

Zellesta 75 micrograms Tablets

- 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 Zellela 75 micrograms Tablets

When and how to take the tablets?

Each strip of Zellela 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 Zellela 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 Zellela 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 Zellela 75 micrograms Tablets on the next day - without interruption and without waiting for a bleed.

Starting your first pack of Zellela 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 Zellela 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 Zellela 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 Zellela 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 Zellela 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 Zellela 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 Zellela 75 micrograms Tablets

Information for breast-feeding women can be found in section 2 "Before you take Zellela 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 Zellela 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. Zellela 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 Zellela 75 micrograms Tablets or have severe diarrhoea, the active ingredient may not have been completely absorbed.

If you take more Zellela 75 micrograms Tablets than you should

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

You can stop taking Zellela 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, Zellela 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 Zellela 75 micrograms Tablets are described in section 2 "Before you take Zellela 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 Zellela 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 Zellela 75 micrograms Tablets is not working. In general, you need not take any action; just continue to take Zellela 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 Zellela 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.

Zellela 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 Zellela 75 micrograms Tablets contains

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

The other ingredients are: Lactose anhydrous, all-rac- α -tocopherol, Povidone, Potato starch, Silica colloidal anhydrous, Stearic acid

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

What Zellela 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 Zellela 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.

Marketing Authorisation Holder

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