

Package leaflet: Information for the user

Azalia 75 microgram film-coated tablets Desogestrel

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.
- 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 Azalia film-coated tablet (hereafter:Azalia) is and what it is used for
2. What you need to know before you take Azalia
3. How to take Azalia
4. Possible side effects
5. How to store Azalia
6. Contents of the pack and other information

1. What Azalia is and what it is used for

Azalia is used to prevent pregnancy. Azalia contains a small amount of one type of female sex hormone, the progestogen, desogestrel. For this reason Azalia is called a progestogen-only pill (POP) or mini-pill. Unlike the combined pill, the POP or mini-pill does not contain an oestrogen hormone, but only a 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 primarily action of combined pills.

Azalia 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, Azalia provides high contraceptive efficacy.

In contrast to the combined pill, Azalia 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 Azalia. You also may not have any bleeding at all.

2. What you need to know before you take Azalia

Azalia like other hormonal contraceptives, does not protect you against HIV infection (AIDS) and any other sexually transmitted diseases.

Do not take Azalia

- If you are allergic to desogestrel or any of the other ingredients of this medicine (listed in section 6).
- If you have 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 the function of your liver (as determined by laboratory investigation of the blood) has not returned to 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 Azalia 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 appears for the first time while using Azalia.

Warnings and precautions

Talk to your doctor or pharmacist before taking Azalia.

Tell your doctor before you start to use Azalia if:

- you have or have ever had breast cancer;
- you have liver cancer, since a possible effect of Azalia cannot be excluded;
- you have or ever had a thrombosis;
- you have diabetes;
- you suffer from epilepsy (see "Other medicines and Azalia");
- you suffer from tuberculosis (see "Other medicines and Azalia");
- you have high blood pressure;
- 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 Azalia 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.

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 Pill 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 Azalia 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 Azalia is believed to be lower than in users of Pills that also contain oestrogens (combined Pills).

Children and adolescents

No clinical data on efficacy and safety are available in adolescents below 18 years.

Other medicines and Azalia

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

Also tell any other doctor or dentist who prescribes another medicine (or your pharmacist) that you take Azalia. 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 Azalia.
- 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 infections (e.g. ritonavir, nelfinavir, nevirapine, efavirenz) ;
- Hepatitis C virus infection (e.g. boceprevir, telaprevir);
- or 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 Azalia less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on Azalia 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.

Azalia 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.

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 Azalia if you are pregnant, or think you may be pregnant.

Breast-feeding

Azalia may be used while you are breast-feeding. Azalia does not influence the production or the quality of breast milk. However, a small amount of the active substance of Azalia passes over into the

milk. The health of children breast-fed for 7 months whose mothers were using desogestrel 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 Azalia, please contact your doctor.

Driving and using machines

There are no indications of any effect of the use of Azalia on alertness and concentration.

Azalia contains lactose

Patients with lactose intolerance should be aware that Azalia tablet contains 52,34 mg lactose (as lactose monohydrate).

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

Regular check-ups

When you are using Azalia, your doctor will 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 pains in the chest, breathlessness, an unusual cough, especially when you cough up blood (possibly indicating a **thrombosis**);
- you have a sudden, severe stomach ache or look jaundiced (possibly indicating **liver problems**);
- you feel a lump in your breast (possibly indicating **breast cancer**);
- 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);
- you are to be immobilised or are to have surgery (consult your doctor at least four weeks in advance);
- you have unusual, heavy vaginal bleeding;
- you suspect that you are **pregnant**.

3. How to take Azalia

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

Each strip of Azalia contains 28 tablets. Arrows and the day of the week are printed on the front side of the strip, which help you take your pill correctly. Take your daily tablet at about the same time each day. Swallow each tablet whole with water.

Each time you start a new strip of Azalia take a tablet in the top row. For example, if you start on a Wednesday, you should take the tablet from the top row marked WED.

You should continue to take one tablet a day, until the strip is empty, always following the direction indicated by the arrows. If you start on a Monday, in the end of the arrows the strip will be empty, but in every other case before you start a new strip you should use the tablets left on the top corner of this strip. In this way you can easily check whether you have taken your daily tablet. You may have some bleeding during the use of Azalia (see "Possible side effects"), but you must continue to take your tablet as normal.

