

## Package leaflet: Information for the user

### Isaniva 75 microgram film-coated tablets

#### Desogestrel

**Read all of this leaflet carefully before you start using the medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, or pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It is not suitable for all women, so you should not give it to anyone else as it may harm them.
- If you get any side effects, talk to your doctor, or pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

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

#### **1. What Isaniva is and what it is used for**

- Isaniva contains a small amount of one type of female sex hormone, the progestogen desogestrel.
- Isaniva 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.
- Isaniva is a progestogen-only-pill (POP), or a mini-pill.
- Most POPs or minipills work primarily by preventing the sperm cells from entering the womb but do not always prevent the egg cell from ripening, which is the main way that combined pills work.
- Isaniva is different from other mini-pills in having a dose that in most cases prevents the egg cell from ripening. As a result, Isaniva is a highly effective contraceptive.

- In contrast to the combined pill, Isaniva 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 Isaniva. On the other hand you may not have any bleeding at all.

#### **2. What you need to know before you take Isaniva**

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

##### **2.1 Do not take Isaniva**

- 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 of having cancer that grows under the influence of sex-steroids, such as certain types of breast cancer.
- If you have any unexplained vaginal bleeding.
- If you are allergic to desogestrel, peanut, soya or any of the other ingredients of this medicine (listed in section 6).

If any of these conditions applies to you, tell your doctor before you start to use Isaniva. 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 Isaniva, consult your doctor immediately.

## **2.2 Warnings and precautions**

Talk to your doctor before using Isaniva if

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

## **2.4 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 Isaniva, is believed to be lower than in

users of Pills that also contain oestrogens (combined Pills).

## **2.5 Other medicines and Isaniva**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines or herbal products, including medicines obtained without a prescription.

Some medicines may stop Isaniva 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.

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

## **2.6 Pregnancy and breast-feeding**

### **Pregnancy**

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

### **Breast-feeding**

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

The health of children breast-fed for 7 months while their mothers were using Isaniva has been studied up until they were 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 Isaniva, please contact your doctor.

## **2.7 Driving and using machines**

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

## **2.8 Isaniva contains lactose and soybean oil**

Isaniva contains lactose (milk sugar) and soybean oil.

Please contact your doctor before taking Isaniva if you have been told by your doctor that you are intolerant to some sugars.

If you are allergic to peanut or soya, do not use this medicinal product.

## **2.9 Use in adolescents**

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

## **2.10 Regular check ups**

When you are using Isaniva, 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 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 Isaniva**

### 3.1 When and how to take the tablets?

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

The Isaniva pack contains 28 tablets.

- Take your tablet each day at about the same time. Swallow the tablet whole, with water.
- The days of the week are printed in the blister and also arrows are printed indicating the order to take the pills. Each day correspond with one tablet.
- Every time you start a new pack of Isaniva, 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 with 'WED' (Wednesday).
- Continue to take one tablet a day until the pack is empty, always following the direction indicated by the arrows. By looking at the pill pack you can easily check if you have already taken a tablet on a particular day.
- You may have some bleeding during the use of Isaniva, but you must continue to take your tablets as normal.
- When a pack is empty, you must start with a new pack of Isaniva on the next day – thus without interruption and without waiting for a bleed.

### 3.2 Starting your first strip of Isaniva

- *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 Isaniva tablet.

Additional contraceptive precautions are not necessary.

If you take your first tablet on days 2-5 of your period use an additional barrier method 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- or 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 Isaniva 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 Isaniva on the day after taking the last active tablet (if you are not sure what this is, ask your doctor or pharmacist)
- If you follow these instructions, additional contraceptive precautions are not necessary.

- *When changing from another progestogen-only (mini-pill)*

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

- *When changing from an injection or implant or hormonal IUS*

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

- *After having a baby*

You can start Isaniva between 21 and 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 Isaniva. Information for breast-feeding women can be found in section 2 'Before you take Isaniva' in the paragraph 'Pregnancy and

breast-feeding'. Your doctor can also advise you.

