Package leaflet: Information for the user

Feminax® Ultra 250 mg Gastro-resistant tablets
Naproxen (250 mg)

This leaflet contains important information about Feminax® Ultra 250 mg Gastro-resistant tablets (referred to as Feminax® Ultra from now on).
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 any further questions, ask your doctor or pharmacist.
- 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.

WHAT IS IN THIS LEAFLET

1. WHAT FEMINAX® ULTRA IS AND WHAT IT IS USED FOR

These tablets contain 250 mg of naproxen. This medicine is used to treat period pain (also called menstrual pain or dysmenorrhoea)
- Naproxen belongs to a group of painkillers called Non-Steroidal Anti-inflammatory Drugs (also called NSAIDs).
- Other medicines in this group include ibuprofen and aspirin.

Who should take Feminax® Ultra

Only take this medicine if you are between 15 and 50 years old.
Ask your doctor, pharmacist or nurse if you need more information.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FEMINAX® ULTRA

Do not take this medicine, if you:
- **have, or have ever had a stomach ulcer, or other serious stomach problems**
- This includes any stomach pain that does not go away and any bleeding in the stomach (passing blood or black tarry stools, or vomiting blood or dark particles that look like coffee grounds).
- If you have ever had anything like this then you should not take these tablets.

Do not take this medicine if you are in the last three months of your pregnancy.
Do not take this medicine if you have severe heart, liver or kidney failure.
Do not take this medicine if you are already taking aspirin, low dose aspirin or any other non-steroidal anti-inflammatory drug (NSAID) like Ibuprofen. This includes cyclo-oxygenase-2 selective inhibitors (COX2) like celecoxib.

Do not take this medicine if you have ever had an allergic reaction to:
- Naproxen, aspirin, ibuprofen, or another non-steroidal anti-inflammatory drug (NSAID).

- Anything else in these tablets (look at the list in the '**What FEMINAX® ULTRA contains**' section, at the end of the leaflet).

Allergic reactions can include wheezing, itchy runny nose, nasal polyps (swelling inside the nose), rashes or swelling of the skin.

Do not take this medicine unless your doctor said you can, if:
- You are breast feeding.
- You started to have period pain more than a year after your first period.
- You are elderly – you may get more side effects.
- You are taking any other painkillers or steroids.
- You have a connective tissue disorder such as SLE (Systemic Lupus Erythematosus).
- You have Stevens-Johnson syndrome or toxic epidermal necrolysis (severe skin problems).
- You are planning to become pregnant or if you have problems becoming pregnant.

Do not take this medicine, unless your doctor said you can, if you have these illnesses:
- Heart problems, previous stroke or think you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker).
- Kidney or liver problems.
- A blood clotting problem.
- Asthma or any allergic illness which makes it hard to breathe.
- Stomach disorders such as ulcerative colitis or Crohn's disease.

Medicines containing 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 (3 tablets a day) or duration of treatment (3 days).

Important information about some of the ingredients of this medicine
- This medicine 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.

Driving and using machines: These tablets may make you dizzy, sleepy or cause vertigo, loss of concentration, difficulty sleeping, depression or visual problems. Do not drive or use machines if this happens to you.

Other medicines and FEMINAX® ULTRA:
Tell your doctor or pharmacist if you are taking, or have recently taken or might take any other medicines, including medicines obtained without a prescription. Especially if you are taking
- Ciclosporin or tacrolimus - medicines used after organ transplants
- Steroids (also called corticosteroids) - like prednisolone
- Quinolone antibiotics (ciprofloxacin, norfloxacin or levofloxacin) or sulphonamides (like co-trimoxazole)
- Painkillers
- Colestyramine – medicine to reduce blood fat level
- Antacids – medicines to treat the symptoms of heartburn
- Lithium – a medicine for depression
- Methotrexate – a medicine for cancer and other illnesses
- Probenecid – a medicine for gout
- Water tablets (diuretics)
- Medicines for high blood pressure (anti-hypertensives)
- Medicines for your heart (digoxin or glycosides)
- Medicines to stop blood clots (anticoagulants such as warfarin or heparin)
- Phenytoin - a medicine for epilepsy

- Mifepristone to terminate a pregnancy in the last 8 - 12 days
- Antidepressants of the serotonin re-uptake inhibitor (SSRI) type like fluoxetine
- Medicines to treat Type 2 diabetes (e.g. sulphonylurea)
- Zidovudine (for HIV infection)
- Aspirin/ acetylsalicylic acid to prevent blood clots.

3. HOW TO TAKE FEMINAX® ULTRA

First day:
- When the pain starts, take **two** tablets.
- Then after 6 to 8 hours, take **one** more tablet that day, if you need it.

Second day:
- Take **one** tablet every 6 to 8 hours if needed.

Third day:
- Take **one** tablet every 6 to 8 hours if needed.

