

novelon^{lite}[®]

Drospirenone BP+Ethinylestradiol BP

Composition: Each film coated pill contains drospirenone BP (a progestogen) 3mg and ethinylestradiol BP (an estrogen) 0.02mg.

Actions
novelon^{lite}[®] is a combined oral contraceptive Pill containing the synthetic progestogen, drospirenone and the synthetic estrogen, ethinylestradiol. The contraceptive effect of **novelon^{lite}[®]** is based on the interaction of various factors, the most important of which are seen as the inhibition of ovulation and the changes in cervical secretion. When **novelon^{lite}[®]** is taken according to instructions, the egg cells are prevented from maturing to the point at which they can be fertilized, the cervical mucus remains thick so as to constitute a barrier to sperm and the endometrium is rendered unresponsive to implantation. As well as protection against pregnancy, estrogen/progestogen combinations have several positive properties which, next to the negative properties, can be useful in deciding on the method of birth control. The cycle is more regular and the menstruation is often less painful and bleeding is lighter. Drospirenone has antiminerocorticoid activity, counteracting estrogen related sodium retention. In combination with ethinylestradiol, drospirenone displays a favourable lipid profile with an increase in high-density lipoprotein HDL. Drospirenone exerts antiandrogenic activity and does not counteract the ethinylestradiol-related sex hormone binding globulin (SHBG) increase which is useful for binding and inactivating the endogenous androgens. Drospirenone is devoid of any androgenic, estrogenic, glucocorticoid and antiglucocorticoid activity. This in combination with the antiminerocorticoid and antiandrogenic properties, gives drospirenone a biochemical and pharmacological profile closely resembling the natural hormone progesterone.

Indications
Oral contraception

WHEN SHOULD YOU NOT USE novelon^{lite}[®] ?

Preparations containing estrogen/progestogen combinations should not be used in the presence of any of the conditions listed below. If any of the conditions appear for the first time during their use, the product should be stopped immediately.

- Thrombosis (venous or arterial) present or in history (e.g. deep venous thrombosis, pulmonary embolism, myocardial infarction, cerebrovascular accident)
- Presence or history of thrombosis (e.g. transient ischaemic attack, angina pectoris)
- Presence or history of migraine with focal neurological symptoms
- Diabetes mellitus with vascular involvement
- Disturbed lipometabolism
- The presence of a severe or multiple risk factor(s) for venous or arterial thrombosis may also constitute a contraindication
- Pancreatitis or severe hypertriglyceridemia
- Presence or history of severe hepatic disease as long as liver function values have not returned to normal
- Severe renal insufficiency or acute renal failure
- Presence or history of liver tumours (benign or malignant)
- Known or suspected malignant conditions of the genital organs or the breasts, if sex steroid-influenced
- Undiagnosed vaginal bleeding
- Known or suspected pregnancy
- Hypersensitivity to any of the components of **novelon^{lite}[®]**

BEFORE YOU START TO USE novelon^{lite}[®]

The clinical and epidemiological evidence for estrogen/progestogen combinations like **novelon^{lite}[®]** is predominantly based on experience with COCs in general. Therefore, the following warnings related to the use of COCs apply also to the use of **novelon^{lite}[®]**. Also, increased risk of arterial, venous thrombotic and thromboembolic diseases such as myocardial infarction, deep venous thrombosis, pulmonary embolism and of cerebrovascular accidents. These events occur rarely.

- Cervical cancer
- Hypertriglyceridemia
- Blood pressure
- Jaundice
- Erythematous
- Haemolytic uraemic syndrome
- Sydenham's chorea
- Herpes gestationis
- Otosclerosis-related hearing loss.
- Hereditary angioedema
- Acute or chronic disturbances of liver or kidney
- Crohn's disease and ulcerative colitis
- Chloasma

The Pill and other Medicines

Some medicines may stop the pill from working properly. These include medicines used for the treatment of epilepsy (e.g. primidone, phenytoin, barbiturates) and tuberculosis (eg. rifampicin); and antibiotics (eg. ampicillin, tetracyclines, griseofulvin); for some other infectious diseases. Always tell the doctor, who prescribes the pill, which medicines you are already using. Also tell other doctor/dentist who prescribes another medicine (or the dispensing pharmacist) that you use **novelon^{lite}[®]**. They can tell you if you need to take additional contraceptive precautions and if so, for how long.

