Package leaflet: Information for the user

Gestrina 75 micrograms film-coated tablets

desogestrel

Read all of this leaflet carefully before you start using 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 symptoms 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 /.../ is and what it is used for

/.../ is used to prevent pregnancy. /…/ contains a small amount of one type of female sex hormone, the progestogen **desogestrel**. For this reason /.../ is called a progestogen-only-pill (POP). Contrary to the combined pill, the POP does not contain an oestrogen hormone next to the progestogen.

Most POPs work primarily by preventing the sperm cells from entering the womb but do not always prevent the egg cell from ripening, which is the primary action of combined pills. /…/ is distinct from most POPs in having a dose that in most cases is high enough to prevent the egg cell from ripening. As a result, /…/ provides high contraceptive efficacy.

In contrast to the combined pill, /…/ can be used by women who do not tolerate oestrogens and by women who are breast feeding. A disadvantage is that vaginal bleeding may occur at irregular intervals during the use of /…/. You also may not have any bleeding at all.

2. What you need to know before you take /.../

/.../, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

Do not take /.../
- if you are **allergic** to desogestrel or any of the other ingredients of this medicine (listed in section 6).
- if you have a thrombosis. Thrombosis is the formation of a **blood clot** in a blood vessel [e.g. of the legs (deep venous thrombosis) or the lungs (pulmonary embolism)].
- if you have or have had **jaundice** (yellowing of the skin) or severe liver disease and your liver function is still not normal.
- if you have or are suspected to have a **cancer** that is sensitive to sex-steroids, such as certain types of breast cancer.
- if you have any unexplained **vaginal bleeding**.

Tell your doctor before you start to use /.../ if any of these conditions apply to you. Your doctor may advise you to use a non-hormonal method of birth control. Consult your doctor immediately if any of these conditions appear for the first time while using /.../.

Warnings and precautions
Talk to your doctor or pharmacist before taking /.../
- if you have ever had **breast cancer**.
- if you have **liver cancer**, since a possible effect of /.../ cannot be excluded.
- if you have ever had a **thrombosis**.
- if you have **diabetes**.
- if you suffer from **epilepsy** (see section 2 "Other medicines and /…/").
- if you suffer from **tuberculosis** (see section 2 "Other medicines and /…/").
- if you have **high blood pressure.**
- if 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.

When /.../ is used in the presence of any of these conditions, you may need to be kept under close observation. Your doctor can explain what to do.

Regular Check-ups
When you are using /.../, your doctor may tell you to return for regular check-ups. In general, the frequency and nature of these check-ups will depend on your personal situation.

Contact your doctor as soon as possible
- if you have severe pain or swelling in either of your legs, unexplained pain in the chest, breathlessness, an unusual cough, especially when you cough up blood (possibly indicating a thrombosis or an embolism respectively);
- if you have a sudden, severe stomach ache or **look jaundiced** (possibly indicating liver problems);
- if you feel a lump in your **breast** (possibly indicating **breast cancer**);
- if you have a sudden or severe pain in the lower abdomen or stomach area (possibly indicating an ectopic pregnancy, this is a pregnancy outside the womb);
- if you are to be immobilised or are to have surgery (consult your doctor at least four weeks in advance);
- if you have unusual, heavy **vaginal bleeding**;
- if you suspect that you are **pregnant**.

Breast cancer
Regularly check your breasts and contact your doctor as soon as possible if you feel any lump in your breasts.

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, the risk gradually decreases, so that 10 years after stopping the risk is the same as for women who have never taken the Pill. Breast cancer is rare under 40 years of age but the risk increases as the woman gets older. Therefore, the extra number of breast cancers diagnosed is higher if the age until which the woman continues to take the Pill is higher. How long she takes the Pill is less important.

In every 10 000 women who take the Pill for up to 5 years but stop taking it by the age of 20, there would be less than 1 extra case of breast cancer found up to 10 years after stopping, in addition to the 4 cases normally diagnosed in this age group. Likewise, in 10 000 women who take the Pill for up to 5 years but stop taking it by the age of 30, there would be 5 extra cases in addition to the 44 cases normally diagnosed. In 10 000 women who take the Pill for up to 5 years but stop taking it by the age of 40, there would be 20 extra cases in addition to the 160 cases normally diagnosed.

The risk of breast cancer in users of progestogen-only pills like /.../ is believed to be similar to that in women who use the Pill, but the evidence is less conclusive.

Breast cancers found in women who take the Pill, seem less likely to have spread than breast cancers found in women who do not take the Pill.

It is not known whether the difference in breast cancer risk is caused by the Pill. It may be that the women were examined more often, so that the breast cancer is noticed earlier.

Thrombosis
See your doctor immediately if you notice possible signs of a thrombosis (see also 'Regular check-ups').

