

Other side effects (not known, frequency cannot be estimated from the available data)

- **Stomach or gut problems:** heartburn; nausea, vomiting, constipation; diarrhoea; flatulence; indigestion; abdominal discomfort or pain.
- **Blood disorders:** changes to the number and types of blood cells causing illness such as anaemia or an increased risk of infections.
- **Mental illness:** difficulty sleeping (insomnia); abnormal dreams; depression; confusion; seeing, hearing or believing things which are not real (hallucinations).
- **Nervous system:** fits or seizures; dizziness; headache; light-headedness; drowsiness; pins and needles or numbness of your hands and feet; difficulty concentrating or forgetfulness.
- **Eyes and ears:** changes to your eyesight; eye pain; changes to your hearing including ringing in your ears (tinnitus) or loss of hearing; spinning sensation (vertigo).
- **Heart and circulation:** swelling of hands, feet or legs (oedema); fluttering feeling in your chest (palpitations); high blood pressure; problems with the way your heart pumps blood around the body or damage to blood vessels (signs include chest pain, tiredness, shortness of breath, feeling faint, general pain).
- **Chest:** difficulty breathing, wheezing or coughing; pneumonia or swelling of your lungs.
- **Urinary:** blood in your urine; kidney problems.
- **General:** thirst; fever; feeling generally tired or unwell; sore mouth or mouth ulcers; muscle pain or weakness; problems for women in getting pregnant; sweating; hair loss.

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 website: 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 Ultravana Period Pain Relief

Keep this medicine out of the sight and reach of children. Do not store above 25°C. Store in the original package.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month. 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 Ultravana Period Pain Relief tablets contain

- The active substance (the ingredient that makes the medicine work) is naproxen. Each tablet contains 250 mg of the active substance.
- The tablet is gastro-resistant, which means that it is covered with a coating which stops the tablet dissolving in the stomach, so that the naproxen is released further down in your gut.
- The other ingredients are methacrylic acid-ethylacrylate copolymer (1:1), lactose, magnesium stearate, maize starch, crospovidone, propylene glycol, sodium hydroxide, triethyl citrate, titanium dioxide (E171), potassium sorbate (E202), sodium citrate (E331), xanthan gum (E415), hydroxypropyl cellulose (E463), purified talc (E553), beeswax.

What Ultravana Period Pain Relief looks like and contents of the pack

Ultravana Period Pain Relief tablets are white, round, biconvex, enteric-coated tablets.

Pack size: 9 tablets.

Marketing Authorisation Holder

Accord Healthcare Limited, Sage House, 319 Pinner Road, North Harrow, Middlesex HA1 4HF, UK.

Manufacturer

Accord, Barnstaple EX32 8NS, UK.

Distributor

Maxwellia Ltd, Alderley Park, Alderley Edge SK10 4TG, UK.

Ultravana™ is a trade mark of Maxwellia Ltd. This leaflet was last revised in November 2023

Package leaflet: Information for the patient



250 mg Gastro-resistant tablets Naproxen

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.
- The full name of this medicine is Ultravana™ Period Pain Relief 250 mg Gastro-resistant tablets but within this leaflet it will be referred to as Ultravana Period Pain Relief.

What is in this leaflet

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

1. What Ultravana Period Pain Relief is and what it is used for

Naproxen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Ultravana Period Pain Relief is used to treat period pains (also called menstrual pain or dysmenorrhoea) in women aged 15 to 50 years old.

2. What you need to know before you take Ultravana Period Pain Relief

Do not take Ultravana Period Pain Relief but see a doctor instead if you:

- are **allergic to naproxen**, medicines containing **naproxen sodium** or to any of the other ingredients of this medicine (listed in section 6)
 - are **allergic to aspirin, ibuprofen or other non-steroidal anti-inflammatory medicines** (NSAIDs), or you have developed signs of asthma (wheezing), runny nose, swelling of the skin or rash when taking these medicines
 - have or have had **stomach or duodenal (gut) ulcers, bleeding in the stomach or intestines** (gastrointestinal bleeding) or have had **two or more** episodes of stomach ulcer, perforation or bleeding
 - have severe **heart failure, liver or kidney failure**
 - are in the **last three months of pregnancy**.
- If you are not sure about any of the above conditions, please ask your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ultravana Period Pain Relief if you:

- are on a **low potassium diet**, as this product contains potassium sorbate – high blood levels of potassium can cause stomach upset and diarrhoea
- have a history of **gastrointestinal disease**, e.g. ulcerative colitis, Crohn's disease
- are **elderly or frail, you have a higher risk of getting side effects**, especially of the stomach
 - if you experience any unusual symptoms from the stomach, you must tell your doctor about it
- have or have had **high blood pressure, a stroke or any heart, liver or kidney problems**
 - if you have kidney or liver problems you should only take Ultravana Period Pain Relief under the supervision of your doctor, for monitoring of your kidney or liver function
 - medicines such as naproxen may be associated with a small increased risk of **heart attack (myocardial infarction) or stroke**. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment

- have **asthma, diabetes, high cholesterol**
- are a **smoker**
- drink **alcohol**
- have **systemic lupus erythematosus** or other connective tissue disorders
- have Stevens-Johnson syndrome or toxic epidermal necrolysis (severe skin problems)
- have any **blood clotting** disorders
- first experienced **period pain** more than a year after starting your periods
- are a woman trying to **become pregnant** or undergoing investigation of **infertility** – naproxen belongs to a group of medicines which may impair fertility in women. This effect is reversible on stopping the medicine. It is unlikely that naproxen, used occasionally, will affect your chances of becoming pregnant, however, tell your doctor before taking this medicine if you have problems becoming pregnant

• Ultravana Period Pain Relief **may hide the symptoms of an infection.**

When taking Ultravana Period Pain Relief, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating physician.

