## Zelleta 75 micrograms Tablets

Read all of this leaflet carefully before you start
Recause 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 nus others. It may harm been prescribed for you only. Do not pass it on to yours. If you get any side effects, talk to your doctor, pharmacist or
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 What you need to know before you take Zelleta 75 micrograms Table How to take Zelleta 75 micrograms Tablet Possible side effects
Contents of the pack and other information

## What Zelleta 75 micrograms Tablets are and what they are used

Zelleta 75 micrograms Tablets are used to prevent pregnancy. Zelleta 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 min
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 fro entering the womb but they do not always prevent the egg cell fro 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 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 ar used by women who do not tolerate oestrogens and by women who are irregular intervals during the use of Zelleta 75 micrograms Tablets. Yo also may not have any bleeding at all.

You must talk to your doctor if you do not feel better or if you fee worse after taking the pill.
2. What you need to know before you take Zelleta 75 micrograms
Tablets
elleta 75 micrograms Tablets, like other hormonal contraceptives, do not prote
disease

Do not take Zelleta 75 micrograms Tablet

- if you are allergic to any of the ingredients of Zelleta 75 micrograms
if you have a thrombosis. Thrombosis is the formation of a blood clot a blood vessel e.g. of the legs (deep venous thrombosis) or the lun (pulmonary embolism)
disease and your liver is still not w if you have or if you are suspetworking normally.
to sex-steroids, such as certain types of breast cancer
if you have any unexplained vaginal bleeding
ell yout thes conditions apply to to use Zelleta 75 micrograms Tablets

Consult your doctor immediately if any of these $c$
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.

## Narnings and precautions

talk to your doctor, pharmacist or nurse before taking Zelleta nicrograms Tablets.
you have ever had breast cance
you have iiver cancer, since a possible effect of Zelleta 75 microgram
Tablets cannot be excluded.
you have ever had
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 muc

When Zelleta 75 micrograms Tablets are used in the presence of any hese conditions, you may need to be kept under close observation. You doctor can explain what to do

## reast cancer

It is inportant to regularly check your breasts and you should contac 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 tak the Pill than in women of the same age who do not take the Pill. If wears 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 hignerithe age untiwhich the voman continues to s importan.
n every 10000 women who take the Pill for up to 5 years but stop taking by the age of 20 , there would be less than 1 extra case of breast cance ound up to 10 years after stopping, in addition to the 4 cases normally vears but stop taking thy the age of 30 , there would be 5 extra cases addition to the 44 cases normally diagnosed. In 10000 women who tak he Pill for up to 5 years but stop taking it by the age of 40 , there would be 0 extra cases in addition to the 160 cases normally diagnosed.
he risk of breast cancer in users of progestogen-only pills like Zelleta 7 nicrograms Tablets is believed to be similar to that in women who use th Pill, but the evidence is less conclusive,
Breast cancers found in women who take the Pill, seem less likely to ha spread than breast cancers found in women who do not take the Pill. is not known whether the difference in breast cancer risk is caused by he pill. It may be that the wom

## Thrombosis

see your doctor immediately'
see also 'Regular check-ups').
Thrombosis is the formation of a blood clot, which may block a bloo dep $A$, If the the s formed, it may reach and block the arteries of the lungs, causing a so called "pulmonary embolism". As a result, fatal situations may occur not you are taking the Pill It can also happen ifyou become pregnant.

The risk is higher in Pill-users than in non-users. The risk with
 ower than in users of Pills that also contain oestrogens (combined Pills).
Other medicines and Zelleta 75 micrograms Tablets
ell your doctor or pharmacist if you are taking, have recently taken or night take any other medicines

Some medicines may stop Zelleta 75 micrograms Tablets from working operly These include medicins used for the treatment
epilepsy (e.g. primidone, phenytoin, carbamazepine, oxcarbazepine
elbamate and phenobarbital
HIV infections (e.g. ritonavir), or other infectious diseases (e.g. griseofulvin)
ach upset (medical charcoal)
depressive moods (the herbal remedy St John's Wort).
Your doctor can tell you if you need to take additional contraceptive recautions and if so, for how long.
elleta 75 micrograms Tablets may also inteffere with edicines work, causing either an increase in effect (e.g. medicines containing cyclosporine) or a decrease in effect.

