

Package Leaflet: Information for the patient

Naprosyn® EC 250mg Gastro-resistant Tablet Naprosyn® EC 500mg Gastro-resistant Tablet Naproxen

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

1. What Naprosyn EC is and what it is used for

Naprosyn EC contains a medicine called naproxen. This is a 'Non Steroidal Anti Inflammatory Drug' or NSAID.

Naprosyn EC can lessen pain, swelling, redness and heat (inflammation) and is used to:

- relieve problems with your muscles, joints and tendons, e.g. strains, back pain, ankylosing spondylitis (pain and stiffness in the neck and back), gout, rheumatoid arthritis or osteoarthritis.
- relieve period pain in women.

Naprosyn EC tablets are used to treat adults and adolescents (16 years and above).

2. What you need to know before you take Naprosyn EC

Do not take Naprosyn EC if you are allergic (hypersensitive) to:

- Naproxen, naproxen sodium or any of the other ingredients of Naprosyn EC (listed in section 6).
- Aspirin, other NSAIDs or any other pain relief medicines (such as ibuprofen or diclofenac).

Do not take Naprosyn EC if:

- you have now or have ever had any problems with your stomach or gut (intestine) e.g. an ulcer or bleeding.
- you have previously experienced bleeding or perforation in your stomach while taking NSAIDs.
- you have **severe** problems with your kidneys, liver or heart.
- you are in the last three months of pregnancy.

Do not take Naprosyn EC if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Naprosyn EC.

Warnings and precautions

Severe skin reactions have been reported with the use of NSAIDs appearing as reddish spots, generalised skin redness, ulcers or widespread rash accompanied by flu-like symptoms, including fever (see section 4). The rash may progress to widespread blistering or peeling of the skin. The highest risk for occurrence of serious skin reactions is

within the first month of treatment, (see section 4). If you have developed any of the serious skin reactions with the use of Naprosyn EC you must not be re-started on Naprosyn EC at any time. If you develop a rash or these skin symptoms, stop using Naprosyn EC and contact your doctor or seek immediate medical attention.

Medicines such as Naprosyn EC may be associated (linked) with a small increased risk of heart attack ('myocardial infarction') or stroke. Any risk is more likely with higher doses and prolonged (longer term) treatment.

Do not exceed (take more than) the recommended dose or duration (length) of treatment.

Talk to your doctor or pharmacist before taking Naprosyn EC if:

- you have heart problems, had a previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker).
- you are an older person as you have a higher risk of getting side effects when taking NSAIDs particularly stomach ulcers or bleeding which may be fatal.
- you have or had a history of a stomach ulcer, stomach bleeding or other stomach problems.
- you have asthma or allergies (like hay fever) or have had swelling of the face, lips, eyes or tongue in the past.
- you have a feeling of weakness (perhaps because of an illness).
- you have or had in the past lumps in your nose (polyps) or you sneeze a lot or have a runny, blocked, or itchy nose (rhinitis).
- you have problems with your kidneys. The signs include feeling tired, bruising easily and passing water (urinating) less often.
- you have problems with your liver such as jaundice (yellowing of your skin or the whites of your eyes) or hepatitis (feeling tired, loss of appetite, feeling or being sick and pale coloured stools).
- you have problems with the way that your blood clots.
- you have problems with the blood vessels (arteries) anywhere in your body.
- you have too much fat (lipid) in your blood (hyperlipidaemia).
- you have an autoimmune condition, such as 'systemic lupus erythematosus' (SLE, causes joint pain, skin rashes and fever) and ulcerative colitis or Crohn's disease (conditions causing inflammation of the bowel, bowel pain, diarrhoea, vomiting and weight loss).

If any of the above apply to you, or if you are not sure, talk to your doctor or pharmacist before you take Naprosyn EC.

Children and adolescents

Naprosyn EC is not for use in children under 16 years of age.

Taking other medicines and Naprosyn EC

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is important, as using more than one medicine at the same time can strengthen or weaken the effect of the medicines. Therefore tell your doctor or pharmacist if you are taking any of the following medicines before you take Naprosyn EC:

- Other pain killers, e.g., aspirin, ibuprofen, diclofenac and paracetamol.
- Medicine to stop your blood clotting, e.g., aspirin/ acetylsalicylic acid, warfarin, heparin or clopidogrel.
- A hydantoin (for epilepsy), e.g., phenytoin.
- Sulfonamide medicines, e.g., hydrochlorothiazide, acetazolamide, indapamide and including sulfonamide antibiotics (for infections).
- A sulfonylurea (for diabetes), e.g., glimepiride or glipizide.
- An 'ACE inhibitor' or any other medicine for high blood pressure e.g., cilazapril, enalapril or propranolol.
- An angiotensin-II receptor antagonist, e.g., candesartan, eprosartan or losartan.
- A diuretic (water tablet) (for high blood pressure), e.g., furosemide.

