

Azalia 0.075 mg film-coated tablets

Desogestrel (0.075 mg)

Consumer Medication Information Leaflet (RiMUP)

What is in this leaflet

1. What *Azalia* is used for
2. How *Azalia* works
3. Before you use *Azalia*
4. How to use *Azalia*
5. While you are using it
6. Side effects
7. Storage and Disposal of *Azalia*
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What *Azalia* is used for

This medicine is for the prevention of pregnancy.

How *Azalia* works

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 or mini-pills 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 other mini-pills 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.

Before you use *Azalia*

- *When you must not use it*

- 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 blood clot in a blood vessel, which may lead to obstruction of this blood vessel {e.g. of the legs, (deep venous thrombosis), the lungs (pulmonary embolism), the heart (heart attack) or brain (stroke)}.
- If you have or have had a severe liver disease and the function of

your liver (as determined by laboratory investigation of the blood) has not returned to normal.

- If you have cancer that grows under the influence of certain hormone (progestagens), such as certain types of breast cancer.
- If you have any unexplained vaginal bleeding.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Azalia.

If Azalia is used in the presence of any of the conditions listed below, you may need to be kept under close observation. Your doctor can explain to you what to do. Therefore if any of these apply to you, tell your doctor before starting to use Azalia:

- you have or have ever had breast cancer;
- you have cancer of the liver;
- you have or ever had venous thromboembolism (clot);
- you have diabetes;
- you suffer from epilepsy (see "Taking other medicines");
- you suffer from tuberculosis (see "Taking other medicines");
- 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.

Breast cancer

Check your breasts regularly 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.

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 "*Contact your doctor as soon as possible if*").

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

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 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 immobilized 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.

Azalia 0.075 mg film-coated tablets

Desogestrel (0.075 mg)

Consumer Medication Information Leaflet (RiMUP)

Children and adolescents

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

Pregnancy and lactation

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.

Do not use Azalia if you are pregnant, or think you may be pregnant.

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.

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.

- Before you start use it

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.

Azalia will not protect you against HIV infection (AIDS) and any other sexually transmitted diseases.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

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 and phenobarbital);

- tuberculosis (e.g. rifampicin, rifabutin);

- HIV infection (e.g. ritonavir, nelfinavir, nevirapine, efavirenz);

- 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 ciclosporin) or a decrease in effect (e.g. lamotrigine).

How to use Azalia

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

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 WE.

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 "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

If you are not using hormonal contraception at present (or 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 patchfree break). If your present Pill pack also contains inactive tablets you can start Azalia on the day after taking

Azalia 0.075 mg film-coated tablets

Desogestrel (0.075 mg)

Consumer Medication Information Leaflet (RiMUP)

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 (mini-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 reastfeeding". Your doctor can also advise you.

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

- How long to use it

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

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

If you are less than 12 hours late

Take the tablet as soon as you remember, and take the next one at the

usual time. The contraceptive action of Azalia is maintained.

If you are more than 12 hours late

Take a tablet as soon as you remember, and take the next one at the usual time. This may mean taking two tablets on the same day. This is not harmful. (If you have forgotten more than one tablet you don't need to take the earlier missed ones). You are not protected against pregnancy. Continue to take your tablets as usual, but you must to use an extra method, such as a condom for the next 7 days.

The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased.

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 vomit, have diarrhoea or use medical charcoal

If you vomit or use medical charcoal within 3-4 hours after taking the pill or have severe diarrhoea, the active substance may not have been completely absorbed. Follow the advice for missed tablets above.

- If you use too much (overdose)

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.

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

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking Azalia.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.
Do not take any new medicines without consulting your doctor.

- Things to be careful of

Driving and using machines

Azalia has no influence on the ability to drive and use machines.

Side effects

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

Serious undesirable effects associated with the use of Azalia are described in the section "Warnings and precautions". 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:

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

Uncommon:

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

Azalia 0.075 mg film-coated tablets

Desogestrel (0.075 mg)

Consumer Medication Information Leaflet (RiMUP)

Rare:

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

Apart from these side effects, breast secretion or leakage may occur. On rare occasions, ectopic pregnancies may occur. You should see your doctor immediately if you experience symptoms of angioedema, such as swollen face, tongue or pharynx; difficulty to swallow; or hives and difficulties to breathe.

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

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine, even if you think the problems are not connected with the medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Azalia

- Storage

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

Store below 30°C.

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.

- Disposal

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

Product Description

- What it looks like

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 75 microgram 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. Pack size: 28x1 film-coated tablet.

- Ingredients

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

- MAL number:

MAL*****AZ

Manufacturer

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

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.
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