PHILITH - norethindrone and ethinyl estradiol tablets
Northstar Rx LLC

PHILITH (Norethindrone and Ethinyl Estradiol Tablets, USP).

28-Day Regimen

Rc Only

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

DESCRIPTION

PHILITH® 28-Day (norethindrone and ethinyl estradiol tablets, USP) provide a continuous regimen for oral contraception derived from 21 tan tablets of norethindrone and ethinyl estradiol to be followed by 7 white tablets of inert ingredients. The structural formulas are:

\[ \text{NORETHINDRONE} \]
\[ \text{ETHINYL ESTRA DiOL} \]

The tan active tablets each contain 0.1 mg norethindrone and 0.03 mg ethinyl estradiol, and contain the following inactive ingredients: titanium dioxide, magnesium stearate, hypromellose, macrogol/polyethylene glycol 8000, lactose monohydrate, magnesium stearate and pregelatinized corn starch.

The white tablets in the 28-Day regimen contain only inert ingredients as follows: titanium dioxide, polydextrose, hypromellose, triacetin, macrogol/polyethylene glycol 8000, lactose monohydrate, magnesium stearate and pregelatinized corn starch.

CLINICAL PHARMACOLOGY

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 reduce 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 continuous use of methods can result in lower failure rates.

**TABLE 1**

<table>
<thead>
<tr>
<th>Method</th>
<th>Lowest Expected* (%)</th>
<th>Typical** (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(No contraception)</td>
<td>0.1</td>
<td>0.15</td>
</tr>
<tr>
<td>Oral contraceptives</td>
<td>0.1</td>
<td>0.04</td>
</tr>
<tr>
<td>combined</td>
<td>0.5</td>
<td>0.04</td>
</tr>
<tr>
<td>progestin only</td>
<td>6.0</td>
<td>0.03</td>
</tr>
<tr>
<td>Depo-Provera with spermicide</td>
<td>6.0</td>
<td>0.03</td>
</tr>
<tr>
<td>Spermicides alone (sperm, cream, gels)</td>
<td>21</td>
<td>0.2</td>
</tr>
<tr>
<td>Vaginal sponge</td>
<td>6.0</td>
<td>0.4</td>
</tr>
<tr>
<td>Intrauterine diaphragm</td>
<td>6.0</td>
<td>0.4</td>
</tr>
<tr>
<td>IUD</td>
<td>0.3-0.4</td>
<td>0.1</td>
</tr>
<tr>
<td>Condom with spermicide</td>
<td>2.0</td>
<td>0.1</td>
</tr>
<tr>
<td>Periodic abstinence (all methods)</td>
<td>20</td>
<td>0.1</td>
</tr>
<tr>
<td>Injectable progestogen</td>
<td>0.3-0.4</td>
<td>0.1</td>
</tr>
<tr>
<td>Implant</td>
<td>0.4</td>
<td>0.1</td>
</tr>
<tr>
<td>6 capsules</td>
<td>0.4</td>
<td>0.1</td>
</tr>
<tr>
<td>2 pills</td>
<td>0.4</td>
<td>0.1</td>
</tr>
<tr>
<td>Female sterilization</td>
<td>0.2</td>
<td>0.1</td>
</tr>
<tr>
<td>Male sterilization</td>
<td>0.1</td>
<td>0.1</td>
</tr>
</tbody>
</table>


**The author** is uncertain of the percentage of women required 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 reason other than pregnancy.

**This 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 reason other than pregnancy.

**Confined typical rate for both combined and progestin only.

**Confined typical rate for both medicated and nonmedicated IUD.

CONTRAINDICATIONS

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

- Thrombophlebitis or thrombotic disorders
- A past history of deep vein thrombophlebitis or thrombotic disorders
- Cerebrovascular or coronary artery disease
- Malignant suspected carcinoma of the breast
- Carcinoma of the endometrium or other malignant suspected estrogen-dependent neoplasia
- Uncontrolled abnormal genital bleeding
- Cholestatic jaundice of pregnancy or jaundice with prior pill use
- Hepatic adenomas or carcinoma
- Malignant breast action

Women receiving Hepatitis C drug combinations containing daclatasvir/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 risk of several serious conditions including myocardial infarction, thromboembolism, stroke, hepatic neoplasms, and gallbladder disease, although the risk of serious mortality or morbidity 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 common 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 a disease, namely, the ratio of the incidence of a disease among oral contraceptive users to that among women. 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 about the actual occurrence of a disease in the population.