The Pill and Breast feeding

novelon^{lite}[®] is generally not recommended for use during breast feeding. If you wish to take the pill while breastfeeding, please seek the advice of your doctor.

The Pill and Pregnancy

novelon^{lite}[®] must not be used by women who are pregnant or who think they may be pregnant.

The Pill and Ability to Drive

There are no observed effects.

WHEN SHOULD YOU CONTACT YOUR DOCTOR ?

Regular check-ups.
When you are using the pill, your doctor will tell you to return for regular check-ups. In general, you should have a check-up every year.

Contact your doctor as soon as possible if:

- you notice any change in your own health, especially involving any of the items mentioned in this leaflet (see also when should you not use **novelon^{lite}[®]**; do not forget about the items related to your immediate family).
- you feel a lump in your breast;
- you are going to use other medications (see also The Pill and Other Medicines).
- you are to be immobilized or are to have surgery (consult your doctor at least four weeks in advance);
- you have unusual, heavy vaginal bleeding;
- you forgot Pills in the first week of the pack and had intercourse in the seven days before;
- you miss your period twice in a row or suspect you are pregnant (do not start the next pack until told by your doctor).

Stop taking Pills and see your doctor immediately if you notice possible signs of thrombosis:

- an unusual cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual severe or prolonged headache or migraine attack;
- partial or complete loss of vision or double vision slurring or speech disability;
- sudden changes to your hearing, sense of smell or taste;

- dizziness or fainting; weakness or numbness in any part of your body;
- severe pain in your abdomen;
- severe pain or swelling in either of your legs.

The situations and symptoms mentioned above are described and explained in more detail elsewhere in this leaflet.

HOW TO TAKE novelon^{lite}[®]?

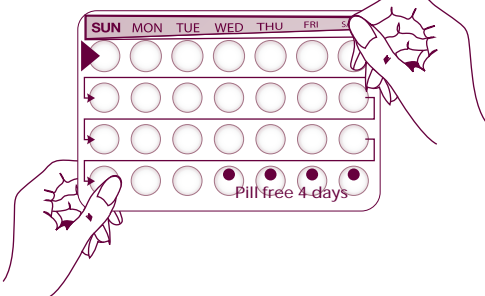
The **novelon^{lite}[®]** pack contains 24 Pills. Take your Pill at about the same time each day. Follow the direction of the arrows until all 24 pills have been taken and next 4 days will be your pill free days. Usually a period will start within pill free days. Then start taking your next pack after 4 days even if your period continues. This means that you will always start new packs on the same day of the week, and also that you have your period on about the same days every month.

How to prepare the blister pack of novelon^{lite}[®]?

The **novelon^{lite}[®]** pack holds a memo-pack, containing 24 pills. In addition to the memo-packs, the outer cartoon contains self-adhesive stickers. Each of these hold 7 self-adhesive strips showing the days of the week. Choose the strip that starts with the day you begin taking the pill. For example, if you start the pill on a Sunday, use the strip that starts with 'SUN'.

Stick the strip along the top of the memo-pack on the clear side where the Pills are visible, so that the first day is above the Pill to which the arrow marked 'Start' is pointing.

You can now see on which day you have to take each Pill.



Starting your first pack of novelon^{lite}[®]

- **When no hormonal contraceptive has been used in the past month.**

Start taking **novelon^{lite}[®]** on the first day of the cycle, (that is, the first day of your period). Than follow the days in order. **novelon^{lite}[®]** will work immediately, it is not necessary to use and additional contraceptive method. You may also start on days 2-5 of your cycle, but in that case make sure you also use and additional contraceptive method (barrier method) for the first 7 days of Pill-taking in the first cycle.

- **When changing from another combined Pill.**

You can start taking **novelon^{lite}[®]** the day after you have the last Pill from your present pill pack (this means no Pill-free break). If your present pill pack also contains inactive Pills you can start **novelon^{lite}[®]** on the day after taking the first active Pill (if you are not sure which this is, ask your doctor or pharmacist). You can also start later, but never later than the day following the Pill-free break of your present pill (or the day after the last inactive Pill of your present pill).

