

Package leaflet: information for the user
Desogestrel CF 0.075 mg, tablets
desogestrel

Read the entire 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.

Do you have any questions? Contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.

Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

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1. What is Desogestrel CF 0.075 mg and what is it used for?

Desogestrel CF 0.075 mg is used to prevent pregnancy. Desogestrel CF 0.075 mg contains a small amount of one type of female sex hormone, the progestogen desogestrel. Therefore, Desogestrel CF 0.075 mg is also called a progestogen-only pill. Progestogen-only pills do not contain an estrogen hormone in addition to the progestogen, unlike combination pills.

The action of most progestogen-only pills is mainly based on the fact that they prevent sperm cells from entering the uterus. The maturation of an egg cell is not always inhibited. This latter is the main action of the combination pill. Desogestrel CF 0.075 mg differs from most progestogen-only pills because the dose is high enough to prevent the maturation of an egg cell in most cases. Therefore, Desogestrel CF 0.075 mg is very reliable.

Unlike combination pills, Desogestrel CF 0.075 mg can be used by women who cannot tolerate estrogens and by women who are breastfeeding. A disadvantage of Desogestrel CF 0.075 mg is that monthly vaginal bleeding may occur at irregular intervals. There is also a chance that these bleedings may stop altogether.

2. When should you not use this medicine or be extra careful with it?

Like other hormonal contraceptives, Desogestrel CF 0.075 mg does not protect against HIV infection (AIDS) or any other sexually transmitted disease (STD).

When should you not use this medicine?

If you are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

If you have thrombosis. Thrombosis is the formation of a blood clot that can block a blood vessel (for example, in the legs [deep vein thrombosis] or in the lungs [pulmonary embolism]).

If you have or have had jaundice (yellowing of the skin) or a severe liver disease and your liver function is not yet normal.

If you have or are suspected to have a form of cancer that is sensitive to sex hormones, such as some forms of breast cancer.

If you have unexplained vaginal bleeding.

Tell your doctor before you start taking Desogestrel CF 0.075 mg if any of these situations apply to you. Your doctor may then recommend a non-hormonal contraceptive method.

Consult your doctor immediately if any of these situations occur for the first time while you are using Desogestrel CF 0.075 mg.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine if:

you have ever had breast cancer;

you have liver cancer, because a possible effect of Desogestrel CF 0.075 mg cannot be excluded;

you have ever had thrombosis;

you have diabetes;

you have epilepsy (see the section "Are you taking any other medicines?");

you have tuberculosis (see the section "Are you taking any other medicines?");

you have high blood pressure;

you have chloasma, or have ever had it (yellow-brown pigment spots, so-called 'pregnancy spots', especially on the face); if this is the case, it is advisable to avoid direct exposure to sunlight or ultraviolet light.

If Desogestrel CF 0.075 mg is used while you have any of these conditions, it may be necessary for you to remain under extra supervision. Your doctor can explain what you need to do.

Breast cancer

It is important to regularly check your breasts and consult your doctor if you feel a lump in your breasts.

Breast cancer is diagnosed slightly more often in women who use the pill than in non-users of the same age. If women stop using the pill, the risk gradually decreases again, so that 10 years after stopping it is the same as for women who have never used the pill. Breast cancer is rare under the age of 40, but the risk increases with age. Therefore, the number of additional cases of breast cancer is higher among women who use the pill until an older age. How long the pill is used is less important.

In every 10,000 women who use the pill for 5 years but stop when they are 20 years old, less than 1 extra case of breast cancer would be found up to 10 years after stopping, in addition to the 4 cases normally diagnosed in this age group. Similarly, in every 10,000 women who use the pill for 5 years but stop when they are 30 years old, 5 extra cases of breast cancer would be found, in addition to the 44 cases normally diagnosed. In 10,000 women who use the pill

for 5 years but stop when they are 40 years old, 20 extra cases of breast cancer would be found, in addition to the 160 cases normally diagnosed.

It is thought that the risk of breast cancer in users of progestogen-only pills, such as Desogestrel CF 0.075 mg, is approximately similar to the risk in users of the combined pill, but the evidence for this is less convincing.

The cases of breast cancer found in pill users are more often in a less advanced stage than those in non-users. It is not known whether the difference in breast cancer risk is caused by the pill. It may also be that pill users are examined more often so that breast cancer is detected earlier.

Thrombosis

Contact your doctor immediately if you suddenly experience symptoms that may indicate thrombosis (see also "Regular check-ups").

Thrombosis is the formation of a blood clot that can block a blood vessel. Thrombosis sometimes occurs in one of the deep veins of the lower leg (deep vein thrombosis). If the clot breaks loose, it can end up in the arteries of the lungs and block a blood vessel there (pulmonary embolism). This can sometimes be fatal. Deep vein thrombosis is rare. It can occur in pill users and non-users. It can also occur during pregnancy.

The risk of thrombosis is higher in users of the combined pill than in non-users. The risk with progestogen-only pills, such as Desogestrel CF 0.075 mg, is considered lower than in users of combined pills that also contain estrogens.