## regnancy, breast-feeding and fertility

regnancy
nay be pregnant.
Breast-feeding
lleta 75 micrograms Tablets may be used while you are breast-feeding elleta 75 micrograms Tablets do not influence the production or the elleta 75 micrograms Tablets passes over ant of the activer

The health of children who were breast-fed for 7 months while their others were using another desogestrel-only pill has been studied up to 5 years of age. No effects on the growth and development of the

鲑idren were observed. f you are breast feeding
please contact your doctor.
riving and Using Machines
here are no indications of any effect of the use of Zelleta 75 micrograms ablets on alertness and concentration.
Zelleta 75 micrograms Tablets contain lactose
elleta 75 micrograms Tablets contains lactose (milk sugar) Please ontact 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-up
When you are using Zelleta 75 micrograms Tablets, your doctor will tell ou to return for regular check-ups. In general, the frequency and nature f 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 hen you cough up blood (possible signs of a cough, especially indicating a thrombosis
dicaling a trombosis 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 stomac area (possibly indicating an ectopic pregnancy, this is a pregnancy utside 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 bleed

you suspect that you are pregnant

## 3. How to take Zelleta 75 micrograms Tablets

## the tablets?

Each strip of Zelleta 75 micrograms Tablets contains 28 tablets. Arrow are printed on the front of the stip, between the tablets. The days of th week are printed on the back of the strip. Each day corresponds with on take a tablet from the top row. Don't start with just any tablet. For exampl if you start on a Wednesday, you must take the tablet from the top row until the pack is empty, always following the direction tablet every . day at about the same time. Swallow the tablet whole, with water. You ma have some bleeding during the use of Zelleta 75 micrograms Tablets, bu 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 th 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 not necessary.
f you take your first tablet on days 2 to 5 of your period use an ada 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 your vaginal ring or patch (this means no tablet-, ring- or patch-fre break). If your present Pill pack also contains inactive tablets you can sta (if you are not sure which this is, ask your doctor or pharmacist). If you follow these instructions, you need not take extra contraceptiv precautions
You can also start at the latest the day following the tablet-, ring-, patch follow these instructions, make sure you use an additional contraceptiv 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 contraceptiv precautions are not necessary.

When you change from an injection, implant or a hormon Intrauterine device (IUS) lets when your next inietion your implant or your IUS is removed. Addition contraceptive precautions are not necessary.

## After you have a baby

You can start Zelleta 75 micrograms Tablets between 21 to 28 days afte the birth of your baby However, if you have already had sex, check that you are not pregna before starting Zelleta 75 micrograms Tablets
nformation for breast-feeding women can be found in section 2 "Befo breast-feeding". Your doctor can also advise you

## fter a miscarriage or an abortio

Your doctor will advise you.

## If you forget to take Zelleta 75 micrograms Tablet

If you are less than 12 hours late:
Take the missed tablet as soon as you remember and take the next one a he usual time. Zelleta 75 micrograms Tablets will still protect you from
egnancy
If you are more than 12 hours late:
f 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 his may mean taking two in one day. Continue to take your tablets a next 7 days. If you missed one or more tablets in the very first week o tablet-intake and had intercourse in the week before missing the tablets you may fall pregnant. Ask your doctor for advice

## fyou vomit or have diarrhoea

ollow the advice for forgotten tablets in the section above. If you vomi within 3-4 hours after taking your Zelleta 75 micrograms Tablets or have severe dia
absorbed.
f you take more Zelleta 75 micrograms Tablets than you should There have been no reports of serious harmful effects from taking too nany Zelleta 75 micrograms Tablets at one time. Symptoms that may ccur are nausea, vomiting and in young girls, slight vaginal bleeding, or more information ask your docto
you stop taking Zelieta 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 you have any further questions on the use of this product, ask you octor or pharmacist.

## 4. Possible side effects

Like all medicines, Zelleta 75 micrograms Tablets can cause side effects though not everybody gets them. Tell your doctor if you notice an unwanted effect, especially if severe or persistent.

Serious side effects associated with the use of Zelleta 75 microgram lablets are described in section 2 "Before you take Zelleta 75 microgram 'ind 'Thrombosis' and consult your doctor at once where appropriate.
Vaginal bleeding may occur at irregular intervals while using Zelleta 75 nicrograms Tablets. This may be just slight staining which may not even
equire 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 nicrograms Tablets is not working. In general, you need not take any ction, just contins is no號

How often are other possible side effects seen
Common (affecting less than 1 in 10 women): mood changes, depresse nood, decreased sexual drive (libido), headache, nausea, acne, breas ain, irregular or no periods, weight increase
ncommon (affecting less than 1 in 100 women) infection of the vagina varian 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 Yngioedema, 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 condition
o not throw away any medicines via wastewater or household was 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

## WhatZelleta 75 micrograms Tablets contain

The active substance is desogestrel. Each tablet contains 75 microgram desogestrel.
The other ingredients are: Lactose anhydrous, all-rac-a-tocophero Povidone, Potato starch, Silica colloidal anhydrous, Stearic acid
(See also 'Important information about some of the ingredients of Zellet 75 micrograms Tablets' in section 2).

## Welleta 75 micrograms Tablets look like and contents of the

pack
Each tablet is round, uncoated, biconvex, debossed with '152' on one side nd other side plain. Each box of Zelleta micrograms rabees contain 3,6 or 13 strips of 28 tablets eac
carton contains blisters packed separately in an aluminium Packs may be ma
may be marketed

## Marketing Authorisation Holde

Morningside Healthcare Ltd
Leicester LE30PA, UK

## Manufacturer

Morningside
5 Pavilion Way
LE115GW
UK
This leaflet was last revised in October 2015

