

novelon^{lite} 28

Ethinylestradiol + Drospirenone

Presentation

Each **Novelon lite[®] 28** contains 28 tablets.

24 Active Tablets:

Each light pink colored tablet contains

Drospirenone BP 3mg &

Ethinylestradiol BP 0.02mg

4 Placebo Tablets:

Each white colored tablet is a placebo tablet

Description

contains two active ingredients- Ethinylestradiol and Drospirenone. Ethinylestradiol is a synthetic version of estrogen and Drospirenone is a synthetic form of progesterone. The hormonal components of **Novelon lite[®] 28** inhibit ovulation by suppressing gonadotropin release. Secondary mechanisms, which may contribute to the effectiveness of **Novelon lite[®] 28** as a contraceptive, include changes in the cervical mucus (which increase the difficulty of sperm penetration) and changes in the endometrium (which reduce the likelihood of implantation).

Drospirenone has antimineralocorticoid activity, counteracting estrogen related sodium retention. In combination with Ethinylestradiol, Drospirenone displays a favourable lipid profile with an increase in high-density lipoproteinHDL. Drospirenone exerts antiandrogenic activity and does not counteract the ethinylestradiol-related sex hormone binding globulin increase which is useful for binding and inactivating the endogenous androgens.

Indications and Uses

Novelon lite[®] 28 is indicated for:

- As an oral contraceptive
- Treatment of moderate acne vulgaris
- Treatment of premenstrual dysphoric disorder (PMDD)

Dosage and Administration

To achieve maximum contraceptive effectiveness tablets must be taken in the order directed on the package every day at about the same time. Tablet-taking should be started with the first pink tablet of the upper row & have to continue daily for 24 consecutive days. After completion of pink tablet, white tablet should be taken from 25th day to 28th day. Withdrawal bleeding usually starts on day 2 - 3 after starting the white tablets & dont stop taking white tablets though your menstruation is already started. Each subsequent new pack is started on the day after the last white tablet of the previous pack.

No preceding hormonal contraceptive use in the past month: Tablet-taking has to start on day 1 of the woman's menstrual cycle. The woman should be instructed to take the first light pink active tablet from the upper row of **Novelon lite[®] 28** according to the direction and in this case no additional methods of contraception are required. Starting on days 2-5 is allowed, but during the first cycle a barrier method is recommended in addition for the first 7 days of tablet-taking.

Changing from another combined hormonal pill or vaginal ring or transdermal patch: In case of combined hormonal pill, woman should start with the first light pink tablet of upper row on the day after the last active tablet of her previous COC. In case of a vaginal ring or transdermal patch has been used, the woman should start using **Novelon lite[®] 28** preferably on the day of removal.

Changing from a progestogen-only-method (minipill, injection, implant) or from a progestogen-releasing intrauterine system (IUS): The woman may switch any day from the minipill (or from an implant or the IUS on the day of its removal, from an injectable when the next injection would be due), but should in all of these cases be advised to additionally use a barrier method (like-condom) for the first 7 days of tablet-taking.

Following first-trimester abortion: The woman may start immediately and in this case no need to take additional contraceptive method.

Following delivery or second-trimester abortion: Women are advised to start at day 21 to 28 after delivery or second-trimester abortion. When starting later, the woman are advised to additionally use a barrier method (like-condom) for the first 7 days of tablet-taking.

Management of Missed Tablets

Missed white pills from the last row of the blister are placebo tablets and thus can be disregarded. But if you forgot to take a light pink tablet one day, take the missed tablet as soon as you remember. This may mean taking two tablets the very next day. Additionally you should use some other method of contraception (like-condom) until next 7 days. If you forget to take the tablets for two continuous days, then it is likely that you will no longer be protected against pregnancy. You should therefore discontinue taking the tablet and adopt some other temporary methods (condom/foam tablet) till your next menstruation. Discard the unfinished pack of tablets and start taking tablets from the light pink tablet of the top row of a fresh pack from the first day of next menstruation.

If you have missed a period after taking Novelon lite[®] 28

If you have taken all of your pills at the right time and you have not vomited or used other medicines then you are very unlikely to be pregnant. Continue to take **Novelon lite[®] 28** as usual. If you miss your period twice in a row, you may be pregnant. Tell your doctor immediately. Do not start the next pack of **Novelon lite[®] 28** until your doctor has checked you are not pregnant.

How to Delay a Period

To delay period women should continue with another new pack of **Novelon lite[®] 28** just after finishing the light pink active tablet of the present pack (that is no need to take white placebo tablet of present pack). The extension can be carried on for as long as wished until the end of light pink color tablet of the second pack. When women wish their period to begin, just stop tablet taking. While using the second pack woman may have some breakthrough bleeding or spotting. Start with your next pack after the usual 4 day white inactive tablet interval.