- **When changing from progestogen-only Pill (Mini Pill).**

You can stop taking the mini pill any day and start taking **novelon^{lite}[®]** the next day, at the same time. But make sure you also use an additional -contraceptive method (a barrier method) for the first 7 days of Pill-taking when having intercourse.

- **When changing from an Injectable or Implant.**

Start using **novelon^{lite}[®]** when your next injection is due or on the day that your implant is removed. But make sure you also use an additional contraceptive method (a barrier method) for the first 7 days of Pill-taking when having intercourse.

- **After having a baby.**

You can start **novelon^{lite}[®]** between 21 and 28 days after having a baby. If you start later than day 28, you must use a so-called barrier method (for example, a condom) during the first seven days of use. If, after having a baby, you have had sex before starting **novelon^{lite}[®]**, you must first be sure that you are not pregnant or you must wait until your next period.

- **After a miscarriage or an abortion.**

Your doctor will advise you.

If too many novelon^{lite}[®] Pills are taken (overdose)

There have been no reports of serious harmful effects from taking too many **novelon^{lite}[®]** Pills at one time. If you have taken several Pills at a time, you may have nausea, vomiting or vaginal bleeding. If you discover that a child has taken **novelon^{lite}[®]** ask your doctor for advice.

When you want to stop taking novelon^{lite}[®]

You can stop taking **novelon^{lite}[®]** at any time you want. If you do not want to become pregnant, ask your doctor about other methods of birth control.

If you stop taking **novelon^{lite}[®]** because you want to get pregnant, it is generally recommended that you wait until you have had a natural period before trying to conceive.

WHAT TO DO IF.....

..... you forget to take Pills

- If you are less than 24 hours late in taking a Pill, the reliability of the Pill is maintained. Take the Pill as soon as you remember and take the next Pills at the usual times.

- If you are more than 24 hours late in taking any Pill, the reliability of the Pill may be reduced. The more consecutive Pills you have missed, the higher the risk that the contraceptive efficacy is decreased. There is a particularly high risk of becoming pregnant if you miss Pills at the beginning or at the end of the pack. Therefore, you should follow the rules given below (see also the diagram below).

More than one Pill forgotten in a pack

Ask your doctor for advice.

1 Pill missed in week 1

Take the missed Pill as soon as you remember (even if this means taking two Pills at the same time) and take the next Pill at the usual time. Use extra contraceptive precautions (barrier method) for the next 7 days. If you had sexual intercourse in the week before missing the Pill, there is a possibility of becoming pregnant. So tell your doctor immediately.

1 Pill missed in week 2

Take the missed Pill as soon as you remember (even if this means taking two Pills at the same time) and take the next Pill at the usual time. The reliability of the pill is maintained. You need not use extra contraceptive precautions.

1 Pill missed in week 3

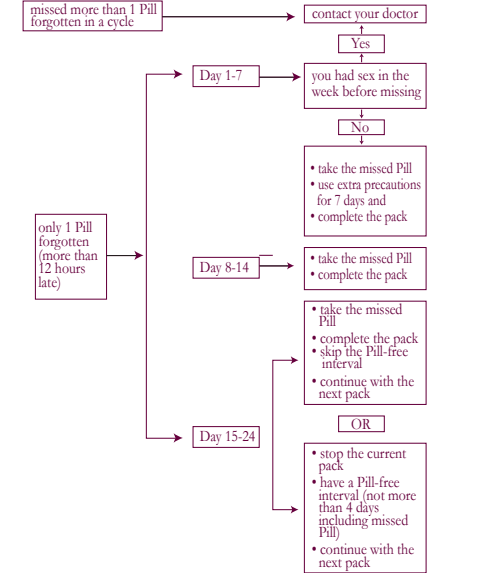
You may choose either of the following options, without the need for extra contraceptive precautions.

1. Take the missed Pill as soon as you remember (even if this means taking two

Pills at the same time) and take the next Pill at the usual time. Start the next pack as soon as the current pack is finished so that no gap is left between packs. You may not have a withdrawal bleed until the end of the second pack but you may have spotting or breakthrough bleeding on Pill-taking days. Or

2. Stop taking Pills from your current pack, have a Pill-free break of 4 days or less (also count the day you missed your Pill) and continue with the next pack. When, following this method, you can always start your next pack on the same day of the week as you usually do.