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

### 3.3 If you forget to take Isaniva

- If you are **less than 12 hours** late:
  - Take the missed tablet as soon as you remember and take the next tablets at the usual time. Isaniva 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 are more than 12 hours late taking your tablet and have sex it is safe to use emergency contraception; please consult your pharmacist or doctor.
  - 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.

### 3.4 If you vomit or use medical charcoal

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

### 3.5 If you take more Isaniva than you should

There have been no reports of serious harmful effects from taking too many Isaniva 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.

### 3.6 If you stop taking Isaniva

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

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

## 4. Possible side effects

Like all medicines, Isaniva 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 Isaniva are described in section 2 "Before you take Isaniva". 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 Isaniva. 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 Isaniva is not working. In general, you need not take any action; just continue to take Isaniva. If bleeding is heavy or prolonged you should consult your doctor.

### How often are other possible side effects seen?

Common (may affect up to 1 in 10 women): mood changes, decreased mood, decreased sexual drive (libido), headache, nausea, acne, breast pain, irregular or no periods, weight increase.

Uncommon (may affect up to 1 in 100 women): infection of the vagina, difficulties in wearing contact lenses, vomiting, hair loss, painful periods, ovarian cyst, tiredness.

Rare (may affect up to 1 in 1,000 women): rash, hives, painful blue-red skin lumps (erythema nodosum).

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; (ii) difficulty to swallow; or (iii) 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.

### **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 (see details below). By reporting side effects, you can help provide more information on the safety of this medicine. Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the IMB via freepost, to the following address:

FREEPOST  
Pharmacovigilance Section  
Irish Medicines Board  
Kevin O'Malley House  
Earlsfort Centre  
Earlsfort Terrace  
Dublin 2  
Tel: +353 1 6764971  
Fax: +353 1 6762517  
Website: [www.imb.ie](http://www.imb.ie)  
e-mail: [imbpharmacovigilance@imb.ie](mailto:imbpharmacovigilance@imb.ie)

### **5. How to store Isaniva**

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton after "Do not use after:" or "EXP:". 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 to protect the environment.

### **6. Contents of the pack and other information**

#### **What Isaniva contains**

The active substance is: desogestrel (75 microgram)

The other ingredients are: lactose monohydrate, maize starch, povidone K30 (E1201), d- $\alpha$ -tocopherol (E307), soybean oil, silica, colloidal hydrated (E551), silica, colloidal anhydrous (E551), stearic acid (E570), hypromellose 2910 (E464), polyethylene glycol, titanium dioxide (E171) (see also "Important information about some of the ingredients of Isaniva" in section 2).

#### **What Isaniva looks like and content of the pack**

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

Not all pack sizes may be available.

#### **Marketing Authorisation Holder and Manufacturer**

##### **Marketing Authorisation Holder**

Actavis Group PTC ehf.  
Reykjavíkurvegi 76-78,  
220 Hafnarfjörður  
ICELAND

**Manufacturer**

Laboratorios León Farma, S.A.  
Pol. Ind. Navatejera  
C/ La Vallina s/n  
24008 - Navatejera, León  
Spain

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

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| UK | Desogestrel 75 micrograms Film-coated Tablets    |
| BE | Diamilla 0,075 mg tabletten                      |
| DK | Diamilla   |
| EE | Diamilla   |
| IE | Isaniva 75 micrograms Film-coated Tablets        |
| LT | Diamilla 75 mikrogramai plėvele dengtos tabletės |
| LU | Diamilla 0,075 mg comprimés                      |
| LV | Diamilla 75 mikrogrami apvalkotās tabletes       |
| PL | Diamilla   |
| RO | Diamilla 75 micrograme comprimate filmate        |
| SK | Isaniva  |

This leaflet was last approved on **June 2013**