

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 (including what to do if you forget to take a pill)**
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
- Sometimes it stops your ovaries releasing an egg

2. What you need to know before you take Noriday

Do not take Noriday if you:

- are allergic to norethisterone or any of the other ingredients of this medicine (listed in section 6)
- are or think you may be pregnant
- have had, or think you may have hormone-dependent cancer of the breast, cervix, vagina, or womb
- have or ever had acute or severe chronic liver disease including:
 - past or present tumours
 - jaundice (yellowing of the skin or eyes) and other types of jaundice such as Dubin-Johnson Syndrome and Rotor Syndrome
- active liver disease or liver tumours
- have had the following during pregnancy:
 - pruritus (itching of the whole body)

- jaundice (yellowing of the skin and eyes) for which your doctor could not find a cause
- have disorders of lipid (fat) metabolism
- have unexplained vaginal bleeding
- have never had a period or suffer from lack of periods (amenorrhoea)
- have inflamed veins (thrombophlebitis)
- have thrombosis (blood clots)
- have heart disease, or you have had a stroke

Warnings and precautions

Talk to your doctor before taking Noriday if you suffer from or have ever suffered from:

- epilepsy
- multiple sclerosis
- porphyria (a rare inherited blood disease)
- tetany (muscle twitches)
- otosclerosis (an inherited form of deafness which sometimes gets worse during pregnancy)
- diabetes or have a family history of diabetes
- gallstones
- impaired carbohydrate tolerance
- migraine headaches – if you develop migraine headaches you should consult your doctor
- heart or kidney problems
- depression
- liver disease
- varicose veins
- high blood pressure
- asthma

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.

Before you take Noriday you should also tell your doctor if you wear contact lenses.

If you are obese or have history of pre-eclampsia and are more than 35 years of age, your doctor will discuss the risk/benefit of using oral contraceptives as compared to other methods of contraception due to additional risks.

Medical check-ups

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. All women are encouraged to undergo cervical smear tests at regular intervals.

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 stop Noriday from working properly (the condition they treat is shown in brackets):

- the herbal remedy St John's wort – Latin name *Hypericum perforatum* (depression)
- carbamazepine (epilepsy)
- oxacarbazepine (epilepsy)
- phenytoin (epilepsy)
- phenobarbital (sleeplessness, anxiety, epilepsy)
- primidone (epilepsy)
- topiramate (epilepsy)
- nelfinavir (HIV-Human Immunodeficiency Virus – infection)
- nevirapine (HIV infection and AIDS)
- ritonavir (HIV infection and AIDS)
- rifabutin (bacterial infection)
- rifampicin (bacterial infection)
- griseofulvin (fungal infection)
- ampicillin (bacterial infection)
- doxycycline (bacterial infection)
- modafinil (narcolepsy i.e. daytime sleep)

If you do need to take any of the medicines listed above, Noriday may not be suitable for you. Your doctor will advise you whether to stop taking these medicines or use an additional contraceptive method, such as a condom whilst taking Noriday.

Noriday may change the effects of other medicines. Tell your doctor if you are taking prednisone, prednisolone, cloprednol or any other corticosteroids, as Noriday may not be suitable for you.

Pregnancy, breast-feeding and fertility

Pregnancy

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).

Do not take Noriday if you are pregnant or trying to become pregnant.

If you miss two consecutive periods while you are taking Noriday, tell your doctor or pharmacist. You will need to have a pregnancy test before you continue to take Noriday.

Breast-feeding

Noriday does not prevent the breast from producing milk. However, it is better for the baby that for the first few weeks after birth its mother's milk contains no trace of any medicines, including Noriday.

Sexually transmitted diseases

Noriday helps to prevent you from becoming pregnant. It 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.

Noriday contains lactose monohydrate

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.

- Start on the first day of your next period. This is 'day one' of your cycle, the day when bleeding starts
- Take one pill each day and swallow the pill with water
- You can take the pill at any time that suits you, **but you must take it at about the same time each day**
- The pack is marked with the days of the week to help you remember to take your pills
- 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
- **If you are three or more hours late taking your pill, follow the instructions under 'What do I do if I forget to take a pill?'**

What do I do if I forget to take a pill?

