol
• Smoke

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

- Premenstrual syndrome
- Carcinoma
- Changes in appetite
- Cystitis-like syndrome
- Headache
- Amenorrhea
- Stomatitis
- Hair loss
- Loss of scalp hair
- Syncope sudden
- Syncope non-sudden
- Hemorrhagic eruption
- Varicobulous
- Impaired renal function
- Hemolytic uremic syndrome
- Rule-Chat syndrome
- Acne
- Changes in libido
- Calcinosis

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

NONCONTRACEPTIVE HEALTH BENEFITS:
The following noncontraceptive health benefits related to the use of oral contraceptives are supported by epidemiological studies which largely utilized oral contraceptive formulations containing estrogens doses exceeding 0.05 mg of ethinyl estradiol or 0.05 mg of mestranol.

Effects on contraception:
- Increased menstrual cycle irregularity
- 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 eczecic pregnancies
- Effects from long-term use:
  - Decreased incidence of fibromatosis 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 following is a summary of the instructions given to the patient in the "HOW TO TAKE THE PILL" section of the "DETAILED PATIENT LABELING.

1. IMPORTANT POINTS TO REMEMBER: The patient is told (a) that she should take one pill every day at the same time, (b) that some women experience spotting or light bleeding or gastric distress during the first one to three cycles, (c) missing pills can also cause spotting or light bleeding, if she should use a backup method for contraception if she has spotting or diarrhea or takes some medication medications, and if she has trouble remembering the pill, (d) if she has any other questions, she should consult her physician.

2. BEFORE SHE STARTS TAKING HER PILLS: She should decide what time of day she wishes to take the pill, check whether her pill pack has 28 pills, and note the order in which she should take the pills (diagrammatic drawings of the pill pack are included in the patient insert).

3. WHEN SHE SHOULD START THE FIRST PACK: The Day-One start is listed as the first choice and the Sunday start (the Sunday after her period starts) is given in the second choice. If she uses the Sunday start she should use a backup method in the first cycle if she has intercourse before she has taken seven pills.

4. WHAT TO DO DURING THE CYCLE: The patient is advised to take one pill at the same time every day until the pack is empty. If she is either 20 day regimen, she should start the new pack the day after the last inactive tablet and not wait any days between packs.

5. WHAT TO DO IF SHE MISSES A PILL OR PILLS: The patient is given instructions about what she should do if she misses one, two or more days in the cycle (the Sunday start (the Sunday after her period starts) is given in the second choice. If she uses the Sunday start she should use a backup method in the first cycle if she has intercourse before she has taken seven pills.

6. HOW TO SUPPLIED:
PHILITH™ 28 Day (norethindrone 0.4 mg and ethinyl estradiol 0.035 mg tablets, USP) are available in a compact blister card (NDC 16714-347-05). Each blister card contains 21 tan, biconvex round tablets debossed with "P" on one side and "N" on the other side.

PHILITH™ Tablets are available in the following:
- Carton of 1 NDC 16714-347-02
- Carton of 3 NDC 16714-347-03
- Carton of 6 NDC 16714-347-04

Store at controlled room temperature, 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F). See USP.

References are available upon request.

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

Oral contraceptives are 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 5% per year when users who miss pills are included.

Oral contraceptive use is associated with 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 yes:

- Have high blood pressure, diabetes, high cholesterol
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.

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 certain women's leotards. These side effects, especially nausea and vomiting, may subside within the first three months of use.

Some women should not use the pill. For example, you should not take the pill if you suspect you are pregnant or have unexplained vaginal bleeding. You should not take the pill if you have had clots in veins or in the lungs, if you have ever had a stroke or heart attack, if you have high blood pressure, if you have heart disease, or if you have certain other medical conditions.

Taking the pill provides some important noncontraceptive effects. These include less painful menstruation, less menstrual blood loss and menorrhagia, fewer pelvic infections, and fewer cancers of the ovary and the lining of the uterus. The pill also provides benefits in other ways as well, such as reducing the risk of ovarian cancer.