When a strip is empty, you must start with a new pack of Azalia on the next day – without interruption and without waiting for a bleeding.

Starting your first pack of Azalia

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 Azalia 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 Azalia 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 Azalia 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.

You may stop taking it any day and start taking Azalia right away. You need not take extra contraceptive precautions.

When changing from an injectable or implant or a progestogen-releasing intrauterine device (IUD).

Start using Azalia 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 Azalia between 21 to 28 days after the birth of your baby. If you start later, make sure you use during the first cycle an additional contraceptive method (barrier method) for the first 7 days of tablet-taking. However, if intercourse has already occurred, pregnancy should be excluded before starting Azalia 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 Azalia

If you are **less than 12 hours** late in taking a tablet, the reliability of Azalia 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 Azalia 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 tablet-intake and had sex 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 the pill or have severe diarrhoea, the active substance may not have been completely absorbed.

If you take more Azalia than you should

There have been no reports on serious harmful effects from taking too many Azalia 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 Azalia

You can stop taking Azalia 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 Azalia are described in the section 2 “What you need to know before you take Azalia”. Please read this section for additional information and consult your doctor at once where appropriate.

Vaginal bleeding may occur at irregular intervals during the use of Azalia. 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 Azalia is decreased. In general, you need not take any action; just continue to take Azalia. 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 people):

- mood altered,
- depression,
- decreased sexual drive (libido),
- headache,
- nausea,
- acne,
- breast pain,
- irregular or no menstruation,
- increased body weight.

Uncommon (may affect up to 1 in 100 people):

- infection of the vagina,
- difficulties in wearing contact lenses,
- vomiting,
- hair loss,
- painful menstruation,
- ovarian cyst,
- tiredness.

Rare (may affect up to 1 in 1,000 people):

- rash,
- hives,
- painful blue-red skin lumps (erythema nodosum) (these are skin conditions).

Apart from these side effects, breast secretion or leakage may occur.

You should see your doctor immediately if you experience symptoms of angioedema, such as (i) swollen face, tongue or pharynx; difficulty to swallow; or hives and difficulties to breathe.

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 HPRÁ Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Azalia

Store in the original package in order to protect from light and moisture.

This medicinal product does not require any special temperature storage conditions.

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 packaging. The expiry date refers to the last day of that month.

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 Azalia contains

The active substance is desogestrel. One film-coated tablet contains 75 microgram desogestrel.

The other ingredients are:

Tablet core:

Lactose monohydrate,
Potato starch,
Povidone K-30,
Silica, colloidal anhydrous
Stearic acid,
all-rac- α -Tocopherol

Tablet coat:

Poly[vinyl alcohol];
Titanium dioxide E171;
Macrogol 3000;
Talc

What Azalia looks like and contents of the pack

Azalia is white or almost white, round, biconvex film-coated tablet of about 5,5 mm in diameter, with a sign "D" on one side and "75" on the other side.

Azalia film-coated tablets are packaged in a blister made of transparent, hard PVC/PVDC-Aluminium foil. Each blister is placed in a laminated aluminium sachet. The blisters in the sachets are packed into a folded carton box with a patient leaflet and etui storing bag.

Pack sizes: 1x28, 3x28, 6x28, 13x28 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Gedeon Richter Plc.
Gyömrői út 19-21
1103, Budapest Hungary

Distributor

Consilient Health Limited,
Block 2A Richview Office park,
Clonskeagh, Dublin 14, Ireland

This medicinal product is authorised in the member states of the EEA under the following names:

AZALIA in Denmark
DESOCEANE in Belgium
AZALIA 75 microgram film-coated tablets in Ireland
AZALIA in Italy
DESOCEANE in Luxemburg
AZALIA in Spain
AZALIA in Portugal
Solgest 0.075 mg filmomhulde tabletten in The Netherlands
AZALIA in Finland
AZALIA in Norway
Azalia in Sweden

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