Thrombosis is the formation of a **blood clot,** which may block a blood vessel. A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this 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". As a result, fatal situations may occur. Deep venous thrombosis is a rare occurrence. It can develop whether or not you are taking the Pill. It can also happen if you become pregnant.

The risk is higher in Pill-users than in non-users. The risk with progestogen-only pills like /.../ is believed to be lower than in users of Pills that also contain oestrogens (combined Pills).

Psychiatric disorders
Some women using hormonal contraceptives including /.../ 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
No clinical data on efficacy and safety are available in adolescents below 18 years.

Other medicines and /.../
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines or herbal products. Also tell any other doctor or dentist who prescribes another medicine (or your pharmacist) that you take /.../. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long or whether the use of another medicine you need must be changed.

Some medicines:
- can have an influence on the blood levels of /.../
- can make it **less effective in preventing pregnancy**
- can cause unexpected bleeding

These include medicines used for the treatment of:
- epilepsy (e.g. primidone, phenytoin, carbamazepine, oxcarbazepine, felbamate, topiramate and phenobarbital),
- tuberculosis (e.g. rifampicin, rifabutin),
- HIV infection (e.g. ritonavir, nelfinavir, nevirapine, efavirenz),
- Hepatitis C virus infection (e.g. boceprevir, telaprevir),
- other infectious diseases (e.g. griseofulvin),
- high blood pressure in the blood vessels of the lungs (bosentan),
- depressive moods (the herbal remedy St. John's wort),
- certain bacterial infections (e.g. clarithromycin, erythromycin),
- fungal infections (e.g. ketoconazole, itraconazole, fluconazole),
- high blood pressure (hypertension), angina or certain heart rhythm disorders (e.g. diltiazem).

If you are taking medicines or herbal products that might make /.../less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on /.../ may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive method for that long. Your doctor can tell you if you need to take additional contraceptive precautions and if so, for how long.

/…/ may also interfere with how other medicines work, causing either an increase in effect (e.g. medicines containing ciclosporine) or a decrease in effect (e.g. lamotrigine).

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

/.../ with food and drink
You can take /.../ with or without food and drink.

Pregnancy and breast-feeding
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.

Pregnancy
Do **not** use /.../ if you are pregnant, or think you may be pregnant.

Breast-feeding
/.../ may be used while you are breast-feeding. /.../ does not appear to influence the production or the quality of breast milk. However, there have been infrequent reports of a decrease in breast milk production while using /.../. A small amount of the active substance of /.../ passes over into the milk.

The health of children breast-fed for 7 months whose mothers were using /.../ has been studied up to 2.5 years of age. No effects on the growth and development of the children were observed.

If you are breast feeding and want to use /.../, please contact your doctor.

Driving and using machines
There are no indications of any effect of the use of /.../ on alertness and concentration.

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

3. How to take /.../

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Method of administration
the /.../ pack contains **28 tablets**
- take **one tablet daily**.
- **Swallow the tablet whole** with a sufficient amount of water.

Arrows are printed on the back side of the pack between the tablets. The days of the week are printed on the foil over each tablet. Each day corresponds with one tablet. Every time you start a new pack of /.../, take a tablet from the top row. **Don’t start with just any tablet**. For example if you start on a Wednesday, you must take the tablet from the top row marked (at the back) with "Wed". Continue to take one tablet a day until the pack is empty. **Always follow the direction indicated by the arrows.** By looking at the back of your pack you can easily check if you have already taken your tablet on a particular day.

Take your tablet each day at about the same time so that **the interval between two tablets is always 24 hours**. You may have some bleeding during the use of /.../, but you must continue to take your tablets as normal. When a pack is empty, you must start with a new pack of /.../ on the next day - thus without interruption and without waiting for a bleed.

Starting your first pack of /.../

- **When no hormonal contraceptive has been used in the past month**
  Wait for your period to begin. On the first day of your period take the first /.../ tablet. You need not take extra contraceptive precautions. 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.

- **When changing from a combined pill, vaginal ring, or transdermal patch**
  You can start taking /.../ on the day after you take the last tablet from the present Pill pack, or on the day of removal of your vaginal ring or patch (this means no tablet-, ring- or patch-free break). If your present Pill pack also contains inactive tablets you can start /.../ on the day after taking the last active tablet (if you are not sure which this is, ask your doctor or pharmacist). If you follow these instructions, you need not take extra contraceptive precautions.

  You can also start at the latest the day following the tablet-, ring-, patch-free break, or placebo tablet interval of your present contraceptive. If you follow these instructions, make sure you use an additional contraceptive method (barrier method) for the first 7 days of tablet-taking.

- **When changing from another progestogen-only pill (POP) to /.../**
  You may stop taking it any day and start taking /.../ right away. You need not take extra contraceptive precautions.