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

5. Thrombotic Disorders and Other Vascular Problems:

The physician should be alert to the surface manifestations of thrombotic 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 in smokers or 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 raise glucose intolerance, while estrogens may create a state of hyperinsulinism. Oral contraceptives have been shown to increase blood pressure among users (see section 5.3).

b. Thromboembolic Disease:

An increased risk of thrombotic and thrombotic disease associated with the use of oral contraceptives is well established. Case control studies have found the relative risk compared to non-users to be 3.0 for the first episode of superficial venous thrombosis, to 8.1 for deep vein thrombosis or pulmonary embolism, and 1.5 to 4.0 for women with predisposing conditions for venous thromboembolic disease. 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. The risk of thrombotic disease due to oral contraceptives is not related to length of use and disappears after pill use is stopped.

A dose-increase in risk relative to postmenopausal thrombotic complications has been reported with the use of oral contraceptives. The relative risk of venous thromboembolism increases with both the amount of estrogen and progestogen in women who have predisposing conditions is twice that of women without such medical conditions. 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 thrombembolism and during and following prolonged immobilization. Since the immediate postpartum period is also associated with an increased risk of thrombotic disorders, oral contraceptives should be started no earlier than four to six weeks after delivery in women elect to breast-feed.

c. Cardiovascular Disease:

Oral contraceptives have been shown to increase both the relative and attributable risk of cardiovascular events (thrombotic and thrombogenic stroke) although, in general, the risk is greatest among older (35-45 years) hypertensive women who also smoke. Hypertension was found to be a risk factor for both users and non-users, for both types of strokes, while smoking was an independent risk factor for hemorrhagic strokes.

No large study, the relative risk of thrombotic strokes has been shown range from 2.5 to 7.0 for nonusers users to 14 for users with severe hypertension. The relative risk of hemorrhagic stroke is expected to be 2.2 for nonusers who used oral contraceptives, 2.6 for smokers who did not use oral contraceptives, 7.4 for smokers who used oral contraceptives, 1.8 for nonusers and 25.7 for users with severe hypertension. The attributable risk is also greater in women with such medical conditions.

4. Dose-Related Risk of Vascular Disease from Oral Contraceptives:

A positive association has been observed between the amount of estrogen and progestogen Content and the risk of vascular disease. A decline in serum high density lipoprotein (HDL) has been reported with many progestational agents. A decline in serum high density lipoprotein has been associated with an increased incidence of ischemic heart disease. Because estrogens increase HDL cholesterol, the net effects of oral contraceptive depend on a balance achieved between doses of estrogen and progestogen and the amount and absolute amount of progestogen used in the contraceptive.

The amount 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 estrogen/progestogen combination, the dosage regimen prescribed should be one which contains the least amount of estrogen and progestogen and the nature and absolute amount of progestogens used in the contraceptive.

a. Thromboembolic Disorders:

Oral contraceptives may compound the effects of well-known risk factors, 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 create a state of hyperinsulinism. Oral contraceptives have been shown to increase blood pressure among users (see section 5.3). 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

TABLE 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>Oral Contraceptives Users</th>
<th>Oral Contraceptives Nonsmokers</th>
<th>Oral Contraceptives Smokers</th>
<th>Controls</th>
<th>Controls Smokers</th>
</tr>
</thead>
<tbody>
<tr>
<td>15-19</td>
<td>2.5</td>
<td>1.6</td>
<td>2.7</td>
<td>0.3</td>
<td>0.4</td>
</tr>
<tr>
<td>20-24</td>
<td>2.6</td>
<td>1.5</td>
<td>3.0</td>
<td>0.7</td>
<td>1.1</td>
</tr>
<tr>
<td>25-29</td>
<td>2.7</td>
<td>1.6</td>
<td>3.2</td>
<td>0.8</td>
<td>1.2</td>
</tr>
<tr>
<td>30-34</td>
<td>2.9</td>
<td>1.7</td>
<td>3.5</td>
<td>1.0</td>
<td>1.4</td>
</tr>
<tr>
<td>35-39</td>
<td>3.1</td>
<td>1.8</td>
<td>4.0</td>
<td>1.2</td>
<td>1.6</td>
</tr>
<tr>
<td>40-44</td>
<td>3.3</td>
<td>2.0</td>
<td>4.5</td>
<td>1.4</td>
<td>2.0</td>
</tr>
</tbody>
</table>

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

Estimates of Mortality from Contraceptive Use:

One study gathered data from a variety of sources which have estimated the morality rate associated with different methods of contraception at different ages (Table 2).
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.

