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Due to regulatory changes, the content of the following Patient Information Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes.

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.

Package leaflet: Information for the user**Noristerat[®]**

Norethisterone enantate

Read all of this leaflet carefully before you start using 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, family planning nurse or pharmacist.
- Noristerat is given by injection for contraception.
- If you get any side effects, talk to your doctor, family planning nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Three important things to know about this medicine.

- It will not protect you against sexually transmitted diseases.
- This medicine can increase your risk of problems such as blood clots
- Some women should not use this medicine because of current medical problems or illnesses. Please read this leaflet to make sure Noristerat is right for you.

What is in this leaflet:

- 1. What Noristerat is and what it is used for**
- 2. Make sure Noristerat is OK for you**
- 3. How to use Noristerat**
- 4. Possible side effects**
- 5. How to store Noristerat**
- 6. What is in Noristerat and who makes it**

1. What Noristerat is and what it is used for

Noristerat is an injectable (depot) contraceptive. It is intended as a short-term method of contraception, for example in women whose partners are undergoing vasectomy, until the vasectomy is effective. It is also for use in women immunised against rubella, to prevent pregnancy while the virus is active.

You use it to stop you getting pregnant.

Noristerat contains a type of female sex hormone, called a progestogen. This hormone stops you getting pregnant by working in three ways: by preventing an egg being released from your ovaries; by making the fluid (mucus) in your cervix thicker, which makes it more difficult for sperm to enter the womb; and by preventing the lining of your womb thickening enough for an egg to grow in it.

The benefits of using Noristerat include:

- it is one of the most reliable reversible methods of contraception if used correctly
- you only have to remember to visit your doctor after 8 weeks for a second injection
- it doesn't interrupt sex

Noristerat will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this.

2. Make sure Noristerat is OK for you

It's important that you understand the benefits and risks of using Noristerat before you are given it, or when deciding whether to have a second injection. Although Noristerat is suitable for most healthy women it isn't suitable for everyone.

→ **Tell your doctor** if you have any of the illnesses or risk factors mentioned in this leaflet.

Before you are given Noristerat

- Your doctor will ask about you and your family's medical problems, check your blood pressure and exclude the likelihood of you being pregnant. You may also need other checks, such as a breast examination, but only if these examinations are necessary for you, or if you have any special concerns.

While you're on Noristerat

- **Check your breasts** and nipples every month for changes – tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.
- **If you need a blood test or other laboratory tests**, tell your doctor or the laboratory staff that you are using Noristerat, because hormonal contraceptives can affect the results of some tests.

- **If you're going to have an operation**, make sure your doctor knows about it. You may need to avoid having a second injection of Noristerat before the operation. This is to reduce the risk of a blood clot (see section 2.1).

2.1 Noristerat and blood clots

Noristerat may slightly increase your risk of having a blood clot (called a *thrombosis*), **especially in the first year of using it.**

A clot in a leg vein – a *deep vein thrombosis* (or DVT) – is not always serious. However, if it moves up the veins and blocks an artery in the lungs, it can cause chest pain, breathlessness, collapse or even death. This is called a *pulmonary embolism* and is very rare.

Very rarely, blood clots can also form in the blood vessels of the heart (causing a **heart attack**) or the brain (causing a **stroke**). In healthy young women the chance of having a heart attack or stroke is extremely small.

You are more at risk of having a blood clot:

- as you get **older**
- if you **smoke**
- if you are seriously **overweight**
- if you have some **diseases of the heart and blood vessels**
- if you suffer from **migraines**
- if you have **recently had a baby**
- if you're **off your feet for a long time** because of major surgery, injury or illness

→ **Tell your doctor** if any of these risk factors apply to you. Noristerat may not be suitable for you.

Signs of a blood clot include:

- a **migraine** for the first time, a migraine that is worse than normal or unusually frequent or severe **headaches**
- any sudden **changes to your eyesight** (such as loss of vision or blurred vision)
- any sudden **changes to your hearing, speech, sense of smell, taste or touch**
- **pain or swelling in your leg**
- **stabbing pain when you breathe**
- **coughing** for no apparent reason
- **pain and tightness in the chest**
- sudden **weakness** or **numbness** in one side or part of your body
- **dizziness** or **fainting**.