- If you are three or more 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

What do I do if my periods are different?

This is quite normal with the progestogen-only pill. Sometimes the time between periods, and the length of the periods is different. There may be bleeding between periods, called 'breakthrough 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.

What do I do if I 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.

What do I do if I take too many Noriday pills?

If you take more than one pill there should be no problems, but you may experience feeling sick or actually being sick, breast enlargement and vaginal bleeding.

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

What do I do if I have a stomach upset or I am 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.

What do I do if I am 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 mention to 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.

What do I do if I am changing pill brands?

Take the first pill of your new pack on the day after you finish your old pack. Do not leave any break at all.

What do I do if I want 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 wish to become pregnant, you should contact your doctor or healthcare professional about stopping Noriday.

What do I do if I have just had a baby?

You can use Noriday after having a baby whether you are breast-feeding or not. You can 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 had a miscarriage or abortion you can start taking the pill straightaway and will be protected immediately.

What do I do if I have had a miscarriage or abortion?

You can start taking the pill straight away and will be protected 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.

If any of the side effects gets serious, or if you notice any side effects not listed in the leaflet please tell your doctor.

These effects should become less of a problem as your body gets used to the pills.

Reasons to get medical help immediately

Stop taking the pills at once and tell your doctor if:

- You become jaundiced (your skin or the whites of your eyes look yellow)

Also seek medical attention immediately if:

- You have a sudden, severe pain in your chest
- You suddenly become short of breath
- You have an unusual, severe or long headache
- 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 in one of your calves

These could be warning signs of thrombosis (a blood clot).

Other side effects that you might have include:

- stomach upsets
- changes in your weight
- swollen or sore breasts
- headaches
- changes in sex drive
- migraines
- changes in appetite
- gallstones
- a rash
- feeling tired
- feeling nervous
- feeling depressed
- high blood pressure
- irregular periods
- a liver disorder, such as a benign liver tumour. These mostly do not cause any symptoms but can sometimes be felt. Benign liver tumours can sometimes cause severe abdominal pain.

Possible risk of breast cancer

Every woman is at risk of breast cancer whether or not she takes the oral contraceptives (OC). Breast cancer is rare under the age of 40 but the risk increases as a woman gets older.

Whilst taking the OC there is a slightly higher incidence of breast cancer when comparing women of the same age. When you stop taking the OC, the risk is reduced such that 10 years after stopping OC, the risk of finding breast cancer is the same as for women who have never taken the OC.

Where breast cancer is identified it seems less likely to have spread in women who take OC than in women who do not.

It is not certain whether the OC causes the increased risk of breast cancer. It may be that women taking the OC are examined more often, so that breast cancer is noticed earlier.

The risk of finding breast cancer is not affected by how long a woman takes a pill like Noriday, POP, but by the age at which she stops. This is because the risk of breast cancer strongly increases as a woman gets older.

For 10,000 women who take a POP for 5 years and then stop any increased risk of finding breast cancer in the following 10 years increases with age, as shown below:

Age at time of stopping	20	30	40
Number of cases in those who have never taken the Pill	4	44	160
Additional cases in those who have used the Pill	1	2-3	10

The possible small extra risk of being diagnosed with breast cancer has to be weighed against the known benefits of taking the progestogen-only pill.

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 of taking the OC. Don't be embarrassed, ask as many questions as you need to.

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. 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 and on the blister after EXP.

The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the blister in the outer carton 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 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 monohydrate'.

What Noriday looks like and contents of the pack

Noriday pills are white, round tablets and have 'SEARLE' debossed on one side and 'NY' on the other side. Noriday tablets are supplied in blister strips in cartons containing 28 or 84 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Pfizer Limited
Ramsgate Road
Sandwich
Kent
CT13 9NJ

Manufacturer:

Piramal Healthcare UK Limited
Morpeth
Northumberland
NE61 3YA

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