

Package Leaflet: Information for the user

Utovlan ® 5 mg 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 further questions, ask your doctor or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

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

1. What Utovlan is and what it is used for

Utovlan is one of a group of medicines called 'Progestogens'. Progestogens are similar to the natural female hormone progesterone. Utovlan contains the progestogen called norethisterone as the active ingredient. Utovlan has many uses.

You can take Utovlan to treat or manage:

- Heavy periods
- Painful periods
- Irregular periods or periods that are more frequent than normal
- Premenstrual tension (PMT)
- Endometriosis (where tissue from your womb is found outside your womb)
- Breast cancer.

Your doctor may also prescribe Utovlan if you want to delay your next period.

2. What you need to know before you take Utovlan

Utovlan may not be suitable for all women. Please read the following list carefully to see if any of these apply to you. Consult your doctor if you are not sure.

Do not take Utovlan:

- if you are allergic to norethisterone or other similar hormone medicines, or to any of the other ingredients of this medicine (listed in Section 6).
- if you are pregnant, or think you might be pregnant. Your doctor may give you a pregnancy test before starting treatment or if you miss a period during treatment.
- if you have now or have ever had any vaginal bleeding (not a period) for which your doctor could not find a cause.
- if you or a member of your family have ever had a problem with blood clots, including deep vein thrombosis (DVT).
- if you have now or have had in the past, a heart attack or angina.
- if you have liver problems.
- if you have ever had a pregnancy where you had jaundice, or an itchy rash known as pemphigoid gestationis. This rash appears as small blisters on your abdomen.
- if you have severe generalised itching all over your body (pruritis)

- if you have a condition known as porphyria (a rare inherited blood disease).

Warnings and precautions

Talk to your doctor or pharmacist before taking Utovlan if you have any of the following conditions. This will help him or her decide if Utovlan is suitable for you:

- Epilepsy
- Migraine headaches
- Asthma
- Heart problems
- Kidney problems.

Risk of Venous Thromboembolism (VTE)

All women have a small chance of having a blood clot in the veins of the leg, in the lung or other part of the body. The chances of getting a clot are very slightly higher if you are taking a hormone medicine like Utovlan. You are more likely to get a clot whether or not you are taking Utovlan if you:

- are very overweight
- have systemic lupus erythematosus. (This is a condition where the immune system attacks healthy tissues, typically causing symptoms such as painful joints and muscles, tiredness, fever and rashes).
- have had a blood clot in the veins or lungs before
- have relatives who have had blood clots
- are unable to move for long periods of time (for example after an operation)
- have a serious injury or have major surgery
- have a history of repeated miscarriage.

Tell your doctor if you have just had an operation or if you are going to have an operation while taking Utovlan. Section 4 of this leaflet ('Possible side effects') also has more information on the warning signs of blood clots.

Other medicines and Utovlan

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes the following medicines, as the effect of Utovlan may be altered when they are taken at the same time:

- Medicines to treat epilepsy (e.g. phenytoin, carbamazepine)
- Antibiotic medicines to treat an infection (e.g. tetracyclines, rifampicin, co-trimoxazole)
- Antiviral medicines to treat HIV (e.g. ritonavir, nelfinavir)
- Anticancer medicines
- Herbal preparations containing St John's wort (*Hypericum perforatum*)
- Aminoglutethimide, sometimes used in Cushing's Syndrome.
- Ciclosporin (for suppressing the immune system)
- Non-steroidal anti-inflammatory drugs (NSAIDs) for treating pain and inflammation
- Medicines for high blood pressure.

Utovlan can also interfere with some laboratory tests, so tell your doctor if you are having any blood tests or hospital investigations.

Tell your doctor or pharmacist if you are taking any other medicines not listed above, including those bought without a prescription.

Pregnancy and breast-feeding

Pregnancy

Utovlan must not be taken if you are pregnant as hormonal medicines can affect the developing baby. It is important you use some form of contraception (e.g. a condom) while taking Utovlan, as it is not a contraceptive.

Breast-feeding

If you are breast-feeding, speak to your doctor before taking this medicine so they can advise whether you should use an alternative method of feeding your baby.

Driving and using machines

No effect on the ability to drive or use machinery has been seen with Utovlan.

Utovlan contains lactose

Lactose is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Utovlan

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

The number of tablets will depend on the condition you are being treated for. This information can also be found on the label on the box the tablets come in. The following information will help you see what the usual dose is for a particular problem.

Taking Utovlan for heavy bleeding and other period problems

You will usually take 1 tablet 3 times a day (15 mg) for 10 days. A few days after you stop taking the tablets you will usually have bleeding like a period. To stop your periods causing problems again, your doctor may tell you to take Utovlan for a few days after your next two periods. You will probably take 1 tablet twice a day (10 mg) for 8 days. You will need to start taking these tablets 19 days after your last period began.