2. 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 medication. The Cancer and Steroid Hormone (CASH) study also showed a lack in effect on the risk of breast cancer for at least a decade following long-term. A few studies have shown a slightly increased relative risk of developing breast cancer, although the methodology of these studies, which included differences in examinations of users and nonusers and differences in age at use of use, has been questioned. Some studies suggest that oral contraceptive use has been associated with an increase in the risk of cervical neoplasia in some populations of women.

However, to be considered are estrogen 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.

3. Ocular Lesions:

Oral contraceptive use has been shown to cause glaucoma in a significant number of users. Oral contraceptives containing greater than 75 micrograms of estrogens cause hyperinsulinism, while lower doses of estrogen cause less glucose intolerance. Progesterone increases insulin secretion and creatine sensitivity; this effect varies with different progestational agents.

However, in the Stockholm women, oral contraceptives appear to have no effect on fasting blood glucose. Because of these demonstrable effects, peripheral and diabetic women should be carefully observed while taking oral contraceptives.

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

6. Oral Contraceptive Use Before or During Early Pregnancy:

Extensive epidemiological studies have revealed an increased risk of birth defects in women who have used oral contraceptives prior to pregnancy. Studies do not suggest a teratogenic effect, particularly insofar as cardiac anomalies and other malformations are concerned, when taken inadvertently during early pregnancy.

The administration of oral contraceptives in the first 2 weeks of gestation should be considered a serious obstetrical risk. Oral contraceptives should not be used during pregnancy to treat threatened or habitual abortuses. Oral contraceptive use should be discontinued if pregnancy is confirmed.

7. Gallbladder Disease:

Earlier studies have reported an increased lifetime relative risk of gallbladder surgery in users of oral contraceptives and estrogens. More recent reports, however, have shown that the relative risk of developing gallbladder disease among oral contraceptive users may be minimal.

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

8. Carbohydrate and Lipid Metabolical Effects:

Oral contraceptives have been shown to cause glucose intolerance in a significant percentage of users. Oral contraceptives containing greater than 75 micrograms of estrogen cause hyperinsulinism, while lower doses of estrogen cause less glucose intolerance. Progesterone increases insulin secretion and creates insulin resistance; this effect varies with different progestational agents.

In the Stockholm women, oral contraceptives appear to have no effect on fasting blood glucose. Because of these demonstrated effects, peripheral and diabetic women should be carefully observed while taking oral contraceptives.

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

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 pattern in women on oral contraceptives, especially during the first three months of use. Nonperiodic 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 ruled out, time or a change in another formulation may solve the problem in the event of amenorrhea, pregnancy should be ruled out.

Women with a history of oligomenorrhea or secondary amenorrhea or young women without regular cycles prior to the oral contraceptives may again have irregular bleeding or amenorrhea after discontinuation of oral contraceptives.

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:

A 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 region, including cervical cytology, and relevant laboratory tests. In case of undiagnosed persistent or recurrent abnormal vaginal bleeding, appropriate measures should be continued 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 programs may relate LDL levels and may render the control of hyperlipidemias more difficult.

4. Liver Function:

If jaundice develops in any woman receiving such drugs, the medication should be discontinued.

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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 symptoms are 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 incidence 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 simeprevir/paritaprevir/ritonavir/daclatasvir, 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 3; increased heparin-like-induced platelet aggregability.

b. Increased thyroid-binding globulin (TBG) leading to increased circulating total thyroid hormone, as measured by protein-bound iodine (PBI), T4 by column or by radioimmunoassay. Free T4 index is decreased, reflecting the elevated TBG; free T4 concentration is unaltered.

c. Other binding proteins may be elevated in serum.

d. Sex-binding globulins are increased and result in decreased levels of serum cholesterol and corticosteroids; 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 sections.