Although the oral contraceptives have important advantages over other methods of contraception, they have certain risks that no other method has and some of these risks may continue after you have stopped using the oral contraceptive. This brochure 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.

The instructions given in the COMBINATION DETAILED PATIENT LABELING AND BRIEF SUMMARY cards are included inside each compact dispenser. The instructions include the directions on starting the first pack on Day-One (first choice) of her period and the Sunday start (Sunday after period ends). The patient is advised that if she uses the Sunday start, she should be taking the first pill in the cycle of the first cycle on or after Sunday before she has a sex act on Sunday. The patient is also instructed as to when she should do if she misses a pill or pills. The patient is warned that she may become pregnant if she misses a pill or pills and that she should use a back-up method of birth control in the event she has intercourse any time during the seven day period following the missed pill or pills.

Interaction on how to use the blister card for the (28 Tablets) are included inside DETAILED PATIENT LABELING.

EFFECTIVENESS OF ORAL CONTRACEPTIVES:

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

INTRODUCTION:

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. Although the oral contraceptives have important advantages over other methods of contraception, they have certain risks that no other method has and some of these risks may continue after you have stopped using the oral contraceptive. This brochure 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.

DOSE AND ADMINISTRATION:

Hormone formulation: 30 mcg estrogen (estadiol); 0.05 mg progestogen (levonorgestrel)

EFFECTIVENESS OF ORAL CONTRACEPTIVES:

Some women should not use the pill. For example, you should not take the pill if you suspect you are pregnant or have unexplained vaginal bleeding. You should not take the pill if you have had clots in veins or in the lungs, if you have ever had a stroke or heart attack, if you have high blood pressure, if you have heart disease, or if you have certain other medical conditions.

Diabetes

Other conditions before taking oral contraceptives:

Tell your health care professional if you have had clots in veins or in the lungs, if you have ever had a stroke or heart attack, if you have high blood pressure, if you have heart disease, or if you have certain other medical conditions.

Diabetes

Other conditions before taking oral contraceptives:

Tell your health care professional if you have had clots in veins or in the lungs, if you have ever had a stroke or heart attack, if you have high blood pressure, if you have heart disease, or if you have certain other medical conditions.
If you wear contact lenses and notice a change in vision or an inability to wear your lenses, contact your health care professional.

3. Contact Lenses:

The most frequent, unpleasant side effects are nausea and vomiting, stomach cramps, bloating, and a feeling of fullness in the abdomen.

If you take oral contraceptives and need elective surgery, need to stay in bed for a prolonged illness, or need to use oral contraceptives while you are taking the pill, consult your doctor before taking oral contraceptives.

1. Vaginal Bleeding:

If any of these adverse conditions occur while you are taking oral contraceptives, consult your doctor immediately.

2. Heart Attacks and Strokes:

Snacking 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:

Contact Lenses:

The most frequent, unpleasant side effects are nausea and vomiting, stomach cramps, bloating, and a feeling of fullness in the abdomen.

If you take oral contraceptives and need elective surgery, need to stay in bed for a prolonged illness, or need to use oral contraceptives while you are taking the pill, consult your doctor before taking oral contraceptives.

1. Vaginal Bleeding:

If any of these adverse conditions occur while you are taking oral contraceptives, consult your doctor immediately.

2. Heart Attacks and Strokes:

Snacking 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:

Contact Lenses:

The most frequent, unpleasant side effects are nausea and vomiting, stomach cramps, bloating, and a feeling of fullness in the abdomen.

If you take oral contraceptives and need elective surgery, need to stay in bed for a prolonged illness, or need to use oral contraceptives while you are taking the pill, consult your doctor before taking oral contraceptives.

1. Vaginal Bleeding:

If any of these adverse conditions occur while you are taking oral contraceptives, consult your doctor immediately.

2. Heart Attacks and Strokes:

Snacking 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:

Contact Lenses:

The most frequent, unpleasant side effects are nausea and vomiting, stomach cramps, bloating, and a feeling of fullness in the abdomen.