Taking Utovlan for premenstrual tension - You will usually take one 5 mg tablet a day for 10 days, starting 16 days after your last period began.

Taking Utovlan for endometriosis - You will usually take 1 tablet 3 times (15 mg) a day for at least 6 months. If you have any irregular bleeding or spotting, your doctor may increase the dose to 4 or 5 tablets (20-25 mg) a day until this bleeding stops.

Taking Utovlan for breast cancer - You will usually take 8 tablets (40 mg) a day. Your doctor may increase this to 12 tablets (60 mg).

Taking Utovlan to delay your periods - You will usually take 1 tablet 3 times (15 mg) a day. You need to start taking the tablets 3 days before your period is due to start. Your period will usually start within 3 days of finishing the tablets.

If you do not have a period after you finish a course of Utovlan, check with your doctor in case you are pregnant.

If you take more Utovlan than you should

If you take too many tablets, contact your doctor straight away.

If you forget to take Utovlan

Take the tablet as soon as you remember, and carry on taking the tablets at the normal times. Do not take a double dose to make up for a forgotten dose.

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 for stopping Utovlan treatment immediately

Very rarely, Utovlan may cause a severe allergic reaction which can be life-threatening in some cases. You can get some or all of the following symptoms:

- wheezing
- difficulty breathing
- feeling faint
- swelling of the face or tongue
- swelling of the hands and feet
- intense itchy skin rash.

If you think you are reacting badly to the medicine, get emergency medical help **immediately**.

The following symptoms could be warning signs of thrombosis (a blood clot) which will need urgent treatment:

Symptoms of a blood clot in the lungs:

- Sudden, severe, sharp pain in your chest
- Coughing up blood
- You suddenly become short of breath
- Your heart beats more rapidly

Symptoms of a blood clot in the brain ('a stroke'):

- You have an unusually 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 feels weak or numb

Symptoms of a deep-vein thrombosis (DVT):

- You have severe pain, tenderness or swelling in your calf, ankle or foot
- You have purple discolouration of the skin of the leg or the skin becomes red and warm to touch

If you get any of these symptoms, you should **stop taking** the tablets and see your doctor **immediately**.

Reasons for seeking medical advice during treatment

It is important to see your doctor straightaway if you get:

- Yellowing of the skin or whites of the eyes (jaundice)
- Migraine headache for the very first time

Your doctor may also decide to stop treatment if your blood pressure gets too high.

Other side effects

You can also get the following side effects with medicines like Utovlan:

Effects on the reproductive system and breasts: bleeding and spotting between periods, lack of periods (amenorrhoea), unexpected or unusual vaginal bleeding, changes in discharge from the cervix, cervical erosions (this may be seen when you have a smear test), cycles where you don't ovulate (anovulation), breast pain and tenderness, a milky discharge from the breast when not pregnant or breastfeeding (galactorrhoea).

Effects on the nervous system: headache, depression, dizziness, fatigue, difficulty sleeping, confusion, nervousness, a feeling of intense happiness (euphoria), feeling sleepy, loss of concentration, vision problems.

Effects on the stomach and intestines: feeling or being sick, constipation, diarrhoea, dry mouth.

Effects on the liver: disturbed liver function, yellowing of the skin or whites of the eyes.

Effects on your metabolism: altered fat levels in the blood, alteration of blood sugar levels, increased levels of insulin between meals and existing diabetes getting worse, decreased tolerance to some sugars like glucose, adrenergic-like effects (e.g. fine hand tremors, sweating, cramps in the calves at night), effects on the adrenal glands (e.g. Cushingoid syndrome), cloudy vision, sugar in your urine.

Effects on your heart and circulation: blood clots, including clots in the lung, and swelling in the veins due to blood clots, stroke, heart attacks, congestive heart failure, increased blood pressure, feeling your

heartbeat, clots in the blood vessels of the retina (this causes visual problems), heart beating faster (tachycardia).

Effects on your skin and hair: acne, increase in body or facial hair, hair loss, itching, rash, hives.

Miscellaneous: fluid retention and swelling of hands and ankles, bloating, weight gain, raised temperature, change in appetite, changes in sex drive, fatigue, increase in calcium (seen in blood tests).

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Utovlan

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 blister strip after EXP. The expiry date refers to the last day of that month.

Do not store your tablets above 25°C, and keep your blister strips securely in the outer carton.

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

6. Contents of the pack and other information

What Utovlan contains

- The active substance is norethisterone 5 mg.
- The other ingredients are lactose monohydrate, maize starch, polyvidone and magnesium stearate.

What Utovlan looks like and contents of the pack

Utovlan tablets are white, flat, circular tablets inscribed 'SEARLE' on one side and 'U' on the other. They are available in packs of 30 and 90 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Pfizer Limited
Ramsgate Road
Sandwich, Kent
CT13 9NJ, UK

Manufacturer:

Piramal Healthcare UK Limited
Morpeth, Northumberland
NE61 3YA, UK

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

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