

Desogestrel & Ethinylestradiol Tablets IP

Noveheal नोवेहील

Composition

Each film coated tablet contains :

Desogestrel IP.....0.15 mg

Ethinylestradiol IP.....0.03 mg

Excipients.....q.s.

Colour : Erythrosine Lake

Please read this leaflet carefully before you start using Noveheal

Keep this leaflet handy - you may need to read it again. This leaflet will provide information about the benefits and risk of using oral contraceptives. It will also advise you about how to take **Noveheal** properly and when to tell your doctor about health related conditions. If you have further questions, ask your doctor or professional health care provider. Do not pass on this medicine to others, which has been prescribed to you, as it may harm them.

The name of your contraceptive pill is Noveheal tablets for oral use

1. What is Noveheal ?

1.1 Oral contraceptive pill"

Noveheal is a combined oral contraceptive (the combined Pill). Each tablet contains a small amount of two different female hormones, these are desogestrel (a progestogen) and ethinylestradiol (an estrogen). Because of the small amounts of hormones, **Noveheal** is considered a low dose oral contraceptive. "As all tablets in the pack combine the same hormones in the same dose, it is considered a monophasic combined oral contraceptive".

1.2 Why use Noveheal ?

Noveheal is used to prevent pregnancy. Oral contraceptives are a very effective method of birth control, when taken correctly (without missing tablets), the chance of becoming pregnant is very low.

2. When you should not use Noveheal ?

Do not use the combined Pill if you have any of the conditions listed below. If any of these conditions apply to you, tell your doctor before starting to use **Noveheal**. Your doctor may advise you to use a different type of Pill or an entirely different (non- hormonal) method of birth control. If you have, or have ever had a disorder effective the blood circulation, particularly those conditions relating to thrombosis (the formation of a blood clot) in the blood vessels of the legs (deep vein thrombosis), the lungs (Pulmonary embolism), the heart (heart attack), or other parts of the body. (See also the section later in this leaflet called 'The Pill and Thrombosis').

- If you have a disease that may increase the risk of a thrombosis in the arteries. This applies to the following diseases;

- 1 diabetes with damaged blood vessels
 - 2 very high blood pressure
 - 3 a very high level of fat in the blood (cholesterol or triglycerides)
- If you have or have had a stroke (caused by a blood clot in or rupture of a blood vessel in the brain) such as transient ischemic attack or small reversible stroke. If you have or have ever had a condition that may be a first sign of a heart attack (such as angina pectoris or chest pain).
 - If you have a history of migraine accompanied by focal neurological symptoms, e.g. Visual symptoms, speech disability, or weakness or numbness in any part of your

body,

- If you have or have had a pancreatitis (an inflammation of the pancreas).
- If you have jaundice (Yellowing of the skin) or severe liver disease. If you have or have had a cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs).

- If you have or have had a benign or malignant liver tumor.
 - If you have any unexplained vaginal bleeding.
 - If you are pregnant or think you might be pregnant.
 - If you are hypersensitive (Allergic) to ethinylestradiol or desogestrel or any of the other ingredients of **Noveheal**
- If any of these conditions appear for the first time while using the Pill stop taking it at once and consult your doctor. In the meantime, use non- hormonal contraceptive measure. See also General Notes' in the next section.

3. What do you need to know before using Noveheal ?

3.1 General Notes

In this leaflet, several situations are described where you should stop taking the Pill or where the reliability of the Pill may be decreased. In such Situations you should not have sex or you should take extra non - hormonal contraceptive precautions e.g. Use a condom or another barrier method. Do not use rhythm or temperature method These methods can be unreliable because the Pill alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle. **Noveheal, like all contraceptive Pill, does not Protect against HIV Infections (AIDS) or any other sexually transmitted disease.**

3.2 Before you start to use Noveheal

If the combined Pill is used in the presence of any of the conditions listed below you may need to be kept under close observation. Your doctor can explain this to you. Therefore, if any of these apply to you tell your doctor before starting to use **Noveheal**.

- you smoke
- you have diabetes
- you are overweight
- you have high blood pressure
- you have a heart valve disorder or a certain heart rhythm disorder;
- you have an inflammation of your veins (superficial phlebitis);
- you have varicose veins
- anyone in your immediate family has had a thrombosis, a heart attack or a stroke:
- you suffer from migraine
- you suffer from epilepsy;
- you or someone in your immediate family has or has had high blood levels of cholesterol or triglycerides (fatty substances);

- anyone in your immediate family has had breast cancer;
- you have liver or gallbladder disease;
- you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- you have systemic lupus erythematosus (SLE: a disease affecting the skin all over the body);
- you have haemolytic uraemic syndrome (HUS: a disorder of blood coagulation causing failure of the kidneys
- you have sickle cell disease;
- you have a condition that occurred for the first time or worsened during pregnancy or previous use of sex hormones (e.g., Hearing loss, a metabolic disease called porphyria, a skin disease called herpes

gestationis, a neurological disease called sydenham's chorea);

- you have or have had chloasma (yellowish brown pigmentation patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet radiation,

If any of the above conditions appear for the first time, recur or worsen while using the Pill, you should contact your doctor.

