

PACKAGE LEAFLET: INFORMATION FOR THE USER

Aizea 75 microgram film-coated tablet

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, 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.

What is in this leaflet

1. What Aizea is and what it is used for
2. What you need to know before you take Aizea
3. How to take Aizea
4. Possible side effects
5. How to store Aizea
6. Contents of the pack and other information

1. What Aizea is and what it is used for

- Aizea is used to prevent pregnancy.
- There are 2 main kinds of hormone contraceptive.
 - The combined pill, "The Pill", which contains 2 types of female sex hormone, an oestrogen and a progestogen
 - The progestogen-only pill, POP or mini-pill, which doesn't contain an oestrogen.
- Aizea is a progestogen-only-pill (POP), or a mini-pill.
- Aizea contains a small amount of one type of female sex hormone, the progestogen desogestrel.
- Most POPs or minipills work primarily by preventing the sperm cells from entering the womb but they do not always prevent the egg cell from ripening, which is the main way that combined pills work.
- Aizea is different from other mini-pills in having a dose that in most cases prevents the egg cell from ripening. As a result, Aizea is a highly effective contraceptive.
- In contrast to the combined pill, Aizea 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 Aizea. On the other hand you may not have any bleeding at all.

2. What you need to know before you take Aizea

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

Do not take Aizea:

- if you are allergic to desogestrel or any of the ingredients of this medicine (listed in section 6).
- if you are pregnant or think you might be pregnant.
- 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 is still not working normally.
- if you have or if you are suspected of having a cancer that grows under the influence of sex-steroids, such as certain types of breast cancer.
- if you have any unexplained vaginal bleeding.

If any of these conditions apply to you, tell your doctor before you start to use Aizea. Your doctor may advise you to use a non-hormonal method of birth control. If any of these conditions appear for the first time while using Aizea, consult your doctor immediately.

Warnings and precautions

Talk to your doctor or pharmacist before taking Aizea. Before you start Aizea tell your doctor or Family Planning Nurse, if

- you have ever had breast cancer.
- you have liver cancer, since a possible effect of Aizea cannot be excluded.
- you have ever had a thrombosis.
- you have diabetes.
- you suffer from epilepsy (See section 'Taking other medicines').
- you have tuberculosis (See section '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.

When Aizea 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

- It is important to regularly check your breasts and you should 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, this reduces the risk, 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 a woman continues to take the Pill when she is older. 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.
- 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 Aizea 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 certain whether the Pill causes the increased risk of breast cancer. 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". A pulmonary embolism can cause chest pain, breathlessness, collapse or even death.

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

Use in adolescents

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

Other medicines and Aizea

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

Some medicines may stop Aizea from working properly. These include medicines used for the treatment of

- epilepsy (e.g. primidone, phenytoin, carbamazepine, oxcarbazepine, felbamate and phenobarbital)
- tuberculosis (e.g. rifampicin)
- HIV infections (e.g. ritonavir), or other infectious diseases (e.g. griseofulvin)
- stomach upset (medical charcoal)
- depressive moods (the herbal remedy St. John's Wort).

Your doctor can tell you if you need to take additional contraceptive precautions and if so, for how long.

Aizea may also interfere with how certain medicines work, causing either an increase in effect (e.g. medicines containing cyclosporine) or a decrease in effect.

Pregnancy, breast-feeding and fertility

Pregnancy - Do not use Aizea if you are pregnant, or think you may be pregnant.

Breast-feeding - Aizea may be used while you are breast-feeding.

Desogestrel does not influence the production or the quality of breast milk. However, a small amount of the active substance of Aizea passes over into the milk.

The health of children who were breast-fed for 7 months while their mothers were using desogestrel has been studied up until they were 2½ years of age. No effects on the growth and development of the children were observed.

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.

Driving and using machines

Aizea has no known effect on the ability to drive or use machines.

Aizea contains lactose. 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 Aizea, 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 notice possible signs of a blood clot (e.g. severe pain or swelling in either of your legs); unexplained pains in the chest, breathlessness, an unusual cough, especially when you cough up blood);
- you have a sudden, severe stomach ache or jaundice (you may notice yellowing of the skin, the whites of the eyes, or dark urine, possibly a sign of liver problems);
- you feel a lump in your breast;
- you have a sudden or severe pain in the lower abdomen or stomach area (possibly a sign of an ectopic pregnancy - 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.

PLEASE TURN OVER

3. How to take Aizea

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

When and how to take the tablets?

Each strip of Aizea contains 28 tablets – 4 weeks supply.

- Take your tablet each day at about the same time. Swallow the tablet whole, with water.
- Arrows are printed on the front of the strip, between the tablets. The days of the week are printed on the back of the strip. Each day corresponds with one tablet.
- Every time you start a new strip of Aizea, 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 (on the back) with WED.
- Continue to take one tablet at every day until the pack is empty, always following 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.
- You may have some bleeding during the use of Aizea, (See Section 4 - Side Effects) but you must continue to take your tablets as normal.
- When a strip is empty, you must start with a new strip of Aizea on the next day - without interruption and without waiting for a bleed.

Starting your first pack of Aizea

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 Aizea tablet. Additional contraceptive precautions are not necessary.

