

GEDAREL® 20/150

microgram film-coated tablets

ethinylestradiol / desogestrel



Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Gedarel is and what it is used for
2. Before you take Gedarel
3. How to take Gedarel
4. Possible side effects
5. How to store Gedarel
6. Further information

1. WHAT GEDAREL IS AND WHAT IT IS USED FOR

Gedarel is a combined oral contraceptive, also called the pill. It contains two types of female hormones: a progestogen, desogestrel, and an oestrogen, ethinylestradiol in a low dose. These help to stop you from getting pregnant, just as your natural hormones would stop you conceiving again when you are already pregnant.

The combined contraceptive pill protects you against getting pregnant in three ways. These hormones

1. stop the ovary from releasing an egg each month (ovulation).
2. also thicken the fluid (at the neck of the womb making it more difficult for the sperm to reach the egg).
3. alter the lining of the womb to make it less likely to accept a fertilised egg.

General information

If taken correctly, the pill is an effective reversible form of contraception. However, in certain circumstances the effectiveness of the pill may reduce or you should stop taking the pill (see later). In these cases either do not have sex, or use extra contraceptive precautions (such as condoms or spermicides) during intercourse to ensure effective contraception.

Do not use rhythm or temperature methods. These methods can be unreliable because Gedarel alters the monthly changes of body temperature and of cervical mucus.

Remember, combined oral contraceptive pills like Gedarel will not protect you against sexually-transmitted diseases (such as AIDS). Only condoms can help to do this.

2. BEFORE YOU TAKE GEDAREL

Before you can begin taking Gedarel, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure, and depending upon your personal situation, may also carry out some other tests.

When you should not use Gedarel

- if you have (or have had in the past) a blood clot (thrombosis) in a blood vessel of the leg, lung (embolus) or other organs
- if you have (or have had in the past) a heart attack or stroke
- if you have (or have had in the past) a disease that can be a predictor of a heart attack (for example, angina pectoris, which causes severe pain in the chest) or of a stroke (for example, a transient slight stroke with no residual effects)
- if you have a disease that may increase the risk of a thrombosis in the arteries. This applies to the following diseases:
 - diabetes with damaged blood vessels
 - very high blood pressure
 - a very high level of fat in the blood (cholesterol or triglycerides)
- if you have a disturbance of blood clotting (for example, protein C deficiency)
- if you have (had) a certain form of migraine (with so-called focal neurological symptoms)
- if you have (had) an inflammation of the pancreas (pancreatitis)
- if you have or have had in the past a liver disease and your liver function is still not normal
- if you have or have had a tumour in the liver
- if you have (had) or if you are suspected of having breast cancer or cancer of the genital organs
- if you have any unexplained bleeding from the vagina
- if you are allergic to ethinylestradiol or desogestrel, or any of the other ingredients of Gedarel. This can be recognised by itching, rash or swelling.

When do you need to take special care with Gedarel

In some situations you need to take special care while using Gedarel or any other combined hormonal contraceptive, and it may be necessary that you are regularly checked by your doctor. If any of the following conditions applies to you, you must inform your doctor before starting to use Gedarel. Also if any of the following conditions develop or worsen during the use of Gedarel you must consult your doctor:

- if a close relative has or has had breast cancer
- if you have a disease of the liver or the gallbladder
- if you have diabetes
- if you have depression
- if you have Crohn's disease or ulcerative colitis (inflammatory bowel disease)
- if you have HUS (haemolytic uraemic syndrome; a blood disease that causes kidney damage)
- if you have sickle cell anaemia (an inherited disease of the red blood cells)
- if you have epilepsy (see "Taking other medicines")
- if you have SLE (systemic lupus erythematosus; a disease of the immune system)
- if you have a disease that first appeared during pregnancy or earlier use of sex hormones {for example, hearing loss, porphyria (a disease of the blood), gestational herpes (skin rash with fluid-filled blisters during pregnancy), Sydenham's chorea (a disease of the nerves in which sudden movements of the body occur)}
- if you have or have ever had chloasma (golden brown pigment patches, so called "pregnancy patches", especially on the face). If this is the case, avoid direct exposure to sunlight or ultraviolet light
- If you have hereditary angioedema, products containing oestrogens may induce or worsen symptoms of angioedema. You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or pharynx and/or difficulty swallowing or hives together with difficulty breathing.

The pill and thrombosis

Venous thrombosis

The use of any combination pill, including Gedarel, increases a woman's risk of developing a venous thrombosis (formation of a blood clot in vessels) compared with a woman who does not take any (contraceptive) pill.