If you take oral contraceptives and need elective surgery, need to stay in bed for a prolonged illness, or need to use oral contraceptives while you are taking the pill, consult your doctor before taking oral contraceptives.

1. Vaginal Bleeding:

If any of these adverse conditions occur while you are taking oral contraceptives, consult your doctor immediately.

2. Heart Attacks and Strokes:

Snacking 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:

Contact Lenses:

The most frequent, unpleasant side effects are nausea and vomiting, stomach cramps, bloating, and a feeling of fullness in the abdomen.

If you take oral contraceptives and need elective surgery, need to stay in bed for a prolonged illness, or need to use oral contraceptives while you are taking the pill, consult your doctor before taking oral contraceptives.

1. Vaginal Bleeding:

If any of these adverse conditions occur while you are taking oral contraceptives, consult your doctor immediately.

2. Heart Attacks and Strokes:

Snacking 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:

Contact Lenses:

The most frequent, unpleasant side effects are nausea and vomiting, stomach cramps, bloating, and a feeling of fullness in the abdomen.

If you take oral contraceptives and need elective surgery, need to stay in bed for a prolonged illness, or need to use oral contraceptives while you are taking the pill, consult your doctor before taking oral contraceptives.

1. Vaginal Bleeding:

If any of these adverse conditions occur while you are taking oral contraceptives, consult your doctor immediately.

2. Heart Attacks and Strokes:

Snacking 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:

Contact Lenses:

The most frequent, unpleasant side effects are nausea and vomiting, stomach cramps, bloating, and a feeling of fullness in the abdomen.

If you take oral contraceptives and need elective surgery, need to stay in bed for a prolonged illness, or need to use oral contraceptives while you are taking the pill, consult your doctor before taking oral contraceptives.

1. Vaginal Bleeding:

If any of these adverse conditions occur while you are taking oral contraceptives, consult your doctor immediately.
doctor or health care provider.

4. 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 health care professional.

5. Melasma:
A slight darkening of the skin is possible, particularly of the face.

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

If any of these side effects bother you, call your doctor or health care professional.

GENERAL PRECAUTIONS

1. Missed Periods and Use of Oral Contraceptives Before or During Early Pregnancy:
There may be times when your periods may not occur 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 health care professional before doing so. If you have not taken the pills daily as instructed and missed a menstrual period, or if you have missed two consecutive menstrual periods, you may be pregnant. Check with your health care professional immediately to determine whether you are pregnant. Do not continue to use 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 if any medications taken during pregnancy.

2. While Breast Feeding:
If you are breastfeeding, consult your doctor before starting oral contraceptives. Some of the drugs will pass into the child's milk. A few adverse effects on the child have been reported, including a slowing of the skin's (puberty) and breast enlargement. In addition, oral contraceptives decrease the amount and quality of your milk. If possible, do not use oral contraceptives while breast feeding. You should use another method of contraception since breastfeeding provides only partial protection from the coming period and this partial protection decreases significantly as you breastfeed for longer periods of time. You should consider stopping oral contraceptives only after you have weaned your child completely.

3. Laboratory Tests:
If you are scheduled for any laboratory test, tell your doctor you are taking oral contraceptives. Certain hormones may be affected by birth control pills. Refer to the sample of the blister card below.

4. Drug Interactions:
Certain drugs may interact with birth control pills to make them less effective in preventing pregnancy and cause an increase in breakthrough bleeding. Such drugs include some antibiotics, blood thinners, and anticonvulsants such as barbiturates (for example, phenobarbital) and phenytoin (Dilantin is one brand of this drug), phenothiazine (for example, chlorpromazine is one brand) and possibly angiotensin-converting-enzyme (ACE) inhibitors. You may need to use an additional method of contraception when you take drugs which make oral contraceptives less effective.

HOW TO TAKE THE PILL

IMPORTANT POINTS TO REMEMBER

SEXUALLY TRANSMITTED DISEASES
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.