Psychiatric disorders:

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

Children and adolescents under 18 years

There is no research information on the efficacy and safety in adolescents under 18 years.

Are you using any other medicines?

Are you using any other medicines besides Desogestrel CF 0.075 mg, have you done so recently, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist.

Some medicines can cause Desogestrel CF 0.075 mg to be less effective.

These include medicines for the treatment of:

epilepsy (for example, primidone, phenytoin, carbamazepine, oxcarbazepine, felbamate, and phenobarbital);

tuberculosis (for example, rifampicin);

HIV infections (for example, ritonavir), or other infectious diseases (for example, griseofulvin);

stomach and intestinal complaints (activated charcoal);

depressive moods (the herbal remedy St. John's Wort).

Your doctor can tell you if and for how long you need to use additional contraceptive measures.

Desogestrel CF 0.075 mg can also affect the action of other medicines, enhancing (for example, cyclosporine) or reducing their effect.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Pregnancy

Do not use Desogestrel CF 0.075 mg if you are pregnant or think you might be pregnant.

Breastfeeding

Desogestrel CF 0.075 mg can be used while breastfeeding. Desogestrel CF 0.075 mg does not appear to affect the production or quality of breast milk. However, there are a small number of reports of a decrease in milk production during the use of Desogestrel CF 0.075 mg. A small amount of the active substance of Desogestrel CF 0.075 mg passes into breast milk.

The health of children who were breastfed for 7 months and whose mothers used a progestogen-only pill was studied until they were 2.5 years old. No effect on the growth or development of the children was observed.

If you are breastfeeding and want to use Desogestrel CF 0.075 mg, contact your doctor.

Driving ability and the use of machines

There are no indications that concentration and reaction ability are affected by the use of Desogestrel CF 0.075 mg.

Desogestrel CF 0.075 mg contains lactose

If your doctor has told you that you do not tolerate certain sugars, contact your doctor before taking this medicine.

Regular check-up

Your doctor may advise you to make regular appointments for a medical check-up if you are using Desogestrel CF 0.075 mg. How often you need to return for a check-up and what examination takes place depends on your personal situation.

Contact your doctor as soon as possible in the following cases:

- in case of severe pain or swelling in one of the legs, unexplained chest pain, shortness of breath, sudden unusual coughing, especially if this is accompanied by coughing up blood (this may indicate thrombosis);
- in case of sudden, severe abdominal pain or jaundice (this may indicate liver problems);
- in case of a lump in the breast (this may indicate breast cancer);
- in case of sudden, severe pain low in the abdomen or in the stomach area (this may indicate an ectopic pregnancy);
- at least four weeks before you have to undergo surgery or when you are bedridden for some time or are not allowed to walk;
- in case of unexplained, severe and persistent vaginal bleeding;
- if you suspect that you might be pregnant.

3. How do you use this medicine?

When and how do you take the tablets?

The Desogestrel CF 0.075 mg strip contains 28 tablets. On the front of the strip, between the tablets, you see arrows. On the foil at the back, the days of the week are printed. Each day corresponds to a tablet.

Start each new strip with a tablet from the top row. Make sure you start with the correct tablet.

For example, if you start on Wednesday, take the tablet from the top row where (on the back) Wed is indicated. Follow the direction of the arrows and take one tablet each day until the strip is empty. On the back of the strip, you can easily see if you have already taken your daily tablet.

Take the tablets at approximately the same time every day, with some water without chewing. While using Desogestrel CF 0.075 mg, you may experience bleeding similar to menstruation, but you should continue taking your tablets. When the strip is empty, start the next day with a new Desogestrel CF 0.075 mg strip immediately - without interruption, and without waiting for a bleeding.

When to start the first strip of Desogestrel CF 0.075 mg?

You have not used a contraceptive pill in the past month

Wait for your menstruation. Take the first Desogestrel CF 0.075 mg tablet on the first day of your menstruation. You do not need to use an extracontraceptive.

You may also start on days 2-5 of your menstruation, but in this case, you must use an extra contraceptive (a condom) during the first 7 days of tablet use.

You are switching from a combination pill, vaginal ring, or transdermal patch.

Start with Desogestrel CF 0.075 mg on the day after you have taken the last tablet of your current pill strip, or on the day of removal of your vaginal ring or patch (so without a tablet-, ring-, or patch-free period). If your current pill strip also contains placebo tablets (without hormones), you should start Desogestrel CF 0.075 mg the day after you have taken the last active tablet (if you are unsure which this is, ask your doctor or pharmacist for advice). You do not need to use an extra contraceptive if you follow these instructions.

You may also start at the latest on the day after your tablet-, ring-, or patch-free period or period with placebo tablets of your current contraceptive. If you follow these instructions, you must use an extra contraceptive (a condom) during the first 7 days of tablet use.

You are switching from another progestogen-only pill.

You can switch to Desogestrel CF 0.075 mg from one day to the next and do not need to use an extra contraceptive.

You are switching from an injection preparation, implant, or ahormone-releasing IUD

You can start Desogestrel CF 0.075 mg on the day the next injection is due or on the day your implant or hormone-releasing IUD is removed. You do not need to use an extra contraceptive.

