Patient Information Leaflet **UK**

Naprosyn® EC 250 mg, 375 mg and 500 mg Gastro-Resistant Tablets **Roche**
Naproxen

Please read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If any of the side effects become serious or troublesome, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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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 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. 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 (see 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.

Take special care with Naprosyn EC
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.

Check with 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 elderly.
- 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.

Taking other medicines
Tell your doctor or pharmacist if you are taking or have recently taken 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 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 and breast-feeding
- Do not take Naprosyn EC if you are in the last three months of pregnancy, as it can harm your baby.
- Talk to your doctor before taking Naprosyn EC if you are up to six months pregnant, think you are pregnant, plan to get pregnant or are breast-feeding. 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 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

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.

Children
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 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.

The elderly 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 Naprosyn EC can cause side effects, although not everyone will get 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.

Severe skin rashes, 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.

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.

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.

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.

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.

5. How to store Naprosyn EC

- Naprosyn EC tablets should be kept in their original packaging to protect them from light. Store below 30 ºC.
- They do not need any special storage conditions.
- Keep out of the reach and sight of children.
- Do not use Naprosyn EC after the expiry date printed on the pack.
- Return any left over tablets to your pharmacist to be disposed of carefully. Only keep them if your doctor tells you to.

6. Further 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. 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.

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