12. Nursing Mothers:
Small amounts of oral contraceptive steroids have been identified in the milk of nursing mothers and a few adverse effects on the child have been reported, including jaundice and breast engorgement. 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. Pediatric 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 reproductive age. Safety and efficacy of this product before menarche are 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 nervous system
- 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:

- Aneurysm of thoracic aorta

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

- Melasma which may persist
- Breast changes: tenderness, enlargement, and secretion
- Change in weight (increase or decrease)
• Have high blood pressure, diabetes, high cholesterol
• Smoke

Significantly if you:

• Cause temporary or permanent disability. The risks associated with taking oral contraceptives increase significantly if you:

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 you:

Characteristics

• Changes in appetite
• Cystitis-like syndrome
• Diaphoresis
• Menorrhagia
• Loss of scalp hair
• Synkinesis
• Synkinesis vertebrobasilar

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 estrogen doses exceeding 0.05 mg of ethinyl estradiol or 0.05 mg of mestranol.

Effects on menstrual function:

• 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 fibromuscular and fibrocystic disease of the breast
• Decreased incidence of acute pelvic inflammatory disease
• Decreased incidence of endometrial cancer
• Decreased incidence of ovarian cancer

DOSE 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.

The patient is given instructions in five (5) categories:

1. IMPORTANT POINTS TO REMEMBER: The patient is told (a) that she should take one pill every day in the same time, (b) that one cannot substitute spotting or light bleeding or gastric distress during the first one to three cycles, (c) missing pills can cause spotting or light bleeding, (d) she should use a backup method for contraception if she has vomiting or diarrhea or takes some concomitant medications, (e) if she has trouble remembering the pill, (f) 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 pills, 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 as 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 in the second 28-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 tablets per cycle or if she misses taking the pill in seven days after missing pills. To avoid this, she must use another birth control method such as condom, foam, or sponge in those seven days.

HOW SUPPLIED

PHILITH® 28-Day (norethindrone 0.4 mg and ethinyl estradiol 0.035 mg tablets, USP) are available in a compact blister card (NDC 16714-347-01). Each blister card contains 21 tan 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° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° 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, 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 women 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 you:

• Have high blood pressure, diabetes, high cholesterol
• Smoke

Significantly if you:

• Cause temporary or permanent disability. The risks associated with taking oral contraceptives increase significantly if you:

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2. BEFORE SHE STARTS TAKING HER PILLS: She should decide what time of day she wishes to take the pills, 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 as 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 in the second 28-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 tablets per cycle or if she misses taking the pill in seven days after missing pills. To avoid this, she must use another birth control method such as condom, foam, or sponge in those seven days.

HOW SUPPLIED

PHILITH® 28-Day (norethindrone 0.4 mg and ethinyl estradiol 0.035 mg tablets, USP) are available in a compact blister card (NDC 16714-347-01). Each blister card contains 21 tan 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° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° 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.
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 lenses. These side effects, especially nausea and vomiting, 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), or a ruptured or a closed vessel in the brain (stroke), blocks of blood (emboli) or other organs 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 extremely rare.
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 booklet given to you with your supply of pills. Notify your doctor or health care provider if you notice any unusual physical or emotional changes while taking the pill. In addition, drugs such as aspirin, as well as some antibiotics and some antifungal drugs may decrease oral contraceptive effectiveness.

Studying the use of contraceptive pills has not shown an increase in the incidence of cancer of the breast or cervix. There is, however, insufficient evidence to rule out the possibility that the pill may cause such cancers.

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

Be sure to discuss any medical condition you may have with your health care provider. Your health care provider will take a medical and family history before prescribing oral contraceptives and will examine you carefully to determine whether you should be advised to use oral contraceptives or whether you should take a back-up method of birth control in the event you have intercourse any time during the seven-day period following the missed pill or pills.

Instructions on how to use the blister card for the (30 Tablets) are included in the DETAIL PATIENT LABELING.
If you wear contact lenses and notice a change in vision or an inability to wear your lenses, contact your doctor or health care provider.

The most frequent, unpleasant side effects are nausea and vomiting, stomach cramps, bloating, and a change in appetite.

Abnormal vaginal bleeding (see SIDE EFFECTS OF ORAL CONTRACEPTIVES, 1. Vaginal bleeding below.)

• Sudden partial or complete loss of vision (indicating a possible clot in the eye)

• 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)

• Pain in the calf (indicating a possible clot in the leg)

• Sharp chest pain, coughing of blood, or sudden unevenness of breath (indicating a possible clot in the lung)

• Difficulty in breathing, weakness, lack of energy, fatigue, or change in mood (possibly indicating serious depression)

• Sudden or a yellowing of the skin or eyes, accompanied frequently by fever, fatigue, loss of appetite, dark-colored urine, or a light-colored bowel movement (indicating possible liver problems)

• Abnormal vaginal bleeding (see SIDE EFFECTS OF ORAL CONTRACEPTIVES, 1. Vaginal bleeding below.)