- **When changing from an injectable or implant or a progestogen-releasing intrauterine device (IUD) to /.../**
  Start using /.../ when your next injection is due or on the day that your implant or your IUD is removed. You need not take extra contraceptive precautions.

- **After having a baby**
  You can start /.../ between 21 to 28 days after the birth of your baby.
  If you start later, make sure you use an additional contraceptive method (barrier method) until you have completed the first 7 days of tablet-taking. However, if intercourse has already occurred, pregnancy should be excluded before starting /.../ use. Additional information for breast-feeding women can be found in “Pregnancy and breast-feeding” in section 2. Your doctor can also advise you.

- **After a miscarriage or an abortion**
  Your doctor will advise you.

If you forget to take /.../

- If you are **less than 12 hours late** in taking a tablet, the reliability of /.../ is maintained. Take the missed tablet as soon as you remember and take the next tablets at the usual times.

- If you are more than 12 hours late in taking any tablet, the reliability of /.../ may be reduced. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased. Take the last missed tablet as soon as you remember and take the next tablets at the usual times. Use an additional contraceptive method (barrier method) too for the next 7 days of tablet-taking. If you missed one or more tablets in the first week of starting the tablets and had intercourse in the week before missing the tablets, there is a possibility of becoming pregnant. Ask your doctor for advice.

If you suffer from gastro-intestinal disturbances (e.g. vomiting, severe diarrhoea)
Follow the advice for missed tablets in the section above. If you vomit within 3-4 hours after taking your /.../ tablet or have severe diarrhoea, the active ingredient may not have been completely absorbed.

If you take more /.../ than you should
There have been no reports of serious harmful effects from taking too many desogestrel-containing tablets at one time. Symptoms that may occur are nausea, vomiting and, in young girls, slight vaginal bleeding. For more information ask your doctor for advice.

If you stop taking /.../
You can stop taking /.../ whenever you want. From the day you stop you are no longer protected against pregnancy.

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

4. Possible side effects

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

Serious undesirable effects associated with the use of /.../ are described in the paragraphs 'Breast cancer' and 'Thrombosis' in section 2 "What you need to know before you take /.../". Please read this section for additional information and consult your doctor at once where appropriate.

You should see your doctor immediately if you experience allergic reactions (hypersensitivity), including swelling of the face, lips, tongue, and/or throat causing difficulty in breathing or swallowing (angioedema and/or anaphylaxis).

Vaginal bleeding may occur at irregular intervals during the use of /.../. This may be just slight staining which may not even require a pad, or heavier bleeding, which looks rather like a scanty period and requires sanitary protection. You may also not have any bleeding at all. The irregular bleedings are not a sign that the contraceptive protection of /.../ is decreased. In general, you need not take any action, just continue to take /.../. If, however, bleeding is heavy or prolonged you should consult your doctor.

Users of desogestrel have reported the following side effects:

Common (may affect up to 1 in 10 users)	**Uncommon** (may affect up to 1 in 100 users)	**Rare** (may affect up to 1 in 1,000 users)	**Not known** (cannot be estimated from the available data)
Mood altered, depressed mood, decreased sexual drive (libido)	Infection of the vagina	Rash, hives, painful blue-red skin lumps (erythema nodosum) (these are skin conditions)	Allergic reaction
Headache	Difficulties in wearing contact lenses		
Nausea	Vomiting		
Acne	Hair loss		
Breast pain, irregular or no menstruation	Painful menstruation, ovarian cyst		
Increased body weight	Tiredness		

Apart from these side effects, breast secretion may occur.

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 /.../

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 carton and blister after EXP. The expiry date refers to the last day of that month.

Medicine stored in pouch
This medicine does not require any special storage conditions.
Medicine not stored in pouch
Store below 30°C.

The active substance shows an environmental risk to fish.

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

6. Contents of the pack and other information

What /.../ contains
- The active substance is: desogestrel.
  Each film-coated tablet contains 75 micrograms desogestrel.
- The other ingredients are: lactose monohydrate (see also '/.../ contains lactose' in section 2), maize starch, povidone, stearic acid, all-rac-alpha-tocopherol, silica, colloidal anydrous, hypromellose, macrogol 400, talc, titanium dioxide.

What /.../ looks like and contents of the pack
/.../ tablets are white to off white, circular, biconvex film-coated tablets of 5.4-5.8 mm diameter without embossing.

One blister pack of /.../ contains 28 film-coated tablets. Each carton contains 1, 3 or 6 blister packs. The blister packs may come with a blister holder.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

This medicine is authorised in the Member States of the European Economic Area under the following names:

Iceland: Gestrina
Sweden: Gestrina

This leaflet was last revised in 2022-05-19.

<[To be completed nationally]>