BEFORE YOU START TAKING YOUR PILLS:

1. BE SURE TO READ THESE DIRECTIONS:
Before you start taking your pills.

2. THE RIGHT WAY TO TAKE THE PILL IS TO TAKE ONE PILL EVERY DAY AT THE SAME TIME.
If you miss pills you can 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 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. MISSED PILLS CAN ALSO CAUSE SPOTTING OR LIGHT BLEEDING, even when you make up three missed pills.
On the days you take 2 pills, you may 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 pills may not work as well.
Use a backup method such as condoms, foam, or sponge until you check with your doctor or clinic.

6. IF YOU HAVE TROUBLE REMEMBERING TO TAKE THE PILL, talk to your doctor or clinic. If possible, take an additional pill at the time you take your next pill.

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 pill pack has 21 "active" tan pills (with hormones) to take for 3 weeks, followed by 1 week of hormone-free white pills (without hormones). Refer to the sample of the blister card below.

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 picture below.

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

A 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, PHILITH™ (norethindrone and ethinyl estradiol tablets, USP): is available in a compact blister card which is designed for a Sunday start. Day 1 is Sunday also provided. Decide with your doctor or clinic which is the best day for you. Pick a time of day which will be easy to remember. Pick the Day of the Week Sticker that starts with the day you want to start. If you have picked the right sticker, throw away the others and place the sticker on the compact over the pre-printed days of the week and make sure it lines up with the pills. If your Physician has instructed you to use a "Sunday Start" method, then use the blister card which is set up for a Sunday start.

DAY 1 START:
1. Take the first “active” tan pill of the first pack during the first 24 hours of your period.
2. 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” tan 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 day.
2. Use another method of birth control as back-up method if you have sex anytime from the Sunday you start your first pack until the next Sunday (7 days). Condoms, foam, or the sponge 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 (anorexia).
   - 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:**
   - Stop taking one pill 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 tan “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 tan “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. Thereafter, 1 pill a day until you finish the pack.

- If you **MISS 2 tan “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.
  2. **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.

- If you **MISS 3 or MORE tan “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.
  2. **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.

   - 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.

- **If you MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills.**
  1. You MUST use another birth control method (such as condoms, foam or sponge) as a back-up for those 7 days.
  2. **If you MISS 2 tan “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.
     2. 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.

   - 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.

- **If you MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills.**
  1. You MUST use another birth control method (such as condoms, foam or sponge) as a back-up for those 7 days.
  2. **If you MISS 3 or MORE tan “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.
     2. 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.

   - 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.

- **If you MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills.**
  1. You MUST use another birth control method (such as condoms, foam or sponge) as a back-up for those 7 days.

**A REMINDER FOR THOSE ON 28-DAY PACKS:**
- If you forget any of the 7 white “reminder” pills in Week 4:
  - THROW AWAY the pills you missed.
  - Keep taking 1 pill every 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 “ACTIVE” PILL EACH DAY until you can reach your doctor or clinic.

**GENERAL:**

1. **Pregnancy Due to Pill Failure:**
   - The incidence of pill failure resulting in pregnancy is approximately 1% (i.e., one pregnancy per 100 women per year) if taken every day as directed, but more typical failure rates are about 3%. If failure does occur, the risk to the fetus is minimal.

2. **Pregnancy After Stopping the Pill:**
   - There may be some delay in becoming pregnant after you stop using oral contraceptives, especially if you had irregular menstrual cycles before you used oral contraceptives. It may be advisable to postpone conception until you have menstruated regularly once you have stopped taking the pill and have been menstruating regularly for at least 3 months in a row.

   - There does not appear to be any increase in birth defects in newborn babies when pregnancy occurs conception until you begin menstruating regularly once you have stopped taking the pill and desire pregnancy. (See “Pregnancy Due to Pill Failure.”)

