

## Package leaflet: Information for the user

### Gedarel 150 micrograms/30 micrograms film-coated tablets Ethinylestradiol, desogestrel

#### **Important things to know about combined hormonal contraceptives (CHCs):**

- They are one of the most reliable reversible methods of contraception if used correctly.
- They slightly increase the risk of having a blood clot in the veins and arteries, especially in the first year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks.
- Please be alert and see your doctor if you think you may have symptoms of a blood clot (see section 2 “Blood clots”).

#### **Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What GEDAREL is and what it is used for
2. What you need to know before you use GEDAREL
3. How to take GEDAREL
4. Possible side effects
5. How to store GEDAREL
6. Contents of the pack and other 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: an oestrogen, ethinylestradiol, and a progestogen, desogestrel 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.

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. What you need to know before you use GEDAREL**

## General notes

Before you start using GEDAREL you should read the information on blood clots in section 2. It is particularly important to read the symptoms of a blood clot – see section 2 “Blood clots”.

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.

## Do not use GEDAREL

You should not use GEDAREL if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor. Your doctor will discuss with you what other form of birth control would be more appropriate.

- if you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis DVT), your lungs (pulmonary embolus, PE) or other organs;
- if you know you have a disorder affecting your blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies;
- if you need an operation or if you are off your feet for a long time (see section ‘Blood clots’);
- if you have ever had a heart attack or a stroke;
- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA – temporary stroke symptoms);
- if you have any of the following diseases that may increase your risk of a clot in the arteries:
  - very high blood pressure
  - severe diabetes with blood vessel damage
  - a very high level of fat in the blood (cholesterol or triglycerides)
  - a condition known as hyperhomocysteinaemia;
- you have (or have ever had) a type of migraine called “migraine with aura”;
- if you have or ever have had in the past 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;
- you have liver tumours or if you have ever had these;
- you have or may have breast cancer or other cancer, for example ovarian cancer, cervical cancer, or cancer of the uterus (womb);
- you have unexplained bleeding from your vagina;
- you are pregnant or think you might be;
- you have endometrial hyperplasia (a condition characterised by overgrowth of the lining of the uterus);
- if you are allergic to ethinylestradiol or desogestrel or any of the other ingredients of this medicine (listed in section 6). This can be recognised by itching, rash or swelling.

Do not use GEDAREL if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir (see also in section Other medicines and GEDAREL).

## Warnings and precautions

Talk to your doctor or pharmacist before taking GEDAREL.

**If you get any of the following diseases/conditions, you can only take GEDAREL under strict medical supervision, since these conditions may get worse while you are taking the pill.**

### When should you contact your doctor?

#### Seek urgent medical attention

- if you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke (see ‘Blood clots’ (thrombosis) section below).

For a description of the symptoms of these serious side effects please go to “How to recognise a blood clot”.

**Tell your doctor if any of the following conditions apply to you.**

If the condition develops, or gets worse while you are using GEDAREL, you should also tell your doctor.

- if you have high blood pressure;
- if you have a heart-valve disorder or a certain heart-rhythm disorder;
- if you have varicose veins;
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- if you have migraine;
- if you have diabetes;
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel diseases);
- if you have the inherited form of deafness known as otosclerosis;
- if you have depressed mood (depression) or mood changes;
- if you have the movement disorder called Sydenham's chorea;
- if you have liver and/or gall bladder disease (yellowing of the skin, gallstones);
- if you have the inherited disease called porphyria;
- if you have sickle cell anaemia (an inherited disease of the red blood cells);
- if you have haemolytic uremic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys);
- if you have systemic lupus erythematosus – (SLE - a disease affecting your natural defence system);
- if you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas).
- if you need an operation, or you are off your feet for a long time (see in section 2 ‘Blood clots’);
- if you have just given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking GEDAREL;
- if you have itching (pruritus);
- if you have the rash known as herpes gestationis;
- if you have brown patches on your face and body (chloasma), which you can reduce by staying out of the sun and not using sunbeds or sunlamps.
- if you have hereditary angioedema, products containing estrogens 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 above conditions may get worse while you are taking the pill; **therefore regular medical check-ups are necessary while you are on the pill.**

**BLOOD CLOTS**

Using a combined hormonal contraceptive such as GEDAREL increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block blood vessels and cause serious problems.

