

## Package leaflet: Information for the user

### Zelleta 75 micrograms Tablets

desogestrel

**Read all of this 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.
- If you have any further questions, ask your doctor, pharmacist or nurse
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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

1. What Zelleta 75 micrograms Tablets are and what they are used for
2. What you need to know before you take Zelleta 75 micrograms Tablets
3. How to take Zelleta 75 micrograms Tablets
4. Possible side effects.
5. How to store Zelleta 75 micrograms Tablets
6. Contents of the pack and other information

#### **1. What Zelleta 75 micrograms Tablets are and what they are used for**

Zelleta 75 micrograms Tablets are used to prevent pregnancy. Zelleta 75 micrograms Tablets contains a small amount of one type of female sex hormone, the progestogen desogestrel. For this reason Zelleta 75 micrograms Tablets are called a progestogen-only-pill (POP), or a mini-pill. Contrary to the combined pill, the POP or mini-pill does not contain an oestrogen hormone next to the progestogen.

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. Zelleta 75 micrograms Tablets 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, Zelleta 75 micrograms Tablets provide high contraceptive efficacy.

In contrast to the combined pill, Zelleta 75 micrograms Tablets 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 Zelleta 75 micrograms Tablets. You also may not have any bleeding at all.

**You must talk to your doctor if you do not feel better or if you feel worse after taking the pill.**

#### **2. What you need to know before you take Zelleta 75 micrograms Tablets**

Zelleta 75 micrograms Tablets, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

#### **Do not take Zelleta 75 micrograms Tablets**

- if you are allergic to any of the ingredients of Zelleta 75 micrograms Tablets.
- 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 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 Zelleta 75 micrograms Tablets if any of these conditions apply to you.

Consult your doctor immediately if any of these conditions appear for the first time while using Zelleta 75 micrograms Tablets.

### **Children and adolescents**

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

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Zelleta 75 micrograms Tablets.

- you have ever had breast cancer.
- you have liver cancer, since a possible effect of Zelleta 75 micrograms Tablets 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 Zelleta 75 micrograms Tablets are 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, 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. 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 Zelleta 75 micrograms Tablets 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 Zelleta 75 micrograms Tablets is believed to be lower than in users of Pills that also contain oestrogens (combined Pills).

## **Other medicines and Zelleta 75 micrograms Tablets**

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

Some medicines may stop Zelleta 75 micrograms Tablets 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.

Zelleta 75 micrograms Tablets 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 Zelleta 75 micrograms Tablets if you are pregnant, or think you may be pregnant.

### Breast-feeding

Zelleta 75 micrograms Tablets may be used while you are breast-feeding. Zelleta 75 micrograms Tablets do not influence the production or the quality of breast milk. However, a small amount of the active substance of Zelleta 75 micrograms Tablets passes over into the milk.

The health of children who were breast-fed for 7 months while their mothers were using another desogestrel-only pill 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 Zelleta 75 micrograms Tablets, please contact your doctor.

## **Driving and Using Machines**

There are no indications of any effect of the use of Zelleta 75 micrograms Tablets on alertness and concentration.

## **Zelleta 75 micrograms Tablets contain lactose**

Zelleta 75 micrograms Tablets contains lactose (milk sugar). Please contact your doctor before taking Zelleta 75 micrograms Tablets if you have been told by your doctor that you are intolerant to some sugars.

## Regular Check-ups

When you are using Zelleta 75 micrograms Tablets, 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 (possible signs of a blood clot); possibly indicating a **thrombosis**
- you have a sudden, severe stomach ache or jaundice (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 Zelleta 75 micrograms Tablets

### When and how to take the tablets?

Each strip of Zelleta 75 micrograms Tablets contains 28 tablets. 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 Zelleta 75 micrograms Tablets, 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 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. Take your tablet each day at about the same time. Swallow the tablet whole, with water. You may have some bleeding during the use of Zelleta 75 micrograms Tablets, but you must continue to take your tablets as normal. When a strip is empty, you must start with a new strip of Zelleta 75 micrograms Tablets on the next day - without interruption and without waiting for a bleed.

### Starting your first pack of Zelleta 75 micrograms Tablets

#### 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 Zelleta 75 micrograms Tablets. 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 changing from a combined pill, vaginal ring, or transdermal patch.

You can start taking Zelleta 75 micrograms Tablets 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 Zelleta 75 micrograms Tablets 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 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 Intrauterine device (IUS)**

Start using Zelleta 75 micrograms Tablets 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 you have a baby**

You can start Zelleta 75 micrograms Tablets 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 Zelleta 75 micrograms Tablets

Information for breast-feeding women can be found in section 2 “Before you take Zelleta 75 micrograms Tablets” 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 forget to take Zelleta 75 micrograms Tablets**

• **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. Zelleta 75 micrograms Tablets 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. 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 have diarrhoea**

Follow the advice for forgotten tablets in the section above. If you vomit within 3-4 hours after taking your Zelleta 75 micrograms Tablets or have severe diarrhoea, the active ingredient may not have been completely absorbed.

**If you take more Zelleta 75 micrograms Tablets than you should**

There have been no reports of serious harmful effects from taking too many Zelleta 75 micrograms 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 Zelleta 75 micrograms Tablets**

You can stop taking Zelleta 75 micrograms Tablets 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 product, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, Zelleta 75 micrograms Tablets 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 Zelleta 75 micrograms Tablets are described in section 2 "Before you take Zelleta 75 micrograms Tablets". 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 Zelleta 75 micrograms Tablets. 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 Zelleta 75 micrograms Tablets is not working. In general, you need not take any action; just continue to take Zelleta 75 micrograms Tablets. 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, depressed mood, 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.

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

## **5. How to store Zelleta 75 micrograms Tablets**

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

Do not use this medicine after the expiry date stated on the package. The expiry date refers to the last day of that month.

Zelleta 75 micrograms Tablets do 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 Zelleta 75 micrograms Tablets contains**

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

The other ingredients are: Lactose anhydrous, all-rac- $\alpha$ -tocopherol, Povidone, Potato starch, Silica colloidal anhydrous, Stearic acid.

(See also 'Important information about some of the ingredients of Zelleta 75 micrograms Tablets' in section 2).

**What Zelleta 75 micrograms Tablets look like and contents of the pack**

Each tablet is round, uncoated, biconvex, debossed with '152' on one side and other side plain. Each box of Zelleta 75 micrograms Tablets contains 1, 3, 6 or 13 strips of 28 tablets each.

Each carton contains blisters packed separately in an aluminium laminated sachet.

Packs may be marketed with or without a desiccant. Not all pack sizes may be marketed.

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