   - There may be some delay in becoming pregnant after you stop using oral contraceptives, especially if you had irregular menstrual cycles before you used oral contraceptives. It may be advisable to postpone conception until you have menstruated regularly once you have stopped taking the pill and have been menstruating regularly for at least 3 months in a row.

**1. Pregnancy Due to Pill Failure:**
- The incidence of pill failure resulting in pregnancy is approximately 1% (i.e., one pregnancy per 100 women per year) if taken every day as directed, but more typical failure rates are about 3%. If failure does occur, the risk to the fetus is minimal.

2. **Pregnancy After Stopping the Pill:**
- There may be some delay in becoming pregnant after you stop using oral contraceptives, especially if you had irregular menstrual cycles before you used oral contraceptives. It may be advisable to postpone conception until you have menstruated regularly once you have stopped taking the pill and have been menstruating regularly for at least 3 months in a row.

**NONCONTRACEPTIVE EFFECTS OF ORAL CONTRACEPTIVES:**

- There does not appear to be any increase in birth defects in newborn babies when pregnancy occurs conception until you begin menstruating regularly once you have stopped taking the pill and desire pregnancy. (See “Pregnancy Due to Pill Failure.”)

- There may be some delay in becoming pregnant after you stop using oral contraceptives, especially if you had irregular menstrual cycles before you used oral contraceptives. It may be advisable to postpone conception until you have menstruated regularly once you have stopped taking the pill and have been menstruating regularly for at least 3 months in a row.

**OVERDOSAGE:**
- The usual symptoms of overdosage are nausea and withdrawal bleeding in females. In case of overdosage, contact your poison control center, health care professional, or nearest emergency room.

**KEEP THIS DRUG AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

**SIDE EFFECTS:**
- Serious ill effects have not been reported following ingestion of large doses of oral contraceptives by young children. Overdosage may cause nausea and withdrawal bleeding in females. In case of overdosage, contact your poison control center, health care professional, or nearest emergency room.

**KEEP THIS DRUG AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

**NONCONTRACEPTIVE EFFECTS OF ORAL CONTRACEPTIVES:**

- There does not appear to be any increase in birth defects in newborn babies when pregnancy occurs conception until you begin menstruating regularly once you have stopped taking the pill and desire pregnancy. (See “Pregnancy Due to Pill Failure.”)

- There may be some delay in becoming pregnant after you stop using oral contraceptives, especially if you had irregular menstrual cycles before you used oral contraceptives. It may be advisable to postpone conception until you have menstruated regularly once you have stopped taking the pill and have been menstruating regularly for at least 3 months in a row.

- There does not appear to be any increase in birth defects in newborn babies when pregnancy occurs conception until you begin menstruating regularly once you have stopped taking the pill and desire pregnancy. (See “Pregnancy Due to Pill Failure.”)

- There may be some delay in becoming pregnant after you stop using oral contraceptives, especially if you had irregular menstrual cycles before you used oral contraceptives. It may be advisable to postpone conception until you have menstruated regularly once you have stopped taking the pill and have been menstruating regularly for at least 3 months in a row.
Product Characteristics

<table>
<thead>
<tr>
<th>Color</th>
<th>WHITE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shape</td>
<td>ROUND (biconvex)</td>
</tr>
<tr>
<td>Size</td>
<td>5mm</td>
</tr>
<tr>
<td>Flavor</td>
<td>Imprint Code P;N</td>
</tr>
</tbody>
</table>

Marketing Information

<table>
<thead>
<tr>
<th>Monitoring Category</th>
<th>Application Number or Monograph Citation</th>
<th>Monitoring Start Date</th>
<th>Monitoring End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANDA</td>
<td>ANDA090947</td>
<td>12/22/2011</td>
<td></td>
</tr>
</tbody>
</table>

Labeler

- Northstar Rx LLC (EIN:000000)

Registrant

- Novast Laboratories, Ltd. (EIN:000000)

Establishment

- Novast Laboratories, Ltd.

Revised: 10/2018

Northstar Rx LLC