Blood clots can develop

- in veins (referred to as a ‘venous thrombosis’, ‘venous thromboembolism’ or VTE)
- in the arteries (referred to as an ‘arterial thrombosis’, ‘arterial thromboembolism’ or ATE).

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, they may be fatal.

**It is important to remember that the overall risk of a harmful blood clot due to GEDAREL is small.**

**HOW TO RECOGNISE A BLOOD CLOT**

Seek urgent medical attention if you notice any of the following signs or symptoms.

Are you experiencing any of these signs?	What are you possibly suffering from?
- swelling of one leg or along a vein in the leg or foot	Deep vein thrombosis

<p>especially when accompanied by:</p> <ul style="list-style-type: none"> <li>- pain or tenderness in the leg which may be felt only when standing or walking</li> <li>- increased warmth in the affected leg</li> <li>- change in colour of the skin on the leg e.g. turning pale, red or blue.</li> </ul>	
<ul style="list-style-type: none"> <li>- sudden unexplained breathlessness or rapid breathing;</li> <li>- sudden cough without an obvious cause, which may bring up blood;</li> <li>- sharp chest pain which may increase with deep breathing;</li> <li>- severe light headedness or dizziness;</li> <li>- rapid or irregular heartbeat;</li> <li>- severe pain in your stomach;</li> </ul> <p>If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a 'common cold').</p>	Pulmonary embolism
<p>Symptoms most commonly occur in one eye:</p> <ul style="list-style-type: none"> <li>- immediate loss of vision or</li> <li>- painless blurring of vision which can progress to loss of vision.</li> </ul>	Retinal vein thrombosis (blood clot in the eye)
<ul style="list-style-type: none"> <li>- chest pain, discomfort, pressure, heaviness;</li> <li>- sensation of squeezing or fullness in the chest, arm or below the breastbone;</li> <li>- fullness, indigestion or choking feeling;</li> <li>- upper body discomfort radiating to the back, jaw, throat, arm and stomach;</li> <li>- sweating, nausea, vomiting or dizziness;</li> <li>- extreme weakness, anxiety, or shortness of breath;</li> <li>- rapid or irregular heartbeats</li> </ul>	Heart attack
<ul style="list-style-type: none"> <li>- sudden weakness or numbness of the face, arm or leg, especially on one side of the body;</li> <li>- sudden confusion, trouble speaking or understanding;</li> <li>- sudden trouble seeing in one or both eyes;</li> <li>- sudden trouble walking, dizziness, loss of balance or coordination;</li> <li>- sudden, severe or prolonged headache with no known cause;</li> <li>- loss of consciousness or fainting with or without seizure.</li> </ul> <p>Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.</p>	Stroke
<ul style="list-style-type: none"> <li>- swelling and slight blue discolouration of an extremity;</li> <li>- severe pain in your stomach (acute abdomen)</li> </ul>	Blood clots blocking other blood vessels

## BLOOD CLOTS IN A VEIN

### What can happen if a blood clot forms in a vein?

- The use of combined hormonal contraceptives has been connected with an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare. Most frequently, they occur in the first year of use of a combined hormonal contraceptive.
- If a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung it can cause a pulmonary embolism.

- Very rarely a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

**When is the risk of developing a blood clot in a vein highest?**

The risk of developing a blood clot in a vein is highest during the first year of taking a combined hormonal contraceptive for the first time. The risk may also be higher if you restart taking a combined hormonal contraceptive (the same product or a different product) after a break of 4 weeks or more. After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive.

