

NORIDAY[®] TABLET

Norethisterone (350 mcg)

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What Noriday is used for

Noriday is a progestogen-only contraceptive pill, or 'POP' for short. Noriday contains the active ingredient norethisterone. Noriday helps to prevent you becoming pregnant.

How Noriday works

Noriday prevents pregnancy 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.

Before you use Noriday

- When you must not use it

Do not take Noriday if you have had:

- An allergic (hypersensitivity) reaction to the active ingredient, norethisterone, or any other ingredients present in Noriday.
- Blood clots in the legs, blood clots in varicose veins, the lungs, the brain or elsewhere (coronary and cerebral thrombotic disorders).
- A heart attack or angina.
- Disorders of body fats.
- Cancer of the breast, cervix, vagina or uterus.
- Known, suspected or a past history of cancer responsive to female hormones.

- The following during previous pregnancy:
 - Severe pruritus (itching of the whole body);
 - Jaundice (yellowing of the skin or eyes), for which your doctor could not find the cause; or
- Acute or severe chronic liver diseases including past or present liver tumours or Dubin-Johnson or Rotor syndrome (certain types of jaundice), active liver diseases.
- Undiagnosed abnormal vaginal bleeding.
- If you are, or could be, pregnant.

Pregnancy and lactation

Do not take Noriday if you are pregnant, trying to get pregnant or think you may be pregnant.

If you think you may have become pregnant whilst using Noriday, stop taking the medicine and 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).

If you take Noriday in higher doses than the doctor suggested, your developing female baby may show male features.

Do not take Noriday if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Before you start taking Noriday, tell your doctor if:

- You are planning to get pregnant.
- You are a smoker especially if you are aged over 35 years.
- You are overweight, has recently had or are planning to undergo any surgery, or are confined to bed for long period of time.
- You have high cholesterol.
- You have diabetes.

- You have a history of pre-eclampsia which is a dangerous pregnancy complication.
- You have migraine.
- You have fits.
- You have any heart, liver or kidney problems.
- You wear contact lenses.
- You have depression.
- You have stones or lumps that develop in the gallbladder or bile duct.
- You have varicose veins.
- You have high blood pressure.
- You have asthma.
- You have otosclerosis (an ear disorder).
- You have multiple sclerosis, a disease causing damage to nerve cells in the brain and spinal cord.
- You have porphyria (a rare inherited blood disease).
- You have tetany (muscle twitches).

Important information about some of the ingredients of Noriday

Noriday tablets contain lactose monohydrate. If you have been told by your doctor that you have rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption contact your doctor before taking this medicinal product.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription, from a pharmacy, supermarket or health food shop.

There are some medicines that may interact with Noriday and reduce its effectiveness. These include:

- Some drugs that treat epilepsy, antibiotics and sedatives.
- The herbal remedy, St. John's Wort.
- Corticosteroids used to provide relief for inflamed areas of the body such as prednisone, prednisolone or cloprednol.

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Your doctor 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.

How to use Noriday

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Take one pill each day. Start on the first day of your period. This is 'day one' of your cycle, the day when bleeding starts.

- When to use it

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.

- How long to use it

Use as directed by your doctor or pharmacist.

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 an additional contraceptive precaution such as condom.

- If you forget to use it

- If you have missed a pill within three hours of the correct time, take the pill as soon as possible.
- 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 use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause nausea, vomiting, breast enlargement and vaginal bleeding.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Noriday.

Tell your doctor immediately if you become pregnant while taking this medication.

What do I do if my periods are different?

This is quite common 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 the 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 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 have stomach problems such as diarrhoea or vomiting. 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 restarted 2 weeks following surgery. Your doctor will discuss what is relevant for you.

What do I do if I have just had a baby, miscarriage or abortion?

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 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?

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. 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.

Take special care with 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

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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 at regular intervals if this is considered necessary by the doctor.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Noriday to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

No effect on the ability to drive or use machines have been seen with Noriday.

Side Effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

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 at once if any of the following occurs:

- You have a sudden, 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. Or
- You have a severe pain or swelling in one of your calves. "These could be warning signs of thrombosis (a blood clot)".
- You notice you are pregnant.

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 experience mood changes.
- You become depressed, even though shortly after starting the medication.
- You are feeling suicidal or demonstrated suicidal behavior.
- You have severe stomach pain.

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'. 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.

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
- migraines
- changes in appetite
- rash
- high blood pressure
- depression
- suicidal behavior
- nervousness
- feeling tired
- liver cancer

Possible risk of thrombosis

Some evidence suggests that women who take the pill are more likely to develop various blood circulation disorders than women who do not 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. When blood clots travel to the lungs, they may cause a condition called pulmonary embolism.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Noriday

- Storage

Keep your tablets out of the reach and sight of children.

Do not use Noriday after the expiry date (EXP) which is stated on the blister and carton. The expiry date refers to the last day of that month.

Store below 30°C.

Store in a cool, dry place away from direct sunlight.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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Product Description

- What it looks like

White, flat, circular with bevel-edged inscribed 'SEARLE' on one side and 'NY' on the other side.

PVC blisters/foil backing in a cardboard carton. Each strip has 4 rows of 7 tablets. Each carton contains 3 x 28 tablets.

- Ingredients

- Active ingredient
Norethisterone

- Inactive ingredients
Maize starch
Polyvidone
Magnesium stearate
Lactose monohydrate

- MAL number

Noriday Tablets: MAL19992549ACZ

Manufacturer

Piramal Healthcare UK Limited
Whalton Road
Morpeth
Northumberland
NE61 3YA
United Kingdom

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.
Level 10 & 11,
Wisma Averis, Tower 2,
Avenue 5, Bangsar South,
No. 8 Jalan Kerinchi,
59200 Kuala Lumpur, Malaysia

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23/10/2024

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