- A ‘cardiac glycoside’ (for heart problems), e.g., digoxin.
- A steroid (for swelling and inflammation), e.g., hydrocortisone, prednisolone and dexamethasone.
- A ‘quinolone antibiotic’ (for infections), e.g., ciprofloxacin or moxifloxacin.
- Certain medicines for mental health problems e.g., lithium or ‘SSRIs’ e.g., fluoxetine or citalopram.
- Probenecid (for gout).
- Methotrexate (used to treat skin problems, arthritis or cancer).
- Ciclosporin (for skin problems or after an organ transplant).
- Zidovudine (used to treat AIDS and HIV infections).
- Mifepristone.

If you need to have a blood or urine test tell your doctor you are taking Naprosyn EC. You may need to stop taking the tablets for a short time before the tests as they may affect the results.

Pregnancy, breast-feeding and fertility

- Do not take Naprosyn EC if you are in the last three 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 Naprosyn EC 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, Naprosyn EC 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.
- If you are pregnant or are breast-feeding, think you may be pregnant, or are planning to have a baby ask your doctor for advice before taking this medicine. Your doctor will decide if you should take Naprosyn EC.
- Naprosyn EC may make it more difficult to become pregnant. You should tell your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

Naprosyn EC may make you tired, drowsy, dizzy, have problems with your balance, depressed or have difficulty sleeping. Talk to your doctor if any of these happen to you and do not drive or use any tools or machines.

3. How to take Naprosyn EC

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

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

While you are taking Naprosyn EC your doctor will want to see you to check you are on the right dose for you and look for any side effects. This is particularly important if you are an older person.

Use in children and adolescents

Naprosyn EC is not for use in children under 16 years of age.

Adults

Muscle, joint or tendon problems and period pain

- The usual starting dose is 500 mg, followed by a 250 mg tablet every 6 to 8 hours as needed. Up to a maximum of 1250 mg a day may be given after the first day.

Arthritis and ankylosing spondylitis

- The usual dose is 500 mg to 1000 mg. The dose can be split and taken at 12 hour intervals.
- The 1000 mg dose can also be taken all at once morning or evening.

Gout

- The usual starting dose is 750 mg, followed by 250 mg every 8 hours until the attack has passed.

Older people and people with liver and kidney problems

Your doctor will decide your dose, it will usually be lower than that for other adults.

If you take more Naprosyn EC than you should

If you take more Naprosyn EC than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Naprosyn EC

- If you forget to take a dose, skip the missed dose. Then take your next dose as normal.
- 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.

Medicines such as Naprosyn EC may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke.

If you are older you have a higher risk of getting side effects when taking NSAIDs particularly stomach ulcers or bleeding which may be fatal.

Important side effects to look out for:

Stop taking Naprosyn EC and tell a doctor straight away if any of the following side effects happen. You may need urgent medical treatment:

Serious stomach or gut problems, signs include:

- Bleeding from the stomach, seen as vomit which has blood in it, or bits that look like coffee grounds.
- Bleeding from your back passage (anus), seen as passing black sticky bowel motions (stools) or bloody diarrhoea.
- Ulcers or holes forming in your stomach or gut. Signs include upset stomach, stomach pain, fever, feeling or being sick.
- Problems with your pancreas. Signs include severe stomach pain which spreads to your back.
- Worsening of ulcerative colitis or Crohn's disease, seen as pain, diarrhoea, vomiting and weight loss.
- Narrowing and/or blockage of the gut. Signs include swollen abdomen, stomach pain and vomiting.

Allergic reactions, signs include:

- Sudden swelling of your throat, face, hands or feet.
- Difficulty breathing, tightness in your chest.
- Skin rashes, blisters or itching.

Severe skin reaction, signs include:

- A severe rash that develops quickly, with blisters or peeling of your skin and possibly blisters in your mouth, throat or eyes. Fever, headache, cough and aching body may happen at the same time.
- Skin blistering when exposed to sunlight (porphyria cutanea tarda) seen most on arms face and hands.
- A distinctive cutaneous allergic reaction known as fixed drug eruption, that usually recurs at the same site(s) on re-exposure to the medication and may look like round or oval patches of redness and swelling of the skin, blistering (hives), itching
- Widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged

lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS). See also section 2.

Liver problems, signs include:

- Yellowing of your skin or the whites of your eyes (jaundice).
- Feeling tired, loss of appetite, feeling or being sick and pale coloured stools (inflammation of the liver (hepatitis) which can be fatal).
- Changes in how well your liver is working (shown by blood tests).

Heart attack, signs include:

- Chest pain which may spread to your neck and shoulders and down your left arm.

Stroke, signs include:

- Muscle weakness and numbness. This may only be on one side of your body.
- A suddenly altered sense of smell, taste, hearing or vision, confusion.

Meningitis, signs include:

- Fever, feeling or being sick, a stiff neck, headache, sensitivity to bright light and confusion (most likely in people with autoimmune conditions such as 'systemic lupus erythematosus').

If you notice any of the serious side effects mentioned above, stop taking Naprosyn EC and tell your doctor straight away.

Other possible side effects:

Stomach and gut

- Heartburn, indigestion, stomach ache, feeling sick or being sick, constipation, diarrhoea, wind.

Blood

- Blood problems, like anaemia or changes to the numbers of white blood cells.
- A severe reduction in the number of white blood cells which makes infections more likely (agranulocytosis).

Mental illness

- Having difficulty sleeping or changes in your patterns of dreaming.
- Depression.

Nervous system

- Headache.
- Fits or seizures, feeling dizzy or light-headed or sleepy.
- Pins and needles or numbness of your hands and feet.
- Difficulty with your memory or concentration.

Eyes and ears

- Changes to your eyesight, eye pain.
- Changes to your hearing, including ringing in the ears (tinnitus) and hearing loss.
- Dizziness that causes problems with your balance.

Heart and circulation

- Swelling of your hands, feet or legs (oedema). This may be with chest pains, tiredness, shortness of breath (cardiac failure).
- A fluttering feeling in your heart (palpitations), slow heart beat or high blood pressure.
- Problems with the way your heart pumps blood around the body or damage to your blood vessels. Signs may include tiredness, shortness of breath, feeling faint, general pain.

Chest

- Difficulty breathing, including shortness of breath, wheezing or coughing.
- Pneumonia or swelling of your lungs.

Skin and hair

- Skin rashes including redness, hives, pimples and blisters on your body and face.
- Bruising, itching, sweating, skin being more sensitive to the sun or hair loss.

Kidney and urinary

- Blood in your water (urine) or kidney problems.
- Decrease/increase in the amount of water you pass.
- Protein in your water (shown in tests).

Other

- Thirst, fever, feeling tired or generally unwell.
- A sore mouth or mouth ulcers.
- Muscle pain or weakness.
- Problems for women in getting pregnant.
- 'Systemic lupus erythematosus' (SLE). Signs include fever, rash, problems with your kidneys and joint pain.
- High levels of potassium in the blood (hyperkalaemia), shown in blood tests. Signs include feeling sick, feeling tired, irregular heartbeat, a slow or weak pulse.

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

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Naprosyn EC

- Keep this medicine out of the sight and reach of children.
- Do not use Naprosyn EC after the expiry date which is printed on the blisters and outer carton after EXP. The expiry date refers to the last day of that month.
- Store in original package to protect from light. Store below 30 °C.
- 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 to protect the environment.

6. Contents of the pack and other information

What Naprosyn EC contains

The active substance in Naprosyn EC 250 mg and 500 mg Tablets is naproxen. Each tablet contains either 250 mg (milligrams) or 500 mg of naproxen. The other ingredients in the tablets are:

Tablet Core: povidone, magnesium stearate, croscarmellose sodium.

Tablet Coating: methacrylic acid copolymer, purified talc, sodium hydroxide, triethyl citrate.

Printing ink: iron oxide black, shellac and propylene glycol.

What Naprosyn EC looks like and contents of the pack

- Naprosyn EC 250 mg Tablets are round, white and marked with NPR EC 250 on one side.
- Naprosyn EC 500 mg Tablets are capsule shaped, white and marked with NPR EC 500 on one side.

Naprosyn EC Tablets are supplied in blister packs containing 56 tablets.

Marketing Authorisation Holder

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