3.3 The Pill and Thrombosis

A thrombosis is the formation of a blood clot which may block a blood vessel. A thrombosis sometime occurs in the deep veins of the legs (deep venous thrombosis). If this blood clot breaks away from the veins where it is formed it may reach and block the arteries of the lungs causing a so-called pulmonary embolism: Deep venous thrombosis is a rare occurrence. It can develop whether or not you are taking the Pill. The risk is higher in Pill user than in non-user. The chance of getting a thrombosis is highest after you started using the Pill for the very first time. Thrombosis can also happen if you become pregnant. The risk of getting deep venous thrombosis for women using Pill with desogestrel may be slightly higher than for women using Pills with levonorgestrel. The absolute numbers remain very small. If 10 000 women use a Pill with levonorgestrel for one year, 2 women would get a thrombosis, if 10 000 women use a Pill with desogestrel for a year approximately 3 to 4 women would get a thrombosis. For comparison, if 10 000 women get pregnant, approximately 6 would get a thrombosis. These findings are based on the results of some studies. Other studies did not find a higher risk for Pills with desogestrel.

Blood clots can also occur very rarely in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke). Extremely rarely blood clots can occur in the liver, gut, kidney or eye.

Very occasionally thrombosis may cause serious permanent disabilities or may even be fatal. The risk of having a heart attack or stroke increase as you get older. It also increases the more you smoke.

When using the Pill you should stop smoking, especially if you are older than about 35 years of age.

If you develop high blood pressure while using the Pill, you may be told to stop using it.

The risk of having deep venous thrombosis is temporarily increased as a result of an operation or immobilization (for example, when you have your leg or legs in plaster or splints). In women who use the Pill, the risk may be yet higher. Tell your doctor you are using the Pill well in advance of any expected hospitalization or surgery. Your doctor may tell you to stop taking the Pill several weeks before surgery or at the time of immobilization. Your doctor will also tell you when you can start taking the Pill again after you are back on your feet. If you notice possible signs of a thrombosis, stop taking the Pill and consult your doctor immediately (See also 'when should you contact your doctor?').

3.4 The Pill and Cancer

Breast cancer has been diagnosed slightly more often in women who use the Pill than in women of the same age who do not use the Pill. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after stopping use of the Pill. It is not known whether the differences are caused by the Pill. It may be that the women were examined more often, so that breast cancer was noticed earlier.

In rare cases benign liver tumors and even more rarely, malignant liver tumors have been reported in user of the Pill. These tumors may lead to. Internal bleeding. Contact your doctor immediately if you have severe pain in your abdomen.

Chronic infection with the Human Papilloma virus (HPV)

is the single most important risk factor for cervical cancer. In women who use COCs for a long time the chance of getting cervical cancer may be slightly higher. This findings may not be caused by the Pill itself but may be related to sexual behaviour and other factors.

3.5 The Pill and Pregnancy

Noveheal must not be used by women who are pregnant, or who think they may be pregnant. If you suspect that you are pregnant while using **Noveheal**, you should consult your doctor as soon as possible.

3.6 The Pill and Breastfeeding **Noveheal** is generally not recommended for use during breastfeeding. If you wish to take the Pill while breastfeeding, please seek the advice of your doctor.

3.7 The Pill and ability to Drive

There are no observed effects.

3.8 The Pill and other Medicine

Some medicines may stop the Pill from working properly. These include medicines used for the treatment of epilepsy (e.g., Primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate); tuberculosis (e.g., Rifampicin, rifabutin) and HIV infections (e.g., Ritonavir); antibiotics (e.g., Penicillins, tetracyclines, griseofulvin) for some other infectious diseases; and the herbal remedy St. John's wort (primarily used for the treatment of depressive moods). The Pill may also interfere with the working of other medicines. Please inform your doctor if you are taking or have recently taken any other medicines or herbal products, even those not prescribed, also tell any other doctor or dentist who prescribes another medicine (or the dispensing pharmacist) that you use **Noveheal**. They can tell you if you need to take additional contraceptive precautions and if so, for how long

4. 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

contact your doctor as soon as as possible if :

- you notice any changes in your own health, especially involving any of the items mentioned in this leaflet (see also when should you not use **Noveheal** and 'Before you start to use **Noveheal**': 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 tablets in the first week of the pack and had intercourse in the seven days before;
- you have severe diarrhea;
- you miss your period twice in a row or suspect you are pregnant (do not start the next pack until told to by your doctor).