After childbirth

Start with Desogestrel CF 0.075 mg between 21 to 28 days after delivery. If you start later, you must use an additional contraceptive (a condom) until you have completed the first 7 days of tablet use. If you have already had intercourse, pregnancy should be excluded before starting Desogestrel CF 0.075 mg. Additional information for breastfeeding women can be found in the section "Pregnancy and breastfeeding" in section 2. Your doctor can also advise you.

After a miscarriage or an abortion

Follow your doctor's advice.

Have you forgotten to take this medicine?

If you are less than 12 hours late in taking a tablet, the reliability of this medicine is not reduced. Take that tablet as soon as you remember and then take the next tablets at the usual time.

If you are more than 12 hours late in taking a tablet, the reliability of this medicine may be reduced. The more tablets you have missed in a row, the greater the chance that the contraceptive effect is reduced. Take the last missed tablet as soon as you remember and then take the next tablets at the usual time. Also use an additional contraceptive, such as a condom, during the first 7 days of tablet use. If you have missed one or more tablets in the first week of the strip and you had intercourse in the 7 days prior to missing, you should consider the possibility of pregnancy. Ask your doctor for advice.

What to do if you have gastrointestinal disturbances (for example vomiting, severe diarrhea)
Follow the advice given above for missed tablets. If you vomit, use activated charcoal, or have severe diarrhea within 3-4 hours after taking a tablet, there is a chance that the active substance is not fully absorbed into the body.

Have you taken too much of this medicine?

There are no reports of serious harmful effects after taking too many Desogestrel CF 0.075 mg tablets at once. You may experience nausea and vomiting. Vaginal bleeding may occur in young girls. For more information, you may ask your doctor for advice.

If you stop taking this medicine

You can stop Desogestrel CF 0.075 mg whenever you want. From the day you stop, you are no longer protected against pregnancy.

Do you have any other questions about the use of this medicine or do you wish to discontinue the treatment? Then contact your doctor or pharmacist.

4. Possible side effects

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

Some serious side effects attributed to the use of Desogestrel CF 0.075 mg are described in the sections "Breast Cancer" and "Thrombosis" in section 2. You can read this part for more information and contact your doctor if necessary.

During the use of Desogestrel CF 0.075 mg, some vaginal bleeding may occur at irregular intervals. This may be limited to a few drops or there may be more bleeding, similar to a light monthly period, for which you may need sanitary pads. There is also a chance that the bleeding may stop altogether. Irregular bleeding is not an indication of reduced protection against pregnancy. In general, you do not need to do anything and can continue taking Desogestrel CF 0.075 mg. However, if the bleeding is severe or prolonged, you should contact your doctor.

Users of Desogestrel 0.075 mg tablets have reported the following side effects:

Common (occur in less than 1 in 10 users):

mood swings, depressed mood, decreased libido, headache, nausea, acne, breast tenderness, irregular or no menstruation, weight gain.

Uncommon (occur in less than 1 in 100 users):

vaginal infection, eye irritation when using contact lenses, vomiting, hair loss, painful menstruation, ovarian cyst, fatigue.

Rare (occur in less than 1 in 1000 users):

skin rash, hives (urticaria), painful blue-red lumps in the skin (erythema nodosum).

In addition to these side effects, breast discharge may also occur.

Contact your doctor immediately if you experience symptoms of angioedema, such as (i) a swollen face, tongue, or throat; (ii) difficulty swallowing; or (iii) hives and breathing problems.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the box or blister pack after "Do not use after" or "EXP". It includes a month and a year. The last day of that month is the expiry date.

There are no special storage conditions for this medicine.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. Contents of the package and other information

What substances are in this medicine?

The active substance in this medicine is desogestrel. Each tablet contains 75 micrograms of desogestrel.

The other substances in this medicine are lactose, potato starch, povidone, all-rac- α -tocopherol, colloidal anhydrous silica, and stearic acid (see also “Desogestrel CF 0.075 mg contains lactose” in section 2).

What does Desogestrel CF 0.075 mg look like and what is in a package?

The tablet is round, white to off-white, uncoated, and biconvex with the inscription “152” on one side and blank on the other side.

Each package contains 1, 3, 6, or 13 calendar blister strips with 28 tablets.

Each blister pack is packed in a tri-laminated aluminum sachet with or without a desiccant.

Not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer Marketing authorization holder Centrafarm B.V.

Van de Reijtstraat 31-E
4814 NE Breda
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STADA Arzneimittel AG
Stadastrasse 2-18
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STADA Arzneimittel GmbH
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Registered under:

RVG 110353 Desogestrel CF 0.075 mg, tablets

This medicine is registered in EEA member states under the following names: Denmark

Desogestrel STADA	Finland
Desogestrel STADA	Italy
MIRZAM	Netherlands:
Netherlands:	Desogestrel CF 0.075 mg, tablets
Spain	Desogestrel STADA 75 micrograms tablets EFG
Sweden	Desogestrel STADA

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