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

Zelleta 75 micrograms Tablets are used prevent pregnancy. Zelleta 75 micrograms Tablets contain a small amount of one type of female sex-steroids, such as certain types of breast cancer.

2. How to take Zelleta 75 micrograms Tablets

Use Zelleta 75 micrograms Tablets for a maximum of 3 years.

3. If you change from another progestogen-only pill (mini-pill)

When changing from another progestogen-only pill (mini-pill) to Zelleta 75 micrograms Tablets, you need to take additional contraceptive precautions (for example condoms) for at least four weeks in advance.

4. Possible side effects.

Tell your doctor or pharmacist if any of the following side effects occur while using Zelleta 75 micrograms Tablets:

- Changes in bleeding pattern
- Heavy and/or irregular bleeding
- Missed periods
- Spotting
- Menstrual cramps

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

Tell your doctor or pharmacist if you have any of the following conditions. It is possible that Zelleta 75 micrograms Tablets might not be suitable for these situations.

- You have had breast cancer.
- You have had endometrial cancer, or a possible effect of Zelleta 75 micrograms Tablets cannot be excluded.
- You have ever had a thrombosis.
- You have diabetes.
- You have heart disease (See section "Taking other medicines").
- You have high blood pressure.
- You have or have had disorders (yellowish brown pigmentation) on the skin, particularly of the face; if so avoid too much exposure to the sun or artificial 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.

Psychiatric disorders

Some women using hormonal contraceptives including Desogen have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicide or death if you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

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 cancers found in women who take the Pill, seem less likely to have been there for a long time and to have grown slowly. This means that they may be noticed earlier.

The risk of breast cancer in users of progestogen-only pills like Zelleta 75 micrograms Tablets is believed to be lower than in non-users. How long she takes the Pill is less important.

It may be that the women were examined more often, so that the breast cancers are diagnosed earlier. In every 100 000 women who take the Pill for up to 5 years but stop taking it by the age of 30, there would be less than 1 extra cases of breast cancer found, up to 10 years after stopping. In addition to the 160 cases normally diagnosed.

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 20 extra cases in addition to the 160 cases normally diagnosed. In 10 000 women who take the Pill for up to 5 years but stop taking it by the age of 50, there would be 60 extra cases in addition to the 44 cases normally diagnosed.

In 10 000 women who take the Pill for up to 10 years but stop taking it by the age of 30, there would be 5 extra cases in addition to the 44 cases normally diagnosed.

Zelleta 75 micrograms Tablets may also interfere with how certain medicines or herbal products that might make Zelleta 75 micrograms Tablets less effective, a barrier contraceptive method should also be used. Using barrier contraceptive method it is not necessary to take any extra contraceptive precautions.

Other medicines and Zelleta 75 micrograms Tablets

Tell your doctor or pharmacist, or Family Planning Nurse if you are taking, have recently taken or might take any other medicines or herbal products that may interact with Zelleta 75 micrograms Tablets. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long and whether the use of another medicine you need must be changed.

Some medicines:

- Some medicines may make Zelleta 75 micrograms Tablets less effective, a barrier contraceptive method should also be used. Using barrier contraceptive method it is not necessary to take any extra contraceptive precautions.

Driving and Using Machines

If you are breast feeding and want to use Zelleta 75 micrograms Tablets, 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.

Zelleta 75 micrograms Tablets contains lactose (milk sugar). Please contact your doctor if you have a lactose intolerance.

No effects on the growth and development of the children were observed. No effects on the skin, particularly of the face; if so avoid too much exposure to the sun or artificial radiation.

Zelleta 75 micrograms Tablets does not appear to influence the production of milk.

If you are taking medicines or herbal products that might make Zelleta 75 micrograms Tablets less effective, a barrier contraceptive method should also be used. Using barrier contraceptive method it is not necessary to take any extra contraceptive precautions.

If you are breast feeding and want to use Zelleta 75 micrograms Tablets, 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.

Your doctor or pharmacist may also be able to help you with WED. Continue to take one tablet every day until the pack is empty. Then start a new pack of Zelleta 75 micrograms Tablets on the day after the last tablet of your current pack has been taken. If you forget to take Zelleta 75 micrograms Tablets, you can still use it up to 12 hours later.

Your doctor or pharmacist may also be able to help you with WED. Continue to take one tablet every day until the pack is empty. Then start a new pack of Zelleta 75 micrograms Tablets on the day after the last tablet of your current pack has been taken. If you forget to take Zelleta 75 micrograms Tablets, you can still use it up to 12 hours later. If you are late taking your first tablet, the pill pack should be used as normal. If a tablet is missed, take two tablets the next day to return to normal dosage.

If you use Miss-PAK, you may have some bleeding during the use of placebo tablets. This bleeding is normal. If a tablet is missed, take two tablets the next day to return to normal dosage.

If you take Zelleta 75 micrograms Tablets between 21 to 28 days after the birth of your baby.

If you take Zelleta 75 micrograms Tablets from days 21 to 28 after the birth of your baby.

If you are late taking your first tablet, the pill pack should be used as normal. If a tablet is missed, take two tablets the next day to return to normal dosage.

If you use Miss-PAK, you may have some bleeding during the use of placebo tablets. This bleeding is normal. If a tablet is missed, take two tablets the next day to return to normal dosage.

If you use Miss-PAK, you may have some bleeding during the use of placebo tablets. This bleeding is normal. If a tablet is missed, take two tablets the next day to return to normal dosage.
Information for breast-feeding women can be found in section 2. “Before you take Zelleta 75 micrograms Tablets.” This information includes possible interactions and dietary considerations.

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

5. How to store Zelleta 75 micrograms Tablets

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

5.5. How to dispose of Zelleta 75 micrograms Tablets

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 unusual effect, especially if severe or persistent.

Serious side effects associated with the use of Zelleta 75 micrograms Tablets described in section 4.5.2: “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 the first sign which may not require a pelvic or vaginal bleeding, which occurs like a regular period. You may need to use tampons or sanitary towels to ensure regular periods. 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, such as continuing as usual.) If bleeding is heavy or prolonged you should consult your doctor.

How often are other possible side effects seen?

Common (affecting more than 1 in 10 women): mood changes, depressed mood, altered sexual desire (libido), headache, nausea, acne, breast pain, irregular or no periods, weight changes.

Uncommon (affecting less than 1 in 100 women): injection 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, urticaria, redness, itching, hives, angioedema, such as: (i) swollen face, tongue or pharynx; (ii) difficulty in swallowing or breathing; (iii) hives and difficulty to breathe.

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5.6. With this medicine

What Zelleta 75 micrograms Tablets contains

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