Stop taking tablets and see your doctor immediately if you notice possible signs of thrombosis, myocardial infarction or a stroke:

- 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 in Section 'What do you need to know before using Noveheal' of this leaflet.
- 5. How do you use Noveheal?**

5.1 When and how to take the tablets?

The Noveheal pack contains 21 tablets. On the pack each tablet is marked with the day of the week on which it is to be taken. Take your tablet at about the same time each day. With some liquid if necessary. Follow the direction of the arrows until all 21 tablets have been taken. During the next 7 days you take no tablets. A period should begin during these 7 days (the withdrawal bleed). Usually it will start on day 2-3 after the last Noveheal tablet. Start taking your next pack on the 8th day even if your period continues. This means that you will always start new pack on the same day of the week, and also that you have your withdrawal bleed on about the same days, each month.

5.2 Starting your first pack of Noveheal

- When no hormonal contraceptive has been used in the past month, start taking Noveheal on the first day of your cycle, i.e. The first day of menstrual bleeding. Take a tablet marked with that day of the week. For example, if your period start on a Friday, take tablet marked Friday. Then follow the days in order. Noveheal will work immediately, it is not necessary to use an additional contraceptive. You may also start on days 2-5 of your cycle, but in that case make sure you also use an additional contraceptive method (barrier method) for the first 7 days of tablet-taking in the first cycle.
- When changing from another combined hormonal contraceptive (combined oral contraceptive pill (vaginal ring, or transdermal patch). (if you are not sure which this is, ask your doctor). In case you use a vaginal ring or transdermal patch, you should start using Noveheal preferably on the day of removal, but at the latest when the next ring or patch would have been applied. If you follow these instructions, it is not necessary to use an additional contraceptive method.
- When changing from a progestogen-only pill (minipill). You can stop taking the minipill any day and start taking Noveheal the next day. But the same time make sure you also use an additional contraceptive method (a barrier method) for the first 7 days of tablet-taking when having intercourse.
- When changing from an injectable, an implant or a progestogen-releasing intrauterine device (IUD) Start using Noveheal when your next injection is due or on the day that you implant or your IUD is removed. But make sure you also use an additional contraceptive method (a barrier method) for the first 7 days of tablet-taking when having intercourse.

After having a baby

- If you have just had a baby, your doctor may tell you to wait until after your first normal period before you start taking Noveheal. Sometimes it is possible to start sooner. Your doctor will advise you. If you are breast-feeding and want to take Noveheal, you should discuss this first with your doctor.
- After a miscarriage or an abortion. Your doctor will advise you.

5.3 If too many Noveheal tablets are taken (overdose)

There have been no reports of serious harmful effects from taking too many Noveheal tablets at one time. If you have taken several tablets at a time, you may have nausea, vomiting or vaginal bleeding. If you discover that

a child has taken Noveheal, ask your doctor for advice

5.4 When you want to stop taking Noveheal

You can stop taking Noveheal at any time you want. If you stop because you want to get pregnant. It is generally recommended that you wait until you have had a natural period before trying to conceive. This helps you to work out when the baby will be due.

If you do not want to become pregnant, ask your doctor about other methods of birth control.

WHAT TO DO IF.....

.....You forget tablets

- If you are **less than 12 hours late** in taking a tablets, the reliability of the Pill is maintained take the tablets soon as you remember and take the next tablets at the usual times.
- If you are **more than 12 hours late** in taking any tablets, the reliability of the Pill may be reduced. The more consecutive tablets 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 tablets 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 tablet forgotten in a pack

Ask your doctor for advice.

1 tablets missed in week

Take the missed tablet as soon as you remember (Even if this means taking two tablets at the same time) and take the next tablets 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 tablets, there is a possibility of becoming pregnant. So tell your doctor immediately.

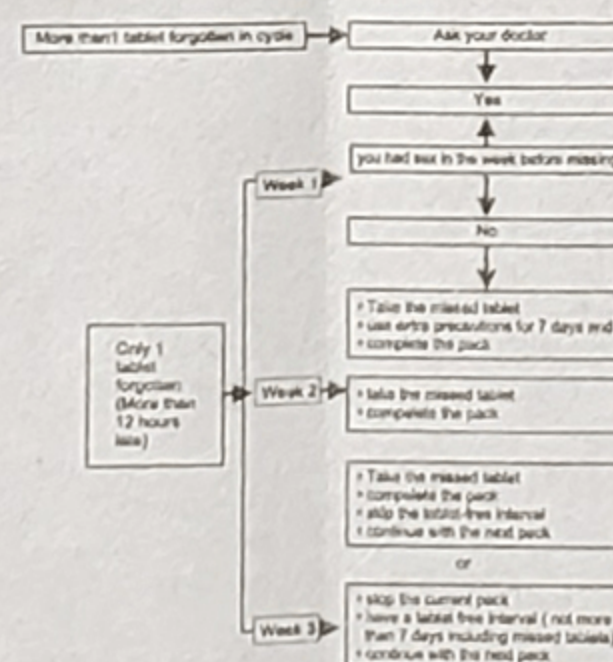
1 tablet missed in week 2

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

1 tablets missed in week 3

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

1. Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets 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 tablet-taking days.