- If you have forgotten Pills in a pack and you do not have the expected period in the first normal Pill-free break, you may be pregnant. Consult your doctor before you start with the next pack.



..... you vomit or have severe diarrhea

If you vomit within 3 to 4 hours after taking your **novelon^{lite}[®]** Pill, the active ingredients may not have been completely absorbed. This is like missing a Pill. Therefore, follow the advice for missed Pills.

..... you want to delay your period

you can delay your period if you start with your next pack of **novelon^{lite}[®]** immediately after finishing your current pack. You can continue with this pack for as long as you wish, until this pack is empty. When you wish your period to begin, just stop Pill taking. While using the second pack you may have some breakthrough bleeding or spotting on Pill-taking days. Start with your next pack after the usual 4 days Pill free break.

..... you want to change the starting day of your period

If you take your Pills as directed, you will have your period on about the same day every 4 weeks. If you want to change this, just shorten, (never lengthen) the next Pill - free break. For example, if your period usually starts on a Friday and in future you want it to start on Tuesday (3 days earlier) you should now start your next pack 3 days sooner than you usually do. If you make your Pill - free break very short (e.g. 3 days or less) you may not have bleeding during the break. You may have some breakthrough bleeding or spotting during the use of the next pack.

..... you have unexpected bleeding

With all pills, for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection, but continue to take your Pills as normal. Irregular vaginal bleeding usually stops once your body has adjusted to the pill (usually after about 3 Pill-taking cycles). If it continues, becomes heavy or starts again, tell your doctor.

..... you have missed a period

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}[®]** as usual.

If you miss your period twice in row, you may be pregnant. Tell your doctor immediately. Do not start the next pack of **novelon^{lite}[®]** until your doctor has checked you are not pregnant.

POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects although not everybody gets them.

The following is a list of the side effects that have been linked with the use of **novelon^{lite}[®]** pill.

Common side effects (between 1 and 10 in every 100 users may be affected): mood swings, headache, nausea, breast pain, problems with your periods, such as irregular periods, absence of periods.

Uncommon side effects (between 1 and 10 in every 1,000 users may be affected):

depression, nervousness, sleepiness, dizziness, 'pins and needles', migraine, varicose veins, increased blood pressure, stomach ache, vomiting, indigestion, intestinal gas, inflammation of the stomach, diarrhoea, acne, itching, rash, aches and pains, e.g. back pain, limb pain, muscle cramps, vaginal fungal infection, pelvic pain, breast enlargement, benign breast lumps, urine/vaginal bleeding (which usually subsides during continued treatment), genital discharge, hot flushes, inflammation of the vagina (vaginitis), problems with your periods(painful periods, reduced periods, very heavy periods),vaginal dryness, abnormal cervical smear, decreased interest in sex, lack of energy, increased sweating, fluid retention, weight gain.

Rare side effects (between 1 and 10 in every 10,000 users may be affected): candida (fungal infection), anemia, allergic reaction, hormonal (endocrine) disorder, increased appetite, loss of appetite, abnormally high concentration of potassium in the blood, abnormally low concentration of sodium in the blood, insomnia, tremor, eye disorders, e.g. inflammation of the eyelid, dry eyes, abnormally rapid heartbeat, inflammation of a vein, nosebleed, fainting, enlarged abdomen, bowel disorder, feeling bloated, stomach hernia, fungal infection of the mouth, constipation, dry mouth.

Storage conditions: Store below 30°C.

Pack

novelon^{lite}[®] pack holds a memo pack containing 24 hormone pills. In addition, there are self-adhesive strips showing the days of the week and an inner pack to hold the memo pack.

Instructions for Use/Handling

Store all drugs properly and keep them out of reach of children.

Keep novelon^{lite}[®] pack out of the reach of children

IF YOU HAVE ANY FURTHER QUESTIONS OR REQUIRE THE FULL PRESCRIBING INFORMATION FOR **novelon^{lite}[®]**, PLEASE CONSULT YOUR DOCTOR OR PHARMACIST



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Renata Limited
Dhaka, Bangladesh
®Trade Mark
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