→ **See a doctor as soon as possible. Do not have a further injection** until your doctor says you can. Use another method of contraception, such as condoms, in the meantime.

2.2 Noristerat and cancer

Noristerat has also been linked to liver diseases, such as jaundice and non-cancer liver tumours, but this is rare. Very rarely, Noristerat has also been linked with some forms of liver cancer in women who have used it for a long time.

→ **See a doctor as soon as possible if you get severe pain in your stomach, or yellow skin or eyes (jaundice).** You may need to stop using Noristerat .

2.3 Noristerat should not be used by some women

→ **Tell your doctor or family planning nurse** if you have any medical problems or illnesses.

Do not use Noristerat if you have any of the problems listed below. Using Noristerat would put your health at risk.

- If you are **pregnant** or might be pregnant
- If you have ever had a problem with your blood circulation. This includes a **blood clot (thrombosis)** in the legs (*deep vein thrombosis*), lungs (*pulmonary embolism*), heart (**heart attack**), brain (**stroke**) or any other parts of the body
- If you have or have ever had **severe liver disease**, and you have been told by your doctor that your liver function test results are not yet back to normal
- If you have or have ever had **liver tumours**
- If you have **severe diabetes affecting your blood vessels**
- If you have **very high blood pressure**
- If you have disorders of **blood fat (lipid) metabolism**
- If you have or suspect you have cancer affected by sex hormones – such as some **cancers of the breast or womb lining** or have ever had either of these conditions
- If you have an inherited disease called **porphyria**
- If you are **allergic (hypersensitive)** to norethisterone enantate or any of the other ingredients in Noristerat (listed in section 6).

→ **If you suffer from any of these**, or get them for the first time while using Noristerat, contact your doctor as soon as possible. It may not be suitable for you to have a second injection of Noristerat.

2.4 Noristerat can make some illnesses worse

Some of the conditions listed below can be made worse by using Noristerat. Or they may mean it is less suitable for you. You may still be able to be given Noristerat but you need to take special care.

- If you have had severe **depression**
- If you have ever had **liver problems, e.g. jaundice** (yellow skin or eyes)
- If you have **any disease that tends to get worse during pregnancy**
- If you have an **irregular menstrual pattern together with stomach pains**
- If you have **abnormal vaginal bleeding**
- If you have **diabetes**

- If you have ever had an **ectopic pregnancy** or **fallopian tube removed**.

The main ingredient of Noristerat (the progestogen, norethisterone enantate) is partly converted into the oestrogen, ethinylestradiol. The expected concentration of ethinylestradiol in your body is relatively low compared to taking combined hormonal contraceptives containing ethinylestradiol. This means that although effects similar to those after taking combined hormonal contraceptives containing ethinylestradiol cannot be completely ruled out, experience to date suggests that this may not be the case.

→ **Tell your doctor or family planning nurse if any apply to you.** Also tell them if you get any of these for the first time after being given Noristerat, or if any get worse or come back, because it may not be suitable for you to have a second injection of Noristerat.

2.5 Psychiatric disorders

Some women using hormonal contraceptives including Noristerat 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.

2.6 Taking other medicines

If you ever need to take another medicine or herbal products at the same time, always tell your doctor, pharmacist or dentist that you've been given Noristerat. Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

Some medicines can stop Noristerat from working properly – for example:

- **certain sedatives** (called *barbiturates*)
- **some medicines used to treat epilepsy**
- **some medicines used to treat HIV and Hepatitis C virus infections** (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors)
- **griseofulvin** (an anti-fungal medicine)
- **phenylbutazone** (an anti-inflammatory medicine)
- **certain antibiotics**
- **St. John's Wort** (a herbal remedy).

If you do need to take one of these medicines, you may need to use extra contraception (for example condoms) for a while. Your doctor, pharmacist or dentist can tell you if this is necessary and for how long.

Noristerat can also affect how well other medicines work. For example, if you have diabetes, you may need to take more insulin or other anti-diabetic drugs after being given Noristerat. Your doctor will tell you if this is necessary.

2.7 Using Noristerat with food and drink

There are no special instructions about food and drink while on Noristerat

2.8 Pregnancy and breast-feeding

Pregnancy

You should not be given Noristerat if you are pregnant. If you think you might be pregnant, do a pregnancy test to confirm that you are and do not have your second injection.