SIDE EFFECTS OF ORAL CONTRACEPTIVES:

In addition to the side effects discussed above (see RISKS OF TAKING ORAL CONTRACEPTIVES, ESTIMATED RISKS OF DEATH FROM A BIRTH CONTROL METHOD OR PREGNANCY, and WARNING SIGNALS sections above), the following may also occur:

1. Vaginal Bleeding:

• Irregular vaginal bleeding or spotting may occur while you are taking the pills. Irregular bleeding may vary from slight spotting between normal periods to breakthrough bleeding which is a little much like a regular period. Irregular bleeding occurs more 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 not necessarily indicate any serious problem. It is important to continue taking your pills on schedule. If the bleeding occurs more than once every 2 to 4 weeks for more than a few days, talk to your doctor or health care provider.

2. Gastrointestinal Effects:

The most frequent, unpleasant side effects are nausea and vomiting, stomach cramps, bloating, and a change in appetite.

3. Contact Lenses:

If you wear contact lenses and notice a change in vision or an inability to wear your lenses, contact your doctor or health care provider.

ANNUAL NUMBER OF RELATED OR METHOD-RELATED DEATHS ASSOCIATED WITH CONTROL OF FERTILITY PER 100,000 NONSTERILE WOMEN, BY FERTILITY CONTROL METHOD ACCORDING TO AGE

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<thead>
<tr>
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<tr>
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<td>51.1</td>
<td>117.2</td>
</tr>
<tr>
<td>Combined*</td>
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<td>0.8</td>
<td>1.0</td>
<td>1.3</td>
<td>1.4</td>
<td>1.4</td>
</tr>
<tr>
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<tr>
<td>Depoprovera*</td>
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<td>1.3</td>
<td>1.7</td>
<td>2.5</td>
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<td>3.6</td>
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</table>

*Deaths are method-related.

It can be seen in the table that for women aged 15 to 39, the risk of death was highest with pregnancy (7.25 deaths per 100,000 women, depending usage). Among pill users who do not smoke, the risk of death was always lower than the associated with pregnancy for any age group, although over the age of 35 the pill was associated with more deaths than the pill at any age. However, for pill users who smoke and are over the age of 35, the estimated number of deaths exceeds those for oral contraceptives for birth control. As a woman is over the age of 40 and smoker, her estimated risk of death is four times higher (117/100,000 women) than the estimated risk associated with pregnancy (28/100,000 women) at that age group.

The suggestion that women over 40 who smoke should not take oral contraceptives is based on information from older high-dose pills and is less accurate in use of pills that 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, menstruating 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.

Before taking the pill, 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 20 who smoke and jill users over the age of 30 if they do not smoke. You should discontinue this discussion with your health care professional.

WARNING SIGNALS:

If any of these adverse condition occurs within you are taking oral contraceptives, call your doctor immediately.

• Sharp chest pain, coughing of blood, or sudden unevenness of breath (indicating a possible clot in the lung)

• Difficulty in breathing, weakness, lack of energy, fatigue, or change in mood (possibly indicating serious depression)

• Sudden or a yellowing of the skin or eyes, accompanied frequently by fever, fatigue, loss of appetite, dark-colored urine, or a light-colored bowel movement (indicating possible liver problems)

• Abnormal vaginal bleeding (see SIDE EFFECTS OF ORAL CONTRACEPTIVES, 1. Vaginal bleeding below.)

ANNUAL NUMBER OF RELATED OR METHOD-RELATED DEATHS ASSOCIATED WITH CONTROL OF FERTILITY PER 100,000 NONSTERILE WOMEN, BY FERTILITY CONTROL METHOD ACCORDING TO AGE
DAY-1 START:
Your physician has instructed you to use a “Sunday Start” method, then use the blister card which is set up for a Sunday start. If you have not taken the pills daily as instructed, then 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 contraceptives 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 medications taken during pregnancy.

WHEN TO START THE PILLS

An EXTRA, FULL PILL PACK. Use a back-up method until you check with your doctor or clinic. You may need to use an additional method of contraception when you take drugs which can make oral contraceptives less effective.