If you take your first tablet on days 2 to 5 of your period use an additional barrier method of contraception for the first 7 days of tablet-taking.

When you change from a combined pill (COC), vaginal ring, or transdermal patch.

If you *have* a tablet-, ring- or patch-free break

- 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 barrier method of contraception for the first 7 days of tablet-taking.

If you *don't have* a tablet-, ring- or patch-free break

- Start taking Aizea 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 Aizea 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, additional contraceptive precautions are not necessary.

When you change from another progestogen-only pill (mini-pill)

Switch on any day from another mini pill. Additional contraceptive precautions are not necessary.

When you change from an injection, implant or a hormonal IUS

Start using Aizea when your next injection is due or on the day that your implant or you IUS is removed. Additional contraceptive precautions are not necessary.

After you have a baby

You can start Aizea between 21 to 28 days after the birth of your baby. If you start later, make sure that during the first cycle you use an additional barrier method of contraception for the first 7 days of tablet-taking. However, if you have already had sex, check that you are not pregnant before starting Aizea. Information for breast-feeding women can be found in section 2 "Before you take Aizea" in the paragraph "Pregnancy and breast-feeding". Your doctor can also advise you.

After a miscarriage or an abortion

Your doctor will advise you

If you take more Aizea than you should

There have been no reports of serious harmful effects from taking too many Aizea 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 forget to take Aizea

If you are *less than 12 hours late*:

- Take the missed tablet as soon as you remember and take the next one at the usual time. Aizea will still protect you from pregnancy.

If you are *more than 12 hours late*:

- If you are more than 12 hours late in taking any tablet, you may not be completely protected against pregnancy. The more consecutive tablets you have missed, the higher the risk that you might fall pregnant.
- Take a tablet as soon as you remember and take the next one at the usual time. This may mean taking two in one day. This is not harmful. (If you have forgotten more than one tablet you don't need to take the earlier missed ones). Continue to take your tablets as usual but you must also use an extra method, such as a condom, for the next 7 days.
- If you missed one or more tablets in the very first week of tablet-intake and had intercourse in the week before missing the tablets, you may fall pregnant. Ask your doctor for advice.

If you vomit or use medical charcoal

If you vomit, or use medical charcoal within 3 - 4 hours after taking your Aizea tablet or have severe diarrhoea, the active ingredient may not have been completely absorbed. Follow the advice for forgotten tablets in the section above.

If you stop taking Aizea

You can stop taking Aizea 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.

Tell your doctor if you notice any unwanted effect, especially if severe or persistent.

Serious side effects associated with the use of Aizea are described in section 2 "Before you take Aizea". Please read this section for additional information on 'Breast cancer' and 'Thrombosis', and consult your doctor at once where appropriate.

Vaginal bleeding may occur at irregular intervals while using Aizea.

This may be just slight staining which may not even require a pad, or heavier bleeding, which looks rather like a scanty period. You may need to use tampons or sanitary towels. You may also not have any bleeding at all. Irregular bleeding is not a sign that Aizea is not working. In general, you need not take any action; just continue to take Aizea. If bleeding is heavy or prolonged you should consult your doctor.

How often are other possible side effects seen?

Common (affecting less than 1 in 10 women): mood changes, decreased sexual drive (libido), headache, nausea, acne, breast pain, irregular or no periods, weight increase.

Uncommon (affecting less than 1 in 100 women) infection of the vagina, difficulties in wearing contact lenses, vomiting, hair loss, painful periods, ovarian cysts, tiredness.

Rare (affecting less than 1 in 1000 women) skin conditions such as: rash, hives, painful blue-red skin lumps (erythema nodosum)

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

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store Aizea

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

This medicinal product does not require any special storage conditions.

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 Aizea contains

- The active substance is desogestrel. Each tablet contains 75 microgram of desogestrel.

- The other ingredients are: colloidal anhydrous silica; Alpha-tocopherol; maize starch; povidone; stearic acid; hypromellose; macrogol 6000; propylene glycol, talc; titanium dioxide (E171); lactose monohydrate (see also "Aizea contains lactose" in section 2).

What Aizea looks like and contents of the pack

White, cylindrical, biconvex film-coated tablet with a diameter of 6.00 mm approximately.

Aizea is packed in PVC / Aluminium blisters. Each individual blister is placed inside a foil sachet, which is then packed into a cardboard box.

Packs with

28 film coated tablets

56 film coated tablets

84 film coated tablets

168 film coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Cyndeia Pharma, S.L.

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

Belgium: Desogestrel Besins 75 microgrammes comprimé pelliculé

Germany: Desogestrel Besins 75 Mikrogramm Filmtabletten

France: Antigone 0,075 mg, comprimé pelliculé

Luxembourg: Desogestrel Besins 75 microgrammes comprimé pelliculé

Poland: Dezogestrel Besins 75 mikrogramów, tabletki powlekane

Slovakia: Dezogestrel Besins 75 mikrogramov filmom obalené tablety

Czech Republic: Desogestrel Besins 75 mikrogramů Potahované tablety

United Kingdom: AIZEA 75 microgram film-coated tablets