Breast-feeding

Noristerat has not been shown to reduce the amount of milk you produce which is an advantage if you wish to breastfeed your baby. Very small amounts of the hormone are found in breast milk. There is no evidence to suggest that the small amounts of the hormone that appear in the milk are harmful to a healthy baby. However, if your baby has severe or long-lasting jaundice that requires medical treatment you should not breast-feed your baby after having your injection.

2.9 Driving and using machines

Noristerat has no known effect on the ability to drive or use machines.

2.10 Noristerat contains benzyl benzoate

This medicine contains 333.8 mg benzyl benzoate in each 1 ml ampoule.

Benzyl benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to use Noristerat

3.1 How to start

Your doctor or family planning clinic will give you the first injection of Noristerat within the first five days of your period (unless you start just after a pregnancy or an abortion). The injection is given into the muscle.

By starting in this way you will have contraceptive protection at once.

3.2 Further injections of Noristerat

One injection will give you contraception for 8 weeks. After 8 weeks a second injection can be given. You must make sure that you leave no longer than 8 weeks between injections or contraceptive protection will be lost.

3.3 Starting Noristerat after having a baby

Noristerat can normally be used straight after having a baby. Your doctor will advise you on when to start.

3.4 Starting Noristerat after having a miscarriage or an abortion

You may be able to have an injection immediately. Your doctor will advise you.

3.5 Missed a period – could you be pregnant?

If, when the second injection is due, you have not had a further period since the first injection, it is unlikely that you are pregnant, but the second injection should not be given until pregnancy has been ruled out.

3.6 Being given more Noristerat than you should

Overdosage is unlikely but if it does occur no serious ill-effects are expected.

4. Possible side effects

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

→ **Tell your doctor, pharmacist or family planning nurse** if you are worried about any side effects which you think may be due to Noristerat.

4.1 Serious side effects – see a doctor straight away

Signs of a blood clot:

- a **migraine** for the first time, a migraine that is worse than normal or unusually frequent or severe **headaches**
- any sudden **changes to your eyesight** (such as loss of vision or blurred vision)
- any sudden **changes to your hearing, speech, sense of smell, taste or touch**
- **pain or swelling in your leg**
- **stabbing pain when you breathe**
- **coughing** for no apparent reason
- **pain and tightness in the chest**
- sudden **weakness** or **numbness** in one side or part of your body
- **dizziness** or **fainting**.

Signs of a severe allergic reaction to Noristerat:

- **swelling** of the **face, lips, mouth, tongue or throat**.

Signs of severe liver problems include:

- severe **pain in your upper abdomen**
- **yellow skin or eyes** (*jaundice*)
- **inflammation of the liver** (*hepatitis*)

- your whole body starts **itching**.

→ If you think you may have any of these, see a doctor straight away. You may need to stop using Noristerat.

4.2 Less serious side effects

- **irregular bleeding**
- **bloating**
- **tender breasts**
- **headaches**
- **depressive moods**
- **dizziness**
- **feeling sick**
- **putting on weight**
- **skin reactions** (e.g. pain or itchy rash) at the injection site
- rarely **coughing** for no apparent reason, **shortness of breath** and **disturbances of the circulatory system** may develop while you are having your injection, or immediately after.

→ Tell your doctor or family planning nurse if you are worried about any side effects which you think may be due to Noristerat. Also tell them if any existing conditions get worse while you are using Noristerat.

Reporting of side effects

If you get any side effects, talk to your doctor, family planning nurse or pharmacist. 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 Noristerat

Keep this medicine out of the sight and reach of children.

Noristerat should not be used after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.

Store below 25°C. Protect from light.

6. What is in Noristerat and who makes it

What is in Noristerat

The active substance is norethisterone enantate.

Each ampoule of Noristerat contains 200mg of the progestogen norethisterone enantate in 1ml of oily solution for injection into a muscle. The other ingredients are benzyl benzoate and castor oil for injection.

What Noristerat looks like and contents of the pack

Noristerat is a solution for intramuscular injection; the injection is given into the muscle.

Noristerat is supplied in single packs of 1 ampoule.

The company that holds the product licence for Noristerat is:

Bayer plc,
400 South Oak Way, Reading, RG2 6AD

Noristerat is made by: Bayer AG, Muellerstrasse 178, 13353 Berlin, Germany.

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