Advice in case of Vomiting

If vomiting occurs within 3-4 hours after light pink tablet taking, absorption may not be complete. In such an event, the advice concerning management of missed tablets is applicable. The woman must take the extra active tablet (light pink color) needed from a back up pack after vomiting.

Side Effects

Different types of tablet suit to different types of woman. At the initial stage some women may experience side-effects like dizziness, headache, breast pain, nausea or unscheduled uterine bleeding. These symptoms may occur in $\geq 3\%$ of users.

After starting one brand of oral contraceptive tablets, if you feel any inconvenience such as migraine, changes in eyesight or speech, unusual pain or swelling in your legs, sharp chest pains or shortness of breath, rash, yellow skin or a rise in blood pressure take immediate advice from your doctor.

Precautions

If any circulatory disorder (like- myocardial infarction, deep venous thrombosis, pulmonary embolism, cerebrovascular injury etc) or other risk factors (like- smoking, obesity, hypertension,dislipidemia, migraine, atrial fibrillation etc) are present, the benefits of COC use should be weighed against the possible risks for each individual woman and discussed with the woman before she decides to start using it. In the event of aggravation, exacerbation or first appearance of any of these conditions or risk factors after taking pill, the woman should contact with her physician. The physician should then decide on whether its use should be discontinued.

Pregnancy & Lactation

Use during pregnancy: **Novelon lite[®] 28** is contraindicated during pregnancy. Pregnancy must be excluded before starting **Novelon lite[®] 28**. If pregnancy occurs during use of **Novelon lite[®] 28**, the preparation must be withdrawn immediately. Women who discontinue oral contraceptives with the intent of becoming pregnant, a non-hormonal method of contraception is recommended for three months before attempting to conceive.

Use during lactation: Lactation may be influenced by combined pill as they may reduce the quantity and change the composition of breast milk, therefore the use of estrogen containing combined pill should generally not be recommended until the nursing mother has completely weaned her child. Small amounts of the contraceptive steroids and/or their metabolites may be excreted with the milk.

Paediatric Use

Novelon lite[®] 28 is only indicated after menarche. There is no data suggesting the need for a dosage adjustment.

Use in the Elderly

Novelon lite[®] 28 is not indicated after menopause.

Contraindications

Novelon lite[®] 28 should not be used :

- Known or suspected pregnancy
- If you have heart disease, clotting of blood in the vein
- If you suffer from liver disease or jaundice
- If you suffer from high blood pressure, migraine, feel something hard in your breast, diabetes with vascular involvement, experience excessive bleeding for which no reason has yet been ascertained
- Presence or a history of venous or arterial thromboembolic events (e.g. deep venous thrombosis, pulmonary embolism, myocardial infarction or of a cerebrovascular accident)
- History of migraine with focal neurological symptoms
- Pancreatitis or a history thereof if associated with severe hypertriglyceridaemia
- Severe renal insufficiency or acute renal failure
- Presence or history of liver tumours (benign or malignant)
- Undiagnosed vaginal bleeding
- Hypersensitivity to any of the components of **Novelon lite[®] 28**

Drug Interactions

Interactions between ethinylestradiol and other drugs may lead to decreased or increased ethinylestradiol concentrations, respectively. Decreased ethinylestradiol serum concentrations may cause an increased incidence of breakthrough bleeding and menstrual irregularities and may possibly reduce efficacy of the oral contraceptive. Example of substances that may decrease serum ethinylestradiol concentrations include rifampicin, phenytoin, primidone, rifabutin, dexamethasone, griseofulvin, topiramate, some protease inhibitors, modafinil, ritonavir and barbiturates. Certain antibiotics including ampicillin, other penicillins and tetracyclines may reduce the efficacy of oral contraceptives. During concomitant use of **Novelon lite[®] 28** & other drugs that may lead to decreased ethinylestradiol serum concentrations, it is recommended that a non-hormonal back-up method of contraception to be used in addition to the regular intake of **Novelon lite[®] 28**.

Overdose

Symptoms of oral contraceptive overdose may include nausea, vomiting, breast tenderness, dizziness, abdominal pain, drowsiness/fatigue; withdrawal bleeding may occur in females. There is no specific antidote and further treatment of overdose, if necessary, is directed to the symptoms.

Storage

Do not store above 30° C. Keep away from light and out of the reach of children

Commercial Pack

Novelon lite[®] 28 : Each Box Contains 24 light pink tablets (each containing Ethinylestradiol BP 0.02mg & Drospirenone BP 3mg) and 4 white color placebo tablets