When you stop GEDAREL your risk of a blood clot returns to normal within a few weeks.

**What is the risk of developing a blood clot?**

The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you are taking.

The overall risk of a blood clot in the leg or lung (DVT or PE) with GEDAREL is small.

- Out of 10,000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains levonorgestrel, norethisterone, or norgestimate about 5-7 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains desogestrel such as GEDAREL between about 9 and 12 women will develop a blood clot in a year.
- The risk of having a blood clot will vary according to your personal medical history (see “Factors that increase your risk of a blood clot” below)

	<b>Risk of developing a blood clot in a year</b>
Women who are <b>not using</b> a combined hormonal pill/patch/ring and are not pregnant	About 2 out of 10,000 women
Women using a combined hormonal contraceptive pill containing <b>levonorgestrel, norethisterone or norgestimate</b>	About 5-7 out of 10,000 women
Women using GEDAREL	About 9-12 out of 10,000 women

**Factors that increase your risk of a blood clot in a vein**

The risk of a blood clot with GEDAREL is small but some conditions will increase the risk. Your risk is higher:

- if you are very overweight (body mass index or BMI over 30 kg/m<sup>2</sup>);
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50). In this case you could have a hereditary blood clotting disorder;
- if you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of GEDAREL may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop GEDAREL ask your doctor when you can start using it again.
- as you get older (particularly above about 35 years);
- if you gave birth less than a few weeks ago.

The risk of developing a blood clot increases the more conditions you have.

Air travel (>4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.

It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that GEDAREL needs to be stopped.

If any of the above conditions change while you are using GEDAREL, for example a close family

member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

## **BLOOD CLOTS IN AN ARTERY**

### **What can happen if a blood clot forms in an artery?**

Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

### **Factors that increase your risk of a blood clot in an artery**

It is important to note that the risk of a heart attack or stroke from using GEDAREL is very small but can increase:

- with increasing age (beyond about 35 years);
- **if you smoke.** When using a combined hormonal contraceptive like GEDAREL you are advised to stop smoking. If you are unable to stop smoking and are older than 35 your doctor may advise you to use a different type of contraceptive;
- if you are overweight;
- if you have high blood pressure;
- if a member of your immediate family has had a heart attack or stroke at a young age (less than about 50). In this case you could also have a higher risk of having a heart attack or stroke;
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides);
- if you get migraines, especially migraines with aura;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation);
- if you have diabetes.

If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot may be increased even more.

If any of the above conditions change while you are using GEDAREL, for example you start smoking, a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

### **The pill and cancer**

Every woman is at risk of breast cancer whether or not she takes the pill. Breast cancer has been found slightly more often in women who take the pill than in women of the same age who do not take the pill. If women stop taking the pill this reduces the risk so that 10 years after stopping the pill, the risk of finding breast cancer is the same as for women who have never taken the pill. It is not certain whether the pill causes the increased risk of breast cancer. It may be that women taking the pill are examined more often, so that breast cancer is noticed earlier.

In women using the pill malignant and benign liver tumours have been reported. Liver tumours may lead to life-threatening intra-abdominal haemorrhage (bleeding in the abdomen). So, if you have pain in your upper abdomen that does not soon clear up, tell your doctor.

An increased risk of cervical cancer in long-term users of the pill has been reported in some studies. It is uncertain whether this increased risk is caused by the pill as it could be due to the effects of sexual behaviour and other factors.

### **Psychiatric disorders**

Some women using hormonal contraceptives including GEDAREL have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

### **Children and adolescents**

The safety and efficacy of desogestrel in adolescents below 18 years has not yet been established. No data are available.

### **Other medicines and GEDAREL**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not use GEDAREL if you have Hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir as this may cause increases in liver function blood test results (increase in ALT liver enzyme).

Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicinal products.

GEDAREL can be restarted approximately 2 weeks after completion of this treatment. See section "Do not use GEDAREL".

