

Reporting of side effects

For patients taking an Exeltis UK medicine: If you experience side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the patient information leaflet.

By reporting side effects you can help provide more information on the safety of a medicine. Side effects can be reported to Exeltis UK Pharmacovigilance at pharmacovigilance.uk@exeltis.com.

You can also report side effects to the MHRA via the Yellow Card Scheme. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google Play or Apple App Store.

Information is intended for women in the UK who have been prescribed Slynd® (drospirenone) by their doctor, pharmacist, or nurse only.

Information for Patients

What is Slynd® (drospirenone)?

A contraceptive pill, that is used to prevent pregnancy and contains the progestogen 'drospirenone', a type of female sex hormone. This type of contraceptive pill is known as a progestogen only pill (POP).

Refer to the package leaflet for more information on how to take this medicine. This information does not replace the advice of your doctor, pharmacist, or nurse. If you are unsure about how to take this medicine, please speak to your doctor, pharmacist, or nurse.



How do I take Slynd®?

28

Each pack contains 28 tablets: 24 white active tablets and 4 green placebo tablets (a placebo is a tablet without active medicine).

1

Take 1 tablet every day with a little water. You may take the tablets with or without food.



1 packet will last you 28 days (1 menstrual cycle). Once you have finished a pack, **start a new one straight away** without any breaks between the 2 packs.



You must take the tablets everyday around the **same time of the day** so that the interval between 2 tablets is always 24 hours.



Slynd® contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Slynd®.



Avoid grapefruit or grapefruit juice while taking Slynd®.

Information for Patients

FAQs



Will I experience bleeding with Slynd®?

Vaginal bleeding may occur at irregular intervals with this medicine. This may just be slight staining which may not even require a pad, or heavier bleeding requiring sanitary protection. You may also not have any bleeding at all.

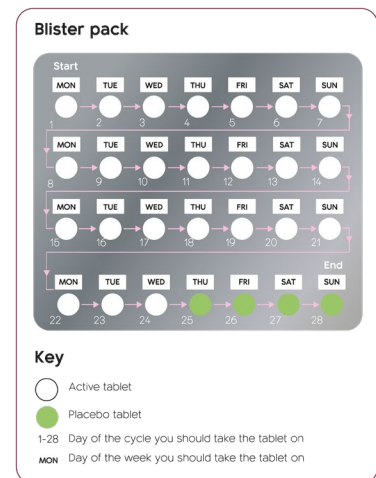
Irregular or no bleeding is not a sign that the contraceptive protection of the pill has decreased. In general, you need not take any action; just continue to take your pill as normal.

If the bleeding is heavy or prolonged you should consult your doctor. If the bleeding is very frequent and irregular, another contraceptive method should be considered. If you don't have vaginal bleeding during the treatment, you may need to do a pregnancy test if you have not taken your pill properly.

The tablets have been arranged in the order you should take them in.

The blister pack has arrows and numbers to help you keep track of which pills you need to take and when. Take a white active tablet for the first 24 days.

- Take a green placebo tablet for the last 4 days.
- Then start a new pack without taking any breaks.
- The packet contains a card envelope that you can keep your blister pack in for discretion.
- To help you keep track of your tablets, days of the week stickers have been provided alongside the packet.



What happens if I miss a pill?

Refer to the package leaflet for more information on what to do if you miss a pill. This information does not replace the advice of your doctor, pharmacist, or nurse. If you are unsure about what to do if you have missed a pill, please speak to your doctor, pharmacist, or nurse.

What should I do if I forget to take Slynd® between days 1-14 (first or second row)?



Less than 24 hours: If you are less than 24 hours late in taking any single tablet, take the missed tablet as soon as it is remembered and take the next tablet at the usual time, even if this means taking two tablets at the same time.



More than 24 hours late: If you are more than 24 hours late in taking any white, active tablet, take the missed tablet as soon as it is remembered, even if this means taking two tablets at the same time, and use an additional method of contraception (such as a condom) for the next 7 days. Then, continue taking the tablets at your usual time.



Risk of pregnancy: If you have forgotten a tablet in the first week of starting the tablets, and you have had sex in the week before forgetting the tablet you must realise that there is a risk of pregnancy. In that case, contact your doctor.



Information for Patients



FAQs continued

What should I do if I forget to take a white Slynd® tablet between days 15-24 (third or fourth row)?

Take the missed tablet as soon as you remember, even if that means that you have to take two tablets at the same time.

Continue taking the white active tablets at the usual time. Instead of taking the green placebo tablets on this strip, throw them away, and start the next strip (the starting day will be different). By skipping the placebo interval, the contraceptive protection is maintained.

What should I do if I forget to take a green tablet between days 25-28 (fourth row)?

The last 4 green tablets in the fourth row of the strip are the placebo tablets. If you forget one of these tablets, this has no effect on the reliability of Slynd®. Throw away the forgotten placebo tablet.



Illness after taking Slynd®

What should I do if I vomit or have severe diarrhoea after taking Slynd®?

If you vomit or have severe diarrhoea, there is a risk that the active substance in the pill will not be fully absorbed by your body. In these cases, an additional method of contraception may be needed. Ask your doctor, pharmacist, or nurse for advice.

What should I do if I vomit or have severe diarrhoea within 3-4 hours after taking Slynd®?

If you vomit or have severe diarrhoea within 3-4 hours after taking your white active tablet, you must take another white tablet from another blister pack as soon as possible.

If possible, take it within 24 hours of when you normally take your pill. Additional contraceptive precautions are not necessary. If this is not possible or 24 hours have passed, you should follow the advice given in the 'If you forget to take Slynd®' section of the package leaflet.

Possible side effects of Slynd®

Like all medicines, the pill can cause side effects, although not everybody gets them.

Common: 1 in 10

- Headache
- Nausea or abdominal pain
- Changes in sexual desire, altered mood
- Acne
- Breast discomfort, painful periods, bleeding and irregular menstrual periods
- Weight gain

Rare: 1 in 1000

- Contact lens intolerance
- Weight loss
- Excessive amount of urine
- Breast cyst, breast secretion, abnormal cervical smear, genital itching

Uncommon: 1 in 100

- Anaemia (decreased number of the red blood cells), fatigue (tiredness), fluid retention
- Dizziness
- Vomiting, diarrhoea, constipation
- Vaginal infections
- Increased amount of the following, shown in blood tests: potassium, liver enzymes (ALT, AST, GGT), bilirubin, creatine phosphokinase, triglycerides
- Appetite changes
- Uterine leiomyoma (benign tumour of the uterus)
- Depressed mood, depression, anxiety
- Absence of menstrual periods, altered menstrual bleeding, pelvic pain, ovarian cysts, vaginal discharge and dryness
- Hair loss, increased sweating, itching, rash, seborrhoea (greasy skin), dermatitis (inflammation of the skin)
- Elevated blood pressure, hot flushes
- Hypersensitivity



Information for Patients



Precautions with Slynd®



Breast Cancer

Regularly check your breasts and 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 combined pill than in women of the same age who do not take the combined pill.

If women stop taking the combined pill, the risk gradually decreases, so that 10 years after stopping the risk is the same as for women who have never taken the combined pill.

Breast cancer is rare under 40 years of age. Breast cancers found in women who take the combined pill seem less likely to spread than breast cancers found in women who do not take the combined pill. It is not known whether the difference in breast cancer risk is caused by the combined pill. It may be that the women were examined more often, so that the breast cancer is noticed earlier.

The risk of breast cancer in users of progestogen-only preparations like Slynd® is believed to be similar to that in women who use the combined pill, but the evidence is less conclusive.



Other medicines and Slynd®

Tell your doctor, pharmacist, or nurse if you are taking, have recently taken or might take any other medicines. They can tell you if you need take additional contraceptive precautions (for example condoms) and if so, for how long, or whether the use of another medicine you need must be changed.



Thrombosis

See your doctor immediately, if you notice possible signs of a thrombosis. 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.

There may be a slightly increased risk of thrombosis with progestogen-only preparations. The risk of thrombosis is higher if a member of your family (a sibling or a parent) has had thrombosis at a relatively early age, with increasing age, obesity, prolonged immobilisation, major surgery, or major trauma.



Psychiatric Disorders

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

Please refer to your package leaflet or speak to your doctor, pharmacist, or nurse for more information.

Developed by Exeltis for patients prescribed Slynd®