The risk of venous thrombosis in users of combined pills increases:

- with increasing age
- if you are overweight
- if one of your close relatives has had a blood clot (thrombosis) in the leg, lung, or other organ at a young age
- if you must have an operation (surgery), any prolonged period of immobilization, or if you have had a serious accident. It is important to tell your doctor in advance that you are using Gedarel as the treatment may have to be stopped. Your doctor will tell you when to start Gedarel again. This is usually about two weeks after you are back on your feet.

Arterial thrombosis

The use of combination pills has been connected with an increase of the risk of arterial thrombosis (obstruction of an artery), for example, in the blood vessels of the heart (heart attack) or the brain (stroke).

The risk of arterial thrombosis in users of combined pills increases:

- **if you smoke. You are strongly advised to stop smoking when you use Gedarel, especially if you are older than 35 years**
- if you have an increased fat content in your blood (cholesterol or triglycerides)
- if you have high blood pressure
- if you have migraines
- if you have a problem with your heart (valve disorder, a disturbance of the heart rhythm).

Stop taking Gedarel and contact your doctor immediately if you notice possible signs of thrombosis, such as:

- severe pain and/or swelling in one of your legs
- sudden severe pain in the chest which may reach the left arm
- sudden breathlessness
- sudden cough without an obvious cause
- any unusual, severe or long-lasting headache or worsening of migraine
- partial or complete blindness or double vision
- difficulty in speaking or inability to speak
- giddiness or fainting
- weakness, strange feeling, or numbness in any part of the body.

The pill and cancer

Breast cancer has been observed slightly more often in women using combined pills, but it is not known whether this is caused by the treatment. For example it may be that more tumours are detected in women on combined pills because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the combination hormonal contraceptives. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in pill users. Contact your doctor if you have unusual severe abdominal pain.

Bleeding between periods

During the first few months that you are taking Gedarel, you may have unexpected bleeding (bleeding outside the gap week). If this bleeding lasts longer than a few months, or if it begins after some months, your doctor must investigate the cause.

What you must do if no bleeding occurs in the gap week

If you have taken all the tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant.

If the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Do not start the next strip until you are sure that you are not pregnant.

Taking other medicines

Always tell the doctor, who prescribes Gedarel, which medicines or herbal products you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the dispensing pharmacist) that you use Gedarel. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long.

- Some medicines can make Gedarel less effective in preventing pregnancy, or can cause unexpected bleeding. These include medicines used for the treatment of epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbamazepine, topiramate, hydantoins, felbamate) and tuberculosis (e.g. rifampicin), or HIV infections (ritonavir, nevirapin) or other infectious diseases (griseofulvin, ampicillin, tetracycline), and the herbal remedy St. John's wort.
- If you want to use herbal products containing St. John's wort while you are already using Gedarel you should consult your doctor first.
- Gedarel may decrease the efficacy of other medicines, e.g. medicines containing cyclosporin, or the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures).

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy and breast-feeding

You must not use Gedarel when you are pregnant. If you become pregnant or you think you might be pregnant, stop taking Gedarel and talk to your doctor immediately.

Gedarel should not be taken during breast-feeding. If you are breast-feeding and want to take the pill, you should discuss this with your doctor.

Driving and using machines

You can drive or operate machinery while taking Gedarel.

Important information about some of the ingredients of Gedarel

This medicinal product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE GEDAREL

Always take Gedarel exactly as your doctor has told you. You should check with your doctor if you are not sure. Each pack of Gedarel contains 1 calendar strip of 21 coated tablets or 3, 6, 13 calendar strips of 21 coated tablets. The calendar strip has been designed to help you remember to take your tablets.

The strip is marked with the day of the week on which each tablet should be taken. Following the direction of the arrow printed on the strip you should take one tablet each day for 21 days until the strip is empty.

Then you have 7 days when you do not take a tablet. During the 7 tablet-free days, on day 2 or 3, you will have menstruation-like withdrawal bleeding, i.e. your "monthly period".

Start your next strip on the 8th day (following the 7 tablet-free days) – even if the bleeding has not yet ended. As long as you take Gedarel correctly, you will always start each new strip on the same day of the week, and you will always have your monthly period on the same day of the week in each month (in every 28 days).

You should try to take your tablet at about the same time each day.

You may find it easiest to take it either last thing at night or first thing in the morning.

Swallow each tablet whole, with water if necessary.

Starting the first pack

If no oral contraception has been used during the preceding cycle

Take the first tablet on the first day of your period. This is the first day of your cycle - the day when bleeding starts. Take a tablet marked for that day of the week (for example, if it is Tuesday when your period starts, take the tablet marked Tuesday on the pack). Follow the direction of the arrow and continue taking one tablet each day until the strip is empty.