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 have an influence on the blood levels of GEDAREL and can make it **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, oxcarbazepine, topiramate, felbamate)
- tuberculosis (e.g. rifampicin)
- HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapin, efavirenz) or other infections (griseofulvin)
- increase of blood pressure in the lung vasculature (bosentan)
- 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,
- the symptomatic treatment of arthrosis (etoricoxib)

GEDAREL may influence the efficacy of other medicines, e.g.

- ciclosporin (medicine used for the treatment of suppression of tissue rejection following transplant surgery),
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures),
- tizanidine (a medicine for the treatment of muscle spasticity),
- theophylline (a medicine for the treatment of asthma),
- levothyroxine (a medicine for the treatment of hormone deficiency).

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

### **Before you have any laboratory tests**

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

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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.

### **GEDAREL contains lactose**

If you have an intolerance to milk sugar (lactose), you should reckon the lactose content of the

preparation (64.3 mg lactose per film-coated tablet). 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 this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Each pack of GEDAREL contains 1 memo strip of 21 coated tablets or 3 memo strips of 21 coated tablets. The memo pack has been designed to help you remember to take your pills.

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

**Then you have 7 days when you do not take a pill. During the 7 pill-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 8<sup>th</sup> day (following the 7 pill-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 month.**

**You should try to take your pill 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 pill whole, with water if necessary.**

#### **Starting the first pack**

##### ***If no oral contraception has been used during the preceding cycle***

Take the first pill on the first day of your period. This is the first day of your cycle - the day when bleeding starts. Take a pill marked for that day of the week (for example, if it is Tuesday when your period starts, take the pill marked Tuesday on the pack). Follow the direction of the arrow and continue taking one pill 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 pill-taking days, but this is only for the first pack.

You do not need to use any other form of contraception during the seven-day break provided you have taken the 21 pills properly and you start the next pack on time.

##### ***Changing to GEDAREL from another combined hormonal contraceptive***

Start taking GEDAREL on the day after you take the last pill from the strip of your previous contraceptive. If your previous pill strip also contains dummy pills, you should start with GEDAREL on the day after the last active hormonal intake, but no later than on the day after the usual hormone-free interval with your previous combined hormonal contraceptive (or after taking the last dummy pill of your previous pack).

If you are unclear or have further questions, ask your doctor or pharmacist.

##### ***Changing to GEDAREL from a progestogen-only pill (POP, or minipill)***

You can stop taking pills only containing progestogen any time, and start taking GEDAREL the next day at the usual time. But be sure to use additional prevention (such as condoms or spermicides) during intercourse in the first 7 days, during which you take the pills.

##### ***Changing to GEDAREL from a contraceptive injection or implant***

If you have had an injection or implant of the hormone progestogen, you can start to take GEDAREL on the day that your next injection is due, or on the day that your implant is removed. However, you



should use another method of contraception (such as condoms or spermicides) during intercourse in the first 7 days, during which you take the pills.

### **Starting after childbirth or miscarriage or abortion**

After a birth, abortion or miscarriage, your doctor should advise you about taking the pill.

You can start using GEDAREL immediately after a miscarriage or abortion which occurs during the first three months of pregnancy. In this case you do not need extra contraceptive precautions.

If you have had a delivery or abortion during the second three months of pregnancy, your doctor will advise you about taking the pill.

### **If you forget to take GEDAREL**

If you forget to take a pill please follow these instructions.

### **If one pill is 12 hours late or less**

You are still protected against pregnancy if you take the late pill as soon as you remember, and keep taking your next pills at the usual time. This may mean taking two pills in one day.

### **If you are more than 12 hours late in taking a pill**

If you are more than 12 hours late in taking a pill, your protection against pregnancy might be reduced so you must use extra contraceptive precautions. The more pills you have missed, the more risk there is that your contraceptive protection is reduced.