Or

2. Stop taking tablets from your current pack, have a tablet-free break of 7 days or less (also count the day you missed your tablet) 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 tablets in a pack and you do not have the expected period in the first normal tablet-free break you start with the next pack

WHAT TO DO IF.....

.....You suffer from gastro-Intestinal disturbances (e.g., Vomiting, severe diarrhea)

If you vomit, or have severe diarrhea, the active ingredients of your Noveheal tablets may not have been completely absorbed. If you vomit within 3 to 4 hours after taking your tablet, this is like missing a tablet, therefore, follow the advice for missed tablets. If you have severe diarrhea, please contact your doctor.

.....You want to delay your period

You can delay your period if you start with your next pack of Noveheal immediately after finishing your current pack. You can continue with this pack for as long as you wish your period to begin, just stop may have some breakthrough bleeding or spotting on tablet-taking days. Start with your next pack after the usual 7 day tablet free break

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

If you take your tablets as directed you will have your period on about the same day every 4 weeks if you want to change this, just shorten, (never lengthier) the next tablet free break for example. If your period usually start on a Friday and in future you want it to start your next pack 3 days sooner than you usually do. If you make your tablets-free break very short (e.g. 3 days or less), you may not have not have a 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 sanitary protection, but continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to the Pill (usually after about 3 tablets taking cycles). If it continues becomes heavy or starts again, tell your doctor

.... You have missed period

If you have taken all of your tablets at the right time, and you have not vomited, not had severe diarrhea or used other medicine than you are' very unlikely to be pregnant continue to take Noveheal 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 Noveheal until your doctor has checked you are not pregnant

6. What side effects might you have while taking Noveheal?

Like all medicines, Noveheal can have side effects. Tell your doctor if you notice any unwanted effect, change in your health that you think might be caused by the pill

6.1 Serious side effects

Serious reactions associated with the use of the Pill as well as the related symptoms are described in the following sections. The pill and Thrombosis/the pill and cancer. Please read these sections for additional information and consult your doctor at once where appropriate.

6.2 other possible side effects

The following side effects have been reported by users of the Pill, although they need not be caused by the Pill side effects may occur in the first few months that you are using the pill and usually lessen with time.

Common/uncommon (occurring in more than one per 1000 user but less 1 in 10 user):

- nausea, vomiting abdominal pain, diarrhea;
 - Increase in body weight, fluid retention;
 - headache, migraine;
 - decreased sexual drive, depressed mood, mood changes;
 - breast pain, breast tenderness, breast entanglement;
 - changes in vaginal secretion; rash, hives,
- Rare (occurring in less than one per 1000 or more users):
- contact lens intolerance;
 - hypersensitivity reactions;
 - decrease in body weight
 - increased sexual drive;
 - breast secretion;
 - vaginal secretion
 - erythema nodosum, erythema multiforme (these are skin conditions).

If you notice any side effects not mentioned in this leaflet, please inform your doctor.

7. More about the Pill

The combined Pill may also have non-contraceptive health benefits.

- Your period may be lighter and shorter. As a result, the risk of anemia may be lower, Your period pains may

- become less severe or may completely disappear.
- In addition, some serious disorders have been reported to occur less frequently in user of Pill containing 0.05 mg of ethinylestradiol (high-dose Pill). These are benign breast disease, ovarian cysts, pelvic infections (pelvic inflammatory disease or PID), ectopic pregnancy (pregnancy in which the embryo implants out side of the womb) and cancer of the endometrium (lining of the womb) and ovaries. This may also be the case for low-dose Pills but so far this has only been confirmed for endometrial and ova rain cancer.

PRESENTATION :

Blister pack of 21 tablets,

8. STORAGE INSTRUCTIONS :

Store protected from moisture, at a temperature not exceeding 30°C.

KEEP THE MEDICINE OUT OF REACH OF CHILDREN.

IF YOU HAVE ANY FURTHER QUESTIONS OR REQUIRE THE FULL PRESCRIBING INFORMATION FOR Noveheal, PLEASE CONSULT YOUR DOCTOR.

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