If you start on day 2-5 of your period, you should use another method of contraception as well, such as the condom, for the first seven tablet-taking days, but this is only for the first pack.

Changing to Gedarel from another combined hormonal

contraceptive, or combined contraceptive vaginal ring or patch

Start taking Gedarel on the day after the tablet-free period of your previous pill finishes (or after the last inactive tablet of your

previous pill). In case a vaginal ring or a transdermal patch has been used, the woman should start using Gedarel preferably on the day of removal, but at the latest when the next application would have been due.

Changing to Gedarel from a progestogen- product (progestogen-only-pills, injection, implant or progestogen releasing IUD)

You may switch any day from the progestogen-only tablet (from an implant or the IUD on the day of its removal, from an injectable when the next injection would be due) but in all of these cases you must use extra protective measures (for example, a condom) for the first 7 days of tablet-taking.

After a miscarriage

Follow the advice of your doctor.

After having a baby

After having a baby, you can start Gedarel between 21 and 28 days later. 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 Gedarel use. If, after having a baby, you have had intercourse before starting Gedarel (again), you must first be sure that you are not pregnant or you must wait until the next menstrual bleed. Let your doctor advise you, in case you are not sure when to start.

If you are breast-feeding and want to start Gedarel (again) after having a baby

Read the section on "Breast-feeding".

If you take more Gedarel than you should

There are no reports of serious harmful results of taking too many Gedarel tablets. If you take several tablets at once then you may have symptoms of nausea or vomiting. Young girls may have bleeding from the vagina. If you have taken too many Gedarel tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

What to do if you forget to take Gedarel tablets

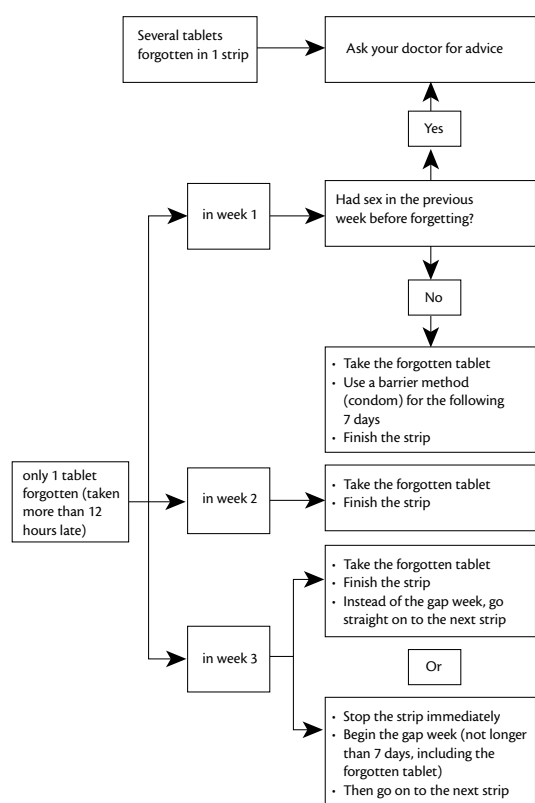
- If you are less than 12 hours late taking a tablet, the protection from pregnancy is not reduced. Take the tablet as soon as you remember and then take the following tablets again at the usual time.
- If you are more than 12 hours late taking a tablet, the protection from pregnancy may be reduced. The greater the number of tablets that you have forgotten, the greater is the risk that the protection from pregnancy is reduced.

The risk of incomplete protection against pregnancy is greatest if you forget a tablet at the beginning or the end of the strip. Therefore, you should adhere to the following rules (see also the diagram below):

- **More than one tablet forgotten in this strip**
Contact your doctor.
- **One tablet forgotten in week 1**
Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Take the tablets again at the usual time and use extra precautions for the next 7 days, for example, a condom. If you have had intercourse in the week before the oversight or you have forgotten to start a new strip after the tablet-free period, you must realize that there is a risk of pregnancy. In that case, contact your doctor.
- **One tablet forgotten in week 2**
Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Take the tablets again at the usual time. The protection from pregnancy is not reduced, and you do not need to take extra precautions.
- **One tablet forgotten in week 3**
You can choose between two possibilities:
 1. Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Take the tablets again at the usual time. Instead of the tablet-free period go straight on to the next strip. Most likely, you will have a period (withdrawal bleed) at the end of the second strip but you may also have spotting or breakthrough bleeding during the second strip.
 2. You can also stop taking tablets from the strip and go directly to the tablet-free period of 7 days (**record the day on which you forgot your tablet**). If you want to start a new strip on your fixed start day, make the tablet-free period less than 7 days.

If you follow either of these two recommendations, you will remain protected against pregnancy.