### **If you have missed more than one pill, ask your doctor for advice.**

#### ***What to do if you miss the pill at the first week***

You must take the last missed tablet as soon as you remember, even if this means that you have to take 2 tablets at the same time. Thereafter, you should continue taking the tablets at the usual time of the day. You must also use a barrier method of contraception, e.g. a condom, for the next 7 days. If intercourse has taken place during the preceding 7 days the possibility of pregnancy must be considered. The more missed tablets and the closer to the tablet-free interval this happens, the greater the risk of pregnancy.

#### ***What to do if you miss the pill at the second week***

You must take the last missed tablet as soon as you remember even if this means that you have to take 2 tablets at the same time. Thereafter, you should continue taking the tablets at the usual time of the day. Provided that the tablets have been taken in a correct manner during the 7 days preceding the missed tablet, it is not necessary to take further contraceptive measures. However, if this is not the case, or if more than 1 tablet has been missed, you should take extra contraceptive precautions for 7 days.

#### ***What to do if you miss the pill at the third week***

The risk of contraceptive failure is imminent because of the ensuing tablet-free interval. The reduced contraceptive protection may, however, be prevented by adjusting the tablet intake. Therefore, by following one of the following two alternatives, it is not necessary to take further contraceptive precautions, provided that all tablets have been taken correctly during the 7 days preceding the first missed tablet. **If you have not taken GEDAREL correctly during the 7 days preceding the first missed tablet, you should follow the first of the two alternatives. Additionally a barrier method (such as a condom) should be used concomitantly for the next 7 days.**

1. You should take the last missed tablet as soon as you remember, even if it means that you have to take 2 tablets at the same time. Thereafter, you should continue taking the tablets at the usual time of the day. You should then start the next pack immediately after taking the last tablet in the current pack, i.e. without a tablet-free interval between the packs. Withdrawal bleeding is unlikely until the end of the second pack, but there may be some spotting, or breakthrough bleeding, on the days you are taking tablets.

2. You may also stop taking tablets from the current pack. In that case, you should keep a period without tablets of up to 7 days, including those days when you forgot to take your tablets, and thereafter continue with the next pack.

If you have missed tablets and then do not get a withdrawal bleeding in the first normal tablet-free interval, the possibility of pregnancy must be considered.

#### **What to do if you have a stomach upset**

If you have been sick or had diarrhoea within 3-4 hours after taking the pill, the active substances in the pill may not be fully absorbed into your body. In this case the advice concerning missed pills, described above should be followed. In case of vomiting or diarrhoea, use extra contraceptive precautions, such as a condom, for any intercourse during the stomach upset and for the next seven days.

#### **What to do if you want to delay or to shift your period**

If you want to delay or to shift your period, you should contact your doctor for advice.

**If you want to delay your period**, you should continue the next pack of GEDAREL after taking the last tablet in the current pack, without a pill-free interval. You can take as many pills from this next pack as you want, until the end of the second blister pack. When you use the second pack, you may have breakthrough bleeding or spotting. Regular intake of GEDAREL is resumed after the usual 7 days tablet-free interval.

#### **If you want to shift your period to another day of the week**

If you take GEDAREL correctly, you will always have your monthly period on the same day of the month. If you want to shift your period to another day of the week, rather than the one you are used to with the present pill intake, you may shorten (but never lengthen) the forthcoming pill-free interval by as many days as you like. For example, if your monthly period usually starts on Friday and you want it to start on Tuesday (i.e. three days earlier), you should start the next pack of GEDAREL three days earlier. The shorter the pill-free interval, the greater the possibility that you will not have a withdrawal bleeding, and that you may have breakthrough bleeding or spotting during the second pack.

#### **If you have bleeding between periods**

A small number of women may have a little breakthrough bleeding or spotting while taking GEDAREL especially during the first few months. Normally, this bleeding is nothing to worry about, and will stop in a day or two. Keep taking the pills as usual, and the problem should disappear after the first few packs.