1. Missed Periods and Use of Oral Contraceptives Before or During Early Pregnancy:

There may be times when you or your doctor must make the decision about when to start your oral contraceptive regimen, in particular, if you have had unprotected sex or are uncertain about whether you are pregnant. In such cases, it is advisable to take an extra pill to prevent pregnancy. If you inadvertently miss one or more pills, the pill pack should be replaced with a new one as soon as possible.

2. While Breastfeeding:

If you are breastfeeding, consult your doctor before starting oral contraceptives. Some of the drugs will pass into the breast milk. A few adverse effects on the child have been reported, including a decrease in the size of the breast and breast engorgement. In addition, oral contraceptives decrease the amount and quality of your milk. If possible, do not use oral contraceptives while breastfeeding.

3. Laboratory Tests:

Certain drugs may interact with birth control pills to make them less effective, including drugs used for epilepsy such as barbiturates (for example, phenobarbital) and phenytoin (Dilantin is one brand of this drug), phenothiazines (thiothixene is one brand) and possibly any tricyclic antidepressants (general brand name). You may need to use an additional method of contraception when you take drugs which can interact with birth control pills.

4. Drug Interactions:

Some medications may interact with birth control pills to make them less effective, including drugs used for epilepsy such as barbiturates (for example, phenobarbital) and phenytoin (Dilantin is one brand of this drug), phenothiazines (thiothixene is one brand) and possibly any tricyclic antidepressants (general brand name). You may need to use an additional method of contraception when you take drugs which can interact with birth control pills.

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, you must be sure to read the directions. Be sure to ask your doctor or clinic about how to make pill-taking easier or about using another method of birth control.

2. THE RIGHT WAY TO TAKE THE PILL IS TO TAKE ONE PILL EVERY DAY AT THE SAME TIME.

If you plan to use oral contraceptives, it is important to take them at the same time every day. If you miss a pill, you may need to use an additional method of contraception.

3. MANY WOMEN HAVE SPOTTING OR LIGHT BLEEDING, OR MAY FEEL SICK TO THEIR STOMACH DURING THE FIRST 1-3 PACKS OF PILLS.

On the days you take 2 pills to make up for missed pills, you could also feel a little sick to your stomach. This is normal and 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 THOSE 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. This is normal and will usually go away. If it doesn’t go away, check with your doctor or clinic.

5. IF YOU HAVE VOMITING OR DIARRHEA, FOR ANY REASONS, OR IF YOU TAKE SOME MEDICATIONS, INCLUDING SOME ANTIHISTORY, YOUR PILL MAY NOT WORK AS WELL.

Use a backup method (such as condoms, foam or sponge) until you check with your doctor or clinic. You may need to use an additional method of contraception when you take drugs which can make oral contraceptives less effective.

6. OTHER SIDE EFFECTS:

If you are breastfeeding, consult your doctor before starting oral contraceptives. Some of the drugs will pass into the breast milk. A few adverse effects on the child have been reported, including a decrease in the size of the breast and breast engorgement. In addition, oral contraceptives decrease the amount and quality of your milk. If possible, do not use oral contraceptives while breastfeeding.

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 PILLS PACK TO SEE IF IT HAS 28 PILLS.

The 28 pill pack has 21 “active” white pills (with hormones) to take for 3 weeks, followed by 1 week of reminder white pills (without hormones). Refer to the sample of the blister card below.

3. ALSO FIND:

1. where on the pack it starts taking pills,
2. in what order to take the pills (follow the arrows), and
3. the week numbers as shown in the picture below.

Example Only:

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.

AS PROVIDED, FULL PILL PACK.

WHEN TO START THE FIRST PACK OF PILLS

You have a choice of a Sunday Start or starting your first pack of pills, PHILIPSS (mononistone and ethinyl estradiol, USP) is available in a compact blister card which is designed for a Sunday Start. Day 1 is also provided with your doctor or clinic in the box by day for you. Pick a time of day which will be easy to remember. Pick the day of the week doctors recommend for taking the pill on a Sunday for many doctors. On the weekend you have to take one pill a day without looking at the calendar. Regularly take one pill a day without looking at the calendar. If you get to the right time, throw away the others and place the pill in the package over the pre-printed days of the week and make sure it lines up with the pills. If you have to take the right pill, throw away the others and place the pill in the package over the pre-printed days of the week and make sure it lines up with the pills. If you have to take the right pill, throw away the others and place the pill in the package over the pre-printed days of the week and make sure it lines up with the pills.
If you want more information about birth control pills, ask your doctor or pharmacist. They have a more detailed leaflet called the Professional Labeling, which you may wish to read.