Do not take more than 3 tablets each day. Always take the lowest effective dose for you. Do not take more than the recommended dose of up to three tablets in a day. Do not take for longer than three days in any one month (menstrual cycle).

Taking the tablets:
- Swallow the tablets whole with a drink of water. Do not chew or crush them.
- **Take the tablets with or after food.**
- Only take the tablets for as long as you need them for the period pain. You may not need to take the tablets all the time for all 3 days. If you still have pain after 3 days of treatment, talk to your doctor. Do not take the tablets for more than 3 days in any one period (cycle).
- If you see a doctor, pharmacist or nurse or go into hospital, tell them you are taking this medicine.
- Overdose: If you (or someone else) takes too many tablets, go to the nearest hospital casualty department or your doctor straight away.

4. POSSIBLE SIDE EFFECTS

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

If any of the following happen to you, stop taking the tablets and tell a doctor, pharmacist or nurse <u>immediately</u>:
- Sickness or being sick (possibly with blood), diarrhoea (sometimes with blood and mucus), dark "tarry" stools.
- Stomach pain, indigestion, stomach ulcers and bleeding in the stomach.
- Worsening of stomach problems (ulcerative colitis or Crohn's disease).
- Sore mouth or unusual painful mouth ulcers.
- Allergic reactions like asthma, wheezing or difficulty breathing. This may be severe.
- Blood in the urine, more or less urine than normal or cloudy urine. Pain around the kidneys (lower side of your back).
- Severe blisters and bleeding of the skin, nose and mouth (Stevens-Johnson syndrome)
- Skin problems including rashes, itching, nettle rash or a bruise-like rash. There may also be blistering and flaking of the skin.

- Swelling of the face, lips, tongue and throat (causing difficulty swallowing or breathing).
- Jaundice (yellowing of the skin or whites of the eyes), and/or pale coloured stools and dark urine.
- Fits (convulsions), altered vision, pins-and-needles or numbness, confusion, hallucinations, dizziness and vertigo, hearing problems, ringing in the ears.

If you have any of the following while taking this medicine, stop taking it and tell your doctor:
- Swelling of the blood vessels and a build up of fluid which may cause swollen ankles.
- Kidney or liver problems: these will show up in blood or water tests.
- Nervous system: headaches, depression, insomnia, tiredness, muscle weakness, drowsiness, inability to concentrate, mental slowing, forgetfulness, abnormal dreams, feeling thirsty, a general feeling of being unwell or fever with a dislike of light.
- Blood problems – these may cause unusual tiredness or weakness, unusual bleeding or unexplained bruising, fever or chills, sore throat, ulcers in your throat.
- Sensitivity of the skin to light.
- Hair loss (alopecia).
- Heartburn, Flatulence or constipation.

Other side effects
- High blood pressure, a fluttering feeling in your heart and heart failure have been reported with NSAID use.
- Medicines which contain NSAIDs such as naproxen may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.
- NSAIDs have been associated with aseptic meningitis which can include symptoms of headache, stiff neck, disorientation, fever and sensitivity to light in people with auto-immune disorders.
- May cause female infertility.
- Raised level of potassium in your blood (hyperkalaemia).
- Eosinophilic pneumonitis (lung infection which causes difficulty in breathing and night sweats).
- Problems with your senses such as vision problems, inflammation of the optic nerve.

If you experience any other symptoms or have concerns about your medicine, talk to your doctor.

Adrenal function tests: The tablets may interfere with these tests – check with your doctor before the test.

Reporting of side effects
If you get any side effects, talk to your doctor 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 FEMINAX® ULTRA

- 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. The expiry date refers to the last day of that month.
- Keep these tablets in their original packaging and do not store above 25ºC
- This medicine is for you ONLY, do not give it to anyone else

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 FEMINAX® ULTRA contains

- The active substance is naproxen.
- The other ingredients are lactose monohydrate, maize starch, polyvidone, sodium starch glycolate and magnesium stearate. Also, the coating contains colloidal silicon dioxide, polyvinyl acetate phthalate, polyethylene glycol, stearic acid, hydroxypropyl methylcellulose, sodium alginate, sodium bicarbonate, purified talc, triethyl citrate, the colour titanium dioxide (E171), antifoam AF emulsion and printing ink (containing shellac, black iron oxide (E172), propylene glycol (E1520)).

What FEMINAX® ULTRA looks like and contents of the pack

The tablets are white, round, biconvex, gastro-resistant tablets and are overprinted in black with '3N3'. The tablets come in a box of 9 tablets. The tablet is gastro-resistant This 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.

Marketing Authorisation Holder and Manufacturer
Marketing authorisation holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacture

TEVA UK Limited, Eastbourne, BN22 9AG, England.

Distributed by: Bayer plc, 400 South Oak Way, Reading RG2 6AD, UK.

REMEMBER

This leaflet does not contain all the information about these tablets.
Please ask your doctor, nurse or pharmacist if you have any questions.
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Contact details:
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