Other medicines and Ultravana Period Pain Relief

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines obtained with or without a prescription. Especially:

- other non-steroidal anti-inflammatory drugs (NSAIDs), e.g. COX II inhibitors (used for pain and inflammation)
- aspirin/acetylsalicylic acid to prevent blood clots
- antacids (to treat heartburn)
- medicines to treat high blood pressure including angiotensin II receptor antagonists or ACE inhibitors, such as captopril, ramipril or propranolol
- diuretics ('water tablets'), such as furosemide
- cardiac glycosides (for heart failure), such as digoxin
- lithium (used for some mental health problems)
- methotrexate (to treat some cancers)
- ciclosporin, tacrolimus (to suppress the immune system)

- mifepristone (used for termination of pregnancy) – Ultravana Period Pain Relief should not be taken within 8-12 days of taking mifepristone
- corticosteroids (used in many different diseases), such as prednisolone
- medicines which thin the blood or prevent blood clotting, such as warfarin
- SSRI antidepressants (for depression), such as fluoxetine
- medicines used to treat Type 2 diabetes, such as sulphonylurea
- quinolone antibiotics (to treat bacterial infections), such as ciprofloxacin
- probenecid (used for gout)
- hydantoins (in epilepsy), such as phenytoin
- zidovudine (anti-viral)
- colestyramine (for high cholesterol) – take naproxen 1 hour before or 4 to 6 hours after colestyramine to avoid interference with absorption.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take Ultravana Period Pain Relief if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected.

You **should not** take Ultravana Period Pain Relief during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, naproxen can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Driving and using machines

Ultravana Period Pain Relief does not normally cause any effects, however you may experience drowsiness, dizziness, spinning sensation, difficulty in sleeping, disturbed vision or depression. If you are affected do not drive or operate machinery.

Ultravana Period Pain Relief contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Information on sodium content

This medicine contains less than 1mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Tests

If you need any blood or urine tests, tell your doctor you are taking Ultravana Period Pain Relief. The tablets may need to be stopped 48 hours before a test, as they may interfere with the results.

3. How to take Ultravana Period Pain Relief

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

Swallow **whole** with water, **with or after food. Do not crush or chew** the tablets.

You should make sure that you have enough to drink (stay well hydrated) when you are taking Ultravana Period Pain Relief. This is particularly important for people who have problems with their kidneys.

You should take the lowest effective dose for the shortest amount of time, to control your symptoms. This will reduce any side effects you may experience.

Women aged 15 to 50 years old

First day of treatment

Initially take two tablets (500mg) then if needed, one tablet (250mg) after 6-8 hours.

Second and third day of treatment

If needed, take one tablet (250mg) every 6-8 hours.

Do not take more than the **maximum** dose of **three tablets a day** for longer than **three days** during each month (menstrual cycle).

If you take more Ultravana Period Pain Relief than you should

It is important not to take too many tablets. Contact your doctor, pharmacist or nearest hospital casualty department **immediately** if you have taken more tablets than you should. Symptoms of an overdose are headache, heartburn, feeling or being sick, stomach pain or bleeding, diarrhoea, disorientation, excitation, drowsiness, dizziness, ringing in the ears, fainting.

If you forget to take Ultravana Period Pain Relief

If you forget to take a tablet, take your forgotten dose as soon as you remember, unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If any of the side effects get worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Serious side effects

Stop taking Ultravana Period Pain Relief and tell a doctor or pharmacist, or go to your nearest hospital casualty department immediately if you experience any of the following serious side effects (not known, frequency cannot be estimated from the available data).

- An **allergic reaction**: swelling of the face, mouth, tongue, airways or body; difficulty breathing or wheezing, coughing up blood; skin reactions including hives (pale/red raised skin with severe itching), itchy skin rash, blood spots, bruising or discolouring of the skin, raised purple rashes, red skin patches, bumpy rashes, blisters, dermatitis (skin shedding, itching, swelling).
- **Severe skin rash** with flushing, blisters or ulcers (Stevens-Johnson syndrome); a severe rash with reddening, peeling and swelling of the skin that resembles burns (toxic epidermal necrolysis); blistering of skin when exposed to sunlight (pseudoporphyria).
- **Heart attack or stroke.**
- **Serious stomach problems**: ulcer or inflammation in the stomach or gut (causing indigestion, heartburn, pains in your stomach, feeling or being sick); worsening of colitis and Crohn's disease (pain, diarrhoea, vomiting, weight loss); black tarry looking stools (signs of bleeding and perforation of the stomach and intestines); vomit any blood or dark particles that look like coffee grounds; pancreatitis (causing fever, stomach pain, sickness).
- Sudden shortness of breath, chest pain, nausea, these could be signs of **hyperkalaemia**.
- **Meningitis** (symptoms include a stiff neck, headache, feeling or being sick, fever, sensitivity to bright light and confusion).
- **Liver problems** including yellowing of the skin or whites of your eyes (**jaundice**); feeling tired, loss of appetite, feeling or being sick, pale coloured stools (**hepatitis** shown in blood tests).