Oral contraceptive use may provide some protection against developing two forms of cancer:

- Cancer of the ovaries
- Cancer of the lining of the uterus

Other possible benefits of oral contraceptive use may include:

- Acute pelvic inflammatory disease may occur less frequently
- Noncancerous cysts or lumps in the breast may occur less frequently
- Pain or other symptoms during menstruation may be encountered less frequently
- Blood flow during menstruation may be lighter and less iron may be lost. Therefore, anemia due to iron deficiency is less likely to occur

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

NONCONTRACEPTIVE EFFECTS OF ORAL CONTRACEPTIVES:

- Your health care professional will take a medical and family history before prescribing oral contraceptives and examine you. The physical examination may be delayed to another time if you have had recent (within 6 months) pregnancy, delivery, abortion, or miscarriage. You should be reexamined at least once per year. Be sure to inform your health care professional if there is a family history of any of the conditions listed previously in this leaflet. Be sure to keep all appointments with your health care provider, because this is a time to determine if there are early signs of side effects of oral contraceptive use.
- Do not use the drug for any condition other than the one for which it was prescribed. This drug has been prescribed specifically for you; do not give it to others who may want birth control pills.
- Keep this drug and all drugs out of the reach of children.
- Serious ill effects have not been reported following ingestion of large doses of oral contraceptives by children, teenagers, or nulliparous women. Oral contraceptive failure is more likely to occur in women who have had an abortion or miscarriage, who have had more than one child, who are 35 years or older, who use tobacco, or who have had irregular menstrual cycles before they used oral contraceptives.

Pregnancy After Stopping the Pill:

While you are using oral contraceptives, 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 are still bleeding at the time you begin to miss pills, you are not pregnant. It may be advisable to postpone your next period. You may be able to control your bleeding by taking 1 pill a day until you finish the pack.

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.

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 tablets are used as directed, but most 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 begin using oral contraceptives regularly once you have stopped taking the pill and decide to become pregnant.

There is no evidence that oral contraceptives increase the risk of birth defects in newborn babies when pregnancy occurs soon after stopping the pill.

2. Pregnancy After Stopping the Pill:

There does not appear to be any increase in birth defects in newborn babies when pregnancy occurs soon after stopping the pill.

3. Other:

- Overdosage:

There does not appear to be any increase in birth defects in newborn babies when pregnancy occurs soon after stopping the pill.

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- Overdosage:

There does not appear to be any increase in birth defects in newborn babies when pregnancy occurs soon after stopping the pill.

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- Overdosage:

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3. Other:

- Overdosage:

There does not appear to be any increase in birth defects in newborn babies when pregnancy occurs soon after stopping the pill.
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.

Manufactured for: Northstar Rx LLC
Memphis, TN 38141
Toll Free 1-800-206-7821
Manufactured by: Novast Laboratories, Ltd.
Nantong, China 226009
Rev. 09/17
10021

PHILITH
norethindrone and ethinyl estradiol tablets kit

Product Information

Product Type: HUMAN PRESCRIPTION DRUG
Item Code (Source): NDC:16714-347

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Part 1 of 2

PHILITH
norethindrone and ethinyl estradiol tablet

Product Information

Route of Administration: ORAL

Active Ingredients:

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Inactive Ingredients:

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<td>MAGNESIUM STEARATE</td>
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Product Characteristics

Color: BROWN (tan)
Shape: ROUND (biconvex)
Size: 5mm
Flavor: Imprint Code: C35

Part 2 of 2

INERT
placebo tablet

Product Information

Route of Administration: ORAL

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Marketing Information

Marketing Category: ANDA
Application Number: ANDA090947
Marketing Start Date: 12/22/2011
Marketing End Date: 12/22/2011

Part 2 of 2

INERT
placebo tablet

Product Information

Route of Administration: ORAL

Inactive Ingredients:

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Marketing Information

Marketing Category: INERT
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## Marketing Information

### Marketing Category: ANDA
- **Application Number or Monograph Citation:** ANDA090947
- **Marketing Start Date:** 12/22/2011
- **Marketing End Date:**

### Labeler: Northstar Rx LLC
- **Registrant:** Novast Laboratories, Ltd. (830546433)

### Establishment
- **Name:** Novast Laboratories, Ltd.
- **Address:** 527695995
- **Business Operations:** analysis, label, manufacture, pack

**Revised:** 11/2018