

PATIENT INFORMATION LEAFLET

Noriday®

Norethisterone

Please read this leaflet carefully before you start to take your pills. The leaflet can't tell you everything about Noriday, so if you have any questions or are not sure about anything, ask your doctor, clinic or pharmacist. Keep this leaflet. You may need to read it again.

Some information about Noriday

The name of your medicine is Noriday. It contains norethisterone, a type of hormone called a 'progestogen'. Noriday is a progestogen-only contraceptive pill, or 'POP' for short. The only hormone it contains is progestogen, unlike the combined contraceptive pill which contains two types of hormones - oestrogen and progestogen.

What is in Noriday?

Each Noriday pill contains:

350 micrograms of norethisterone, and inactive ingredients: maize starch, polyvidone, magnesium stearate and lactose.

Noriday pills are white and have 'SEARLE' written on one side and 'NY' on the other side. They are packed in blister strips and supplied in packs of 84 pills.

Who supplies Noriday?

Pfizer Limited

Ramsgate Road, Sandwich, Kent, CT13 9NJ, United Kingdom.

Who makes Noriday

Piramal Healthcare UK Limited

Morpeth, Northumberland, NE61 3YA, United Kingdom.

What is Noriday for?

Noriday helps to prevent you becoming pregnant. It does this in several ways. It thickens the fluid at the entrance to the womb. 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.

Before you take Noriday

Noriday may not be suitable for all women. Do not take Noriday if you have ever had any of the following:

- cancer of the breast, cervix, vagina, or womb
- malignant or benign liver tumours
- liver problems, for example jaundice (yellowing of the skin or eyes)
- pruritus (itching all over your body) or jaundice while you were pregnant
- high levels of fat in your blood
- vaginal bleeding for which your doctor could not find the cause
- amenorrhoea (lack of periods)
- thrombophlebitis (inflamed veins), coronary artery disease, heart attack, angina, blood clots, or a stroke
- a disease of your red blood cells, such as sickle cell anaemia
- an allergic reaction to any of the ingredients in Noriday

Also, please tell your doctor if you could be pregnant. You should not be taking Noriday if there is a possibility that you may be pregnant.

Tell your doctor if you suffer from any of the following conditions, as some diseases may get worse when you are taking the contraceptive pill.

- epilepsy
- heart or kidney problems
- diabetes
- gallstones
- high blood pressure
- multiple sclerosis
- otosclerosis (an inherited form of deafness which may get worse during pregnancy)
- migraine
- depression
- varicose veins
- asthma
- tetany (muscle twitches)
- porphyria (a rare inherited blood disease)

If any of these get worse, or if you get them for the first time, your doctor may tell you to stop taking Noriday.

Noriday tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Your doctor or clinic will give you regular checkups while you are taking Noriday. Your blood pressure will be checked before you start 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. Your breasts and reproductive organs may also be checked, including taking a cervical smear at regular intervals if this is considered necessary by the doctor.

Breast Cancer

Every woman is at risk of breast cancer whether or not she takes the pill. Breast cancer is rare under 40 years of age but the risk increases as a woman gets older.

Breast cancer has been found slightly more often in women who take the pill than in women of the same age who do not take the pill. If women stop taking the pill, this reduces the risk, so that 10 years after stopping the pill, the risk of finding breast cancer is the same as for women who have never taken the pill. Breast cancer seems less likely to have spread when found in women who take the pill than in women who do not take the pill.

It is not certain whether the pill causes the increased risk of breast cancer. It may be that women taking the pill 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 the pill, but by the age at which she stops. This is because the risk of breast cancer strongly increases as a woman gets older.

In 10,000 women who take progestogen-only pills like Noriday for up to 5 years but stop taking it by the time they are aged 20, it is estimated that less than 1 additional case of breast cancer would be found up to 10 years afterwards, compared with the number found in 10,000 women who had never taken the pill. For 10,000 women who take a pill like Noriday for 5 years and stop it by the age of 30, there would be 2 or 3 extra cases of breast cancer found up to 10 years afterwards, (in addition to the 44 cases of breast cancer found in 10,000 women in this age group who have never taken the pill).

For 10,000 women who take Noriday for 5 years and stop it by the age of 40, there would be about 10 extra cases found up to 10 years afterwards (in addition to 160 cases of breast cancer found in 10,000 women in this age group who had never taken the pill).

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 pill. Don't be embarrassed, ask as many questions as you need to.

Other medicines and Noriday

Some medicines may stop Noriday from working properly. These include some drugs that treat epilepsy, arthritis, some antibiotics and sedatives. If you take any other medicines while you are taking Noriday, make sure that your doctor knows. You will be advised whether you need to use additional contraceptives while you are taking the medicine.

The herbal remedy St John's wort (*Hypericum perforatum*) should not be taken at the same time as this medicine. If you already take a St John's wort preparation, stop taking the St John's wort and mention it to your doctor.

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 best to stop smoking anyway.

How to take Noriday

You should 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 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 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 do I do if I forget to take a pill?'**

Overdose

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 forget to take a pill?

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.

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 clinic at once.

What do I do if I become pregnant whilst taking Noriday?

If you suspect that you might be pregnant, seek confirmation and see your doctor immediately. Stop taking the tablets and use another method of contraception until you are sure that you are

not pregnant.

Noriday can increase your risk of having an ectopic pregnancy (a pregnancy developing outside of the womb).

The exposure of the foetus to sex hormones such as Noriday has been shown to be associated with an increased rate of birth defects such as heart and limb malformations. Please discuss how advisable a continuation of any pregnancy under Noriday is with your doctor.

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 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 or become immobilised?

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 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 want a baby?

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.

Does Noriday have side effects?

All medicines can sometimes cause problems. These effects should become less of a problem as your body gets used to the pills. If you are worried about any of the side effects below or any others not listed, then talk to your doctor.

Side effects might include:

- a rash
- headache
- stomach upset
- feeling depressed
- high blood pressure
- swollen or sore breasts
- migraine
- feeling tired
- feeling nervous
- changes in appetite
- changes in sex drive
- changes in your weight

Reasons to get medical help immediately

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

- you become jaundiced (i.e. your skin and/or the whites of your eyes look yellow)

Or,

- 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, i.e. partial or complete loss of vision, with gradual or sudden onset
- 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).

What do I do if my periods are different?

This is quite normal with the progestogen-only pill. Some women 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' or your periods may stop. 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 nurse at the next checkup.

How to store Noriday

Store your Noriday pills in a cool, dry place, away from direct sunlight. Keep out of reach and sight of children.

Do not take Noriday after the 'expiry date' shown on the box. If your pack is out of date, take it to your pharmacist who will get rid of the pills safely.

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

Date this leaflet was last revised: July 2010

Ref: NO 3_0 UK