- If you have forgotten any of the tablets in a strip, and you do not have bleeding in the first tablet-free period, this may mean that you are pregnant. You must contact your doctor before you go on to the next strip.



What to do in case of vomiting or severe diarrhoea

If you vomit within 3-4 hours of taking a tablet or you have severe diarrhoea, there is a risk that the active substances in the tablet are not fully absorbed into your body. The situation is similar to if you forget a tablet. After vomiting or diarrhoea, you must take another tablet from a reserve strip as soon as possible. If possible take it within 12 hours of when you normally take your tablet. If this is not possible or more than 12 hours have passed, you should follow the advice given under "If you forget to take Gedarel".

Delay of menstrual period: what you must know

Even if not recommended, delay of your menstrual period (withdrawal bleed) is possible by going straight on to a new strip of Gedarel instead of the tablet-free period, to the end of the second strip. You may experience spotting (drops or flecks of blood) or breakthrough bleeding while using this second strip. After the usual tablet-free period of 7 days, continue with the following strip.

You might ask your doctor for advice before deciding to delay your menstrual period.

Change of the first day of your menstrual period: what you must know

If you take the tablets according to the instructions, then your menstrual period/withdrawal bleed will begin during the tablet-free week. If you have to change this day, you do this by making the tablet-free period shorter (but never longer!). For example, if your

tablet-free period begins on a Friday, and you want to change this to a Tuesday (3 days earlier) you must start a new strip 3 days earlier than usual. If you make the tablet-free period very short (for example, 3 days or less) then it may be that you do not have any bleeding during this tablet-free period. You may then experience spotting (droplets or flecks of blood) or breakthrough bleeding.

If you are not sure how to proceed, contact your doctor for advice.

If you want to stop taking Gedarel

You can stop taking Gedarel whenever you want. If you do not want to become pregnant, ask your doctor for advice about other reliable methods of birth control.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Gedarel can have side effects, although not everybody gets them.

Serious reactions

More serious reactions associated with combined hormonal contraceptive pills are detailed above in section 2 under "The pill and thrombosis" and "The pill and cancer". Please read these subsections carefully, and if you have any questions, ask your doctor.

Other possible side effects

The following side effects have been reported in women using the pill, which can occur in the first few months after starting Gedarel, but they usually stop once your body has adjusted to the pill. The most commonly reported undesirable effects (> 10 %) are irregular bleeding and weight increase.

Common and uncommon (more than 1 in 1,000 but less than 1 in 10 women): none or reduced bleeding, tender breasts, breast enlargement, breast pain, decreased sexual desire, depression, headache, nervousness, migraine, dizziness, nausea, vomiting, acne, rash, nettle-rash (urticaria), fluid retention, high blood pressure.

Rare (less than one in 1,000 women): vaginal candidiasis (fungal infection), impaired hearing (otosclerosis), thromboembolism, hypersensitivity, increased sexual desire, eye irritation due to contact lens, loss of hair (alopecia), itching, skin disorders (erythema nodosum, erythema multiforme), abnormal cervical smear, breast discharge.

The following serious side effects have been reported in women using the pill:

Crohn's disease or ulcerative colitis (chronic inflammatory bowel diseases), systemic lupus erythematosus (SLE, a disease of the connective tissue), epilepsy, the rash known as herpes gestationis, chorea (a movement disease), a blood disorder called haemolytic uraemic syndrome - HUS (a disorder where blood clots cause the kidneys to fail), brown patches on the face and body (chloasma), movement disorder called Sydenham's chorea, yellowing of the skin, gynaecological disorders (endometriosis, uterine myoma).

Before you have any blood tests

Tell your doctor or the laboratory staff that you are taking the pill, because oral contraceptives can affect the results of some tests.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE GEDAREL

Keep out of the reach and sight of children.

Do not use Gedarel after the expiry date (EXP.) which is stated on the package. The expiry date refers to the last day of the month.

Store below 30°C. Store in the original package.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Gedarel contains

The active substances are ethinylestradiol and desogestrel. One film-coated tablet contains 20 micrograms ethinylestradiol and 150 micrograms desogestrel.

The other ingredients are:

Tablet core: Potato starch; stearic acid; all-rac-alpha-tocopherol; lactose monohydrate; magnesium stearate; silica colloidal anhydrous; povidone K 30; quinoline yellow (E 104).

Tablet coating: Hypromellose; Macrogol 6000; propylene glycol.

What Gedarel looks like and contents of the pack

Slightly yellow, round shaped, biconvex film-coated tablets of about 6 mm diameter, with PG sign on one side and RG on the other side.

Each box contains 1, 3, 6 or 13 calendar pack(s) of 21 film-coated tablets.

Not all pack sizes may be marketed.

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