If the bleeding keeps on returning, is annoying or long-lasting, talk to your doctor.

#### **If you miss a period**

If you have taken all your pills correctly, and you have not had a stomach upset, or used other medicines, then you are very unlikely to be pregnant. Continue to take GEDAREL as usual.

If you have missed your period twice in a row, then you might be pregnant and you should see your doctor immediately. You are only allowed to continue taking the pill after doing a pregnancy test and for your doctor's advice.

#### **If you take more GEDAREL than you should**

If you take more GEDAREL than you should, it is not likely that it will do you any harm, but you may have nausea, vomiting or vaginal bleeding. If you have any of these symptoms, you should talk to your doctor who can tell you what, if anything, you need to do.

#### **If you stop taking GEDAREL**

You can stop taking GEDAREL at any time. If you stop taking GEDAREL to have a baby, use another method of contraception until you have had a true period. In this case it will be easier for your doctor to tell you when your baby will be born

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be due to GEDAREL, please talk to your doctor.

An increased risk of blood clots in your veins (venous thromboembolism (VTE)) or blood clots in your arteries (arterial thromboembolism (ATE)) is present for all women taking combined hormonal contraceptives. For more detailed information on the different risks from taking combined hormonal contraceptives please see section 2 “What you need to know before you use GEDAREL”.

*Very common (may affect more than 1 in 10 people):* irregular menstruation.

*Common (may affect up to 1 in 10 people):* depression, mood altered, nervousness, headache, dizziness, nausea, abdominal pain, acne, tender breasts, breast pain, absence of menstruation, painful menstruation, pre-menstrual syndrome (physical and emotional problems before the start of menstruation), weight gain.

*Uncommon (may affect up to 1 in 100 people):* fluid retention, decreased sexual desire, migraine, impaired hearing (otosclerosis), high blood pressure, diarrhoea, vomiting, rash, nettle-rash (urticaria), breast enlargement.

*Rare (may affect up to 1 in 1,000 people):* hypersensitivity, increased sexual desire, eye irritation due to contact lens, itching, skin disorders (erythema nodosum - a skin disease associated with joint pain, fever, hypersensitivity, or infection, and characterized by small, painful, pink to blue nodules under the skin and on the shins that tend to recur, erythema multiforme - a skin disease characterized by solid raised spots on the skin or fluid-filled blisters lesions and reddening or discoloration of the skin often in concentric zones about the lesions), chloasma (discolouration of the skin, so called “pregnancy patches”), vaginal discharge, breast discharge and weight loss.

Harmful blood clots in a vein or artery for example:

- in a leg or foot (i.e. DVT)
- in a lung (i.e. PE)
- heart attack
- stroke
- mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA)
- blood clots in the liver, stomach/intestine, kidneys or eye.

The chance of having a blood clot may be higher if you have any other conditions that increase this risk (see section 2 for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot).

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store GEDAREL

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the package. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original packaging.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What GEDAREL contains**


The active substances are ethinylestradiol and desogestrel. One film-coated tablet contains 30 micrograms ethinylestradiol and 150 micrograms desogestrel.

The other ingredients are:

Tablet core: Potato starch; stearic acid; alpha-tocopherol; lactose monohydrate; magnesium stearate; colloidal anhydrous silica; povidone K 30;

Tablet coating: Hypromellose; Macrogol 6000, propylene glycol

### **What GEDAREL looks like and contents of the pack**

White or off-white round tablet of biconvex shape with engraving “” (Grünenthal logo) on one side and “P8” on the other side.

Each box contains 1, 3, calendar pack(s) of 21 coated tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder:**

#### **Manufacturer:**

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Gedarel 150 micrograms/30 micrograms film-coated tablet: Denmark

Regulon 150 micrograms/30 micrograms film-coated tablet: Spain

Regulon (30) 150 micrograms/30 micrograms film-coated tablet: Portugal

**This leaflet was last revised in**