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PACKAGE LEAFLET: INFORMATION FOR THE USER

Naproxen Tablets BP 250 mg
Naproxen Tablets BP 500 mg

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 side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Naproxen Tablets are and what they are used for
2. What you need to know before you take Naproxen Tablets
3. How to take Naproxen Tablets
4. Possible side effects
5. How to store Naproxen Tablets
6. Contents of the pack and other information

1. What Naproxen Tablets are and what they are used for

Naproxen Tablets contain a medicine called naproxen. This is a ‘Non Steroidal Anti Inflammatory Drug’ or NSAID.

Naproxen Tablets can lessen pain, swelling, redness and heat (inflammation) and is used to treat adults for:

- Problems with your muscles, joints and tendons, like strains, gout, ankylosing spondylitis (pain and stiffness in the neck and back) or arthritis.
- Women, while having period pain. It can also be used in children over 5 years with rheumatoid arthritis.

2. What you need to know before you take Naproxen Tablets

DO NOT take Naproxen Tablets

- if you are **allergic** (hypersensitive) to naproxen or any of the other ingredients of Naproxen Tablets (listed in section 6)
- if you are allergic to or have ever had a reaction to **aspirin**, other NSAIDs or any other pain relief medicines (non-steroidal anti-inflammatory drug) such as ibuprofen, diclofenac or meloxicam
- if you have a stomach ulcer or if you often get stomach ulcers
- if you have a duodenal ulcer (in the first part of the small intestine) or if you often get duodenal ulcers
- if you have serious liver, kidney or heart disease
- if you are suffering or have ever suffered from bleeding in the stomach or intestines while taking NSAIDs
- if you are in the last three months of pregnancy or if you are breast-feeding (see section 2 “**Pregnancy and breast-feeding**”)
- if you have severe heart failure.

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

Warnings and precautions:

Talk to your doctor or pharmacist before taking Naproxen Tablets if you:

- have heart problems, have previously had a 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)
- have problems with how your blood clots
- have ever had 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 the blood vessels (arteries) anywhere in your body. suffer from localised swelling, high blood pressure or heart failure
- have too much fat (lipid) in your blood (hyperlipidaemia)
- have problems with your kidneys or liver
- have an autoimmune condition, such as ‘systemic lupus erythematosus’ that causes joint pain, skin rashes and fever
- have colitis or Crohn’s disease, the symptoms are inflammation of the bowel, bowel pain, diarrhoea, vomiting and weight loss.

If you are **elderly** you may have an increased risk of side effects. Tell your doctor **immediately** if you suffer with any unusual symptoms of the stomach or bowel.

If any of the above applies to you, or if you are not sure, talk to your doctor or pharmacist before you take Naproxen Tablets.

Serious skin reactions including (Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS)) have been reported in association with Naproxen Tablets. Stