Package leaflet: Information for the user

Noriday® 350 microgram tablets
Norethisterone

Read all of this leaflet carefully before you start taking 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. See section 4.

What is in this leaflet

1. What Noriday is and what it is used for
2. What you need to know before you take Noriday
3. How to take Noriday
4. Possible side effects
5. How to store Noriday
6. Contents of the pack and other information

1. What Noriday is and what it is used for

Noriday is a progestogen-only contraceptive pill, or 'POP' for short.
Noriday contains the active substance norethisterone.

Noriday helps to prevent you becoming pregnant. It does this in several ways.
- It thickens the fluid at the entrance to your womb and this makes it hard for sperm to travel through and enter the womb.
- It also changes the lining of your womb so that a fertilised egg cannot grow there.
- By changing the lining of the fallopian tubes (allows transport of egg(s) to the womb), transport of the egg to the womb could be slowed.

2. What you need to know before you take Noriday

Do not take Noriday
- If you are allergic to the active substance, norethisterone, or any of the other ingredients of this medicine (listed in section 6).
- If you have had blood clots in the legs, blood clots in veins, the lungs, the brain or elsewhere, or conditions which would make you more susceptible to them e.g. (abnormal heart rhythm (atrial fibrillation), heart and brain clot disorders).
- If you have had a heart attack or stroke, or have or have had angina or a disease of your heart valves.
- If you have or have had high levels of fats in your blood (hyperlipidaemia) or other disorders of body fats.

- If you have or have had cancer of the breast, cervix, vagina or womb.
- If you have or have had known or suspected cancer responsive to female hormones (oestrogen-dependent neoplasia).
- If you have had the following during a previous pregnancy: pruritus (itching of the whole body) or jaundice (yellowing of the skin or eyes), for which your doctor could not find the cause; or otosclerosis (a condition that causes deafness).
- If you have or have had certain types of jaundice (Dubin-Johnson or Rotor syndrome).
- If you have or have had liver tumours or other severe chronic liver diseases that may result in bleeding in the stomach.
- If you have had viral hepatitis in the last six months.
- If you have or have had vaginal bleeding (not a period), for which your doctor could not find the cause.
- If you are pregnant or think you could be pregnant.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Noriday if you have or have had any of the following conditions:

- Asthma
- Epilepsy (a condition where you suffer from fits)
- Diseases of the heart and blood vessels (cardiovascular disease)
- High blood pressure (hypertension) or have had very high blood pressure (pre-eclampsia) during pregnancy
- Kidney disease
- Diabetes
- Migraine headaches
- Multiple sclerosis (a problem of the nervous system)
- Muscle twitches (tetany)
- Breast problems of any sort (for example breast cancer, breast nodules or fibrocystic disease of the breast)
- Varicose veins (widened or twisted vein usually in the leg)
- Severe depression
- Systemic lupus erythematosus or SLE (an allergic condition that causes joint pain, skin rash and fever)
- Fibroids in your uterus
- Endometriosis (pelvic pain with painful heavy periods)
- Otosclerosis (an inherited form of deafness)
- Porphyria (a metabolic disease)
- Sydenham’s chorea (a disorder leading to jerky movements of face, hands and feet)
- If you wear contact lenses (as you may experience discomfort whilst taking Noriday)
- Liver diseases

Your doctor, pharmacist or nurse will advise you whether you can still take Noriday if you have or have had any of the conditions listed above.

Psychiatric disorders

Some women using hormonal contraceptives including Noriday 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.

Medical check-ups while taking Noriday
Your doctor or clinic will give you regular check-ups while you are taking Noriday. Your blood pressure will be checked before you start using the pill and then at regular intervals whilst you are on the pill. If your blood pressure goes up, your doctor may tell you to stop taking Noriday. They may also check your breasts and reproductive organs including taking a cervical smear test at regular intervals, if this is considered necessary by the doctor.

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

The following medicines may interact with Noriday and reduce its effectiveness:
- Medicines that treat epilepsy
- Medicines that treat arthritis (medicines called corticosteroids)
- Some antibiotic medicines (e.g. rifampicin)
- Antidepressants
- Anticoagulants (drugs that stop your blood from clotting)
- Sedatives
- Herbal remedies containing St John's wort (*Hypericum perforatum*).

Your doctor, pharmacist or nurse will advise you whether to stop taking these medicines or to use another contraceptive method, such as a condom, while you are taking these medicines.

Tell your doctor, pharmacist or nurse if you are taking or have recently taken any other medicines, including those bought without a prescription, because they might interact with Noriday.

Pregnancy, breast-feeding and fertility
Do not take Noriday if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

If you think you may have become pregnant whilst using Noriday, tell your doctor immediately. If you become pregnant while you are taking this type of pill there is a slightly higher chance that it could be an ectopic pregnancy (a pregnancy developing outside the womb).

Protection against sexually transmitted diseases
Noriday will not protect you against sexually-transmitted diseases, including AIDS. For safer sex, use a condom as well as your usual contraceptive.

Driving and using machines
No effects on the ability to drive or use machines have been seen with Noriday.

Smoking
Smoking increases the risk to your health and increases some of the risks of the combined pill. It is not known if these risks also apply to the progestogen-only pill. It is recommended that you give up smoking if you want to take oral contraceptives.

Noriday contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Noriday

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Take one pill each day. Start on the first day of your next period. This is 'day one' of your cycle, the day when bleeding starts. The pack is marked with the days of the week to help you remember to take your pills. If you cannot start taking the tablets on the first day of your period you may start to take it on any day up to the fifth day.
- Follow the direction of the arrows on the pack and take a pill every day until the pack is empty. When you finish the first pack, start a new pack on the next day. This means that you will be taking pills through your period. There must be no breaks between packs.
- For the first seven days of the first pack you should also use a condom, or a cap and spermicide.
- You can take the pill at a time that suits you. **But you must take it at about the same time each day**. Swallow the pill whole with some water. **If you are three or more hours late taking your pill, follow the instructions under 'What to do if you forget to take a pill?'**

If you notice a change in your periods
This is quite normal with the progestogen-only pill. Your periods may be irregular and you may have some bleeding between periods. You may even have no periods at all. Make a note of what happens so that you can tell your doctor or healthcare professional at your next check-up.

If you miss a period
This may happen with this type of pill. If you have taken all your pills properly, you are very unlikely to be pregnant. Take your next pack as normal. If you miss a second period see your doctor or healthcare professional at once.

If you forget to take Noriday

- If you are more than three hours late taking your pill you may not be protected from pregnancy.
- Take the pill as soon as you remember, and take the next one at the normal time.
- This may mean taking two pills in one day.
- Continue to take your pills as normal but also use a condom for the next seven days.

If you are changing brands of oral contraceptive (pill)
Take the first pill of your new pack on the day after you finish your old pack. Do not leave any break at all.

If you have a stomach upset or you are sick
Noriday may not work if you are sick or have diarrhoea. Continue to take your pills as normal but use a condom while you are ill and for the next seven days.

If you are having an operation
If you are going to have an operation, or if you are ill or injured and there may be a risk of blood clots, please tell your doctor that you take Noriday. Noriday should be discontinued 4 weeks prior to surgery and can normally be re-started 2 weeks following surgery. Your doctor will discuss what is relevant for you.

If you have just had a baby
You can use Noriday after having a baby. Start taking the pill from day 21 after childbirth. This protects you as soon as you have taken the first pill. If you start later than this you may not be protected until you have taken the pill for another seven days.

If you have just had a miscarriage or abortion
If you have had a miscarriage or abortion you can start taking the pill straightaway and will be protected immediately.

If you want to have a baby
Stop taking Noriday if you want to have a baby. It is helpful to wait until your regular periods return before you try to get pregnant. Therefore it is recommended that you stop taking Noriday tablets three months before a planned pregnancy. You can use another type of contraceptive, such as a condom until then. Once you have had a period it will be easier to work out when the baby is due. However, if you get pregnant as soon as you stop taking Noriday, this is not harmful.

If you or someone else takes too many pills
If you take too many pills or you find out that someone else has taken a lot of pills, contact a doctor immediately.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Reasons to get medical help immediately
The following side effects have been reported in patients taking oral contraceptives but may not always have been caused by them.

Stop taking Noriday and contact your doctor straight away if you notice any of the following serious side effects. These may be signs of thrombosis (a blood clot):

- You have a sudden sharp or severe pain in your chest
- You suddenly become short of breath
- You have an unusual, severe or long headache or migraine for the first time
- Your sight is affected in any way
- You find it difficult to speak
- You collapse or faint
- Any part of your body suddenly feels weak or numb
- You have a severe pain or swelling in one of your calves.

For more information on this possible side effect, see also 'Possible risk of thrombosis (blood clot)' section further below.

Also seek medical attention immediately if:

- You become jaundiced (your skin or the whites of your eyes look yellow) or your whole body itches
- You have a fit
- You become very depressed
- You have severe stomach pain

Other side effects that you might have include:

- Stomach upsets
- Changes in your weight or fluid retention
- Swollen or sore breasts
- Headaches
- Changes in sex drive
- Thrush
- A severe rash
- High blood pressure
- Acne
- Hair loss or an increase in body and facial hair
- A liver disorder, such as a benign liver tumour

Taking any medicine carries some risk. You can use the information in this leaflet, and the advice your doctor or clinic has given you to weigh up the risks and benefits of taking the pill. Don't be embarrassed, and ask as many questions as you need to.

Changes in the length of periods and bleeding between two periods
Some women taking Noriday find that their periods are different. Sometimes the time between periods, and the length of the periods, is different. There may be bleeding between periods, called 'break-through bleeding'. This tends to happen more in the first few months of taking Noriday. If your periods seem different, do not stop taking Noriday but mention it to your doctor or healthcare professional at your next check-up.

Possible risk of thrombosis (blood clot)

- Some evidence suggests that women who take the pill are more likely to develop various blood circulation disorders than women who don't take the pill.
- A thrombosis is a blood clot. A thrombosis can develop in veins or in arteries and can cause a blockage. The chance of a thrombosis forming in women taking the pill and women not taking the pill is rare. When blood clots form in the arteries they can cause chest pain (angina), strokes (blood clots in or bleeding from the blood vessels in the brain) and heart attacks.
- If blood clots form in veins, they can often be treated with no long term danger. On rare occasions a piece of thrombosis may break off. It can travel to the lungs to cause a condition called pulmonary embolism. Therefore in rare cases a thrombosis can cause serious permanent disability or could even be fatal.
- It is important to note that a thrombosis can form in people who are not taking the pill as well as those who are taking it. The risk is higher in women who take the pill than in women who don't take the pill, but is not as high as the risk during pregnancy. The extra risk of thrombosis is highest during the first year that a woman ever uses an oral contraceptive pill.
- The risk of heart attacks and strokes for women who use the pill increases with age and smoking. Other conditions also increase the risk of blood clots in the arteries. These include being greatly overweight, having diseased arteries (atherosclerosis), high blood pressure during pregnancy (pre-eclamptic toxaemia), high blood levels of cholesterol, and diabetes. If you have any of these conditions, you should check with your doctor or clinic to see if the pill is suitable for you. Smokers over 35 are usually told to stop taking these pills.

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 HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Noriday

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton or blister strip after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package in order to protect from light and moisture.

- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Noriday contains
- The active substance is norethisterone. Each pill contains 350 micrograms of norethisterone.
- The other ingredients in each tablet are maize starch, povidone, magnesium stearate and lactose monohydrate. Please also refer to Section 2, ‘Noriday contains lactose’.

What Noriday looks like and contents of the pack
Noriday pills are white and have 'SEARLE' written on one side and 'NY' on the other side. Noriday is available in blister packs containing 28 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Pfizer Healthcare Ireland
9 Riverwalk
National Digital Park
Citywest Business Campus
Dublin 24, Ireland.

Manufacturer
Piramal Pharma Solutions (Dutch) B.V.
Level, 7e verdieping
Bargelaan 200
2333 CW
Leiden
Netherlands

For further information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Pfizer Healthcare Ireland (Medical Information)
9 Riverwalk
National Digital Park
Citywest Business Campus
Dublin 24, Ireland

This leaflet was last revised in 02/2021

Ref: NO 14_0