

Package leaflet: Information for the patient

Naprosyn® EC 250 mg, 375 mg and 500 mg Gastro-Resistant Tablets 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. See section 4.

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 treat adults for:

- Problems with your muscles, joints and tendons, like strains, back pain, ankylosing spondylitis (pain and stiffness in the neck and back) or arthritis.
- Women, while having period pain.

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) like 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

If you have heart problems, 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 should discuss your treatment with your doctor or pharmacist.

Talk to your doctor or pharmacist before taking Naprosyn EC if any of the following apply to you:

- Asthma or allergies (like hayfever) or have had swelling of the face, lips, eyes or tongue in the past.
- A feeling of weakness (perhaps because of an illness) or you are an older person.
- Lumps in your nose (polyps) or you sneeze a lot or have a runny, blocked, or itchy nose (rhinitis).
- Problems with your kidneys or liver.
- Problems with the way that your blood clots.
- Problems with the blood vessels (arteries) anywhere in your body.
- Too much fat (lipid) in your blood (hyperlipidaemia).
- 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 recommended for use in children under 16 years of age.

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.

In particular, tell your doctor or pharmacist if you are taking:

- Other pain killers, like aspirin, ibuprofen, diclofenac and paracetamol.
- Medicine to stop your blood clotting, like aspirin/ acetylsalicylic acid, warfarin, heparin or clopidogrel.
- A hydantoin (for epilepsy), like phenytoin.
- Sulfonamide medicines, like hydrochlorothiazide, acetazolamide, indapamide and including sulfonamide antibiotics (for infections).
- A sulfonylurea (for diabetes), like glimepiride or glipizide.
- An ‘ACE inhibitor’ or any other medicine for high blood pressure like cilazapril, enalapril or propranolol.
- An angiotensin-II receptor antagonist, like candesartan, eprosartan or losartan.
- A diuretic (water tablet) (for high blood pressure), like furosemide.
- A ‘cardiac glycoside’ (for heart problems), like digoxin.
- A steroid (for swelling and inflammation), like hydrocortisone, prednisolone and dexamethasone.
- A ‘quinolone antibiotic’ (for infections), like ciprofloxacin or moxifloxacin.
- Certain medicines for mental health problems like lithium or ‘SSRIs’ like fluoxetine or citalopram.
- Probenecid (for gout).
- Methotrexate (used to treat skin problems, arthritis or cancer).
- Ciclosporin or tacrolimus (for skin problems or after an organ transplant).
- Zidovudine (used to treat AIDS and HIV infections).
- Mifepristone (used to end pregnancy or to bring on labour if the baby has died).

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.

Pregnancy, breast-feeding and fertility

- 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.
- Do not take Naprosyn EC after 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.
- 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.
- 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 eyesight and 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.

The recommended dose is:

Adults

Muscle, joint or tendon problems and period pain

- The usual starting dose is 500 mg, followed by 250 mg tablet every 6 to 8 hours as needed.

Arthritis and ankylosing spondylitis

- The usual dose is between 500 mg and 1000 mg.
- The dose can be taken all at once, or split in two and taken twice a day.

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.

Use in children and adolescents

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

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.**

Check with your doctor if you are not sure.

Swallow the tablets whole with a little 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 Naprosyn EC. This is particularly important for people who have problems with their kidneys.

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 elderly.

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.

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.

Allergic reactions, signs include:

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

Severe skin rashes, signs include:

- A severe rash 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.

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 (hepatitis) and problems (including hepatitis), shown in blood tests.
- Liver enzyme elevations.

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.
- Blood abnormalities (eosinophilia).

Mental illness

- Having difficulty sleeping or changes in your patterns of dreaming.
- Depression.
- Confusion or seeing and possibly hearing things that are not there (hallucinations).

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.

Urinary

- Blood in your water (urine) or kidney problems.

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 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 Naprosyn EC

- Keep this medicine out of the sight and reach of children.
- Store in original package in order to protect from light. Store below 30°C.
- Do not use Naprosyn EC after the expiry date printed on the pack. The expiry date refers to the last day of that month.
- Do not throw 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 Naprosyn EC contains

The active substance in Naprosyn EC 250 mg, 375 mg and 500 mg Tablets is naproxen. Each tablet contains either 250 mg (milligrams), 375 mg or 500 mg of naproxen.

The other ingredients in the tablets are povidone, magnesium stearate, water, croscarmellose sodium, methacrylic acid – ethyl acrylate copolymer, purified talc, sodium hydroxide, triethyl citrate, 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 375 mg Tablets are oval, white and marked with NPR EC 375 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

Atnahs Pharma UK Limited
Sovereign House, Miles Gray Road,
Basildon, Essex SS14 3FR
United Kingdom.

Manufacturer

Recipharm Leganés S.L.U.
C/Severo Ochoa, 13
Poligono Industrial de Leganes
28914 Madrid

Spain

Misom Labs Ltd.
Malta Life Sciences Park
LS2.01.06 Industrial Estate
San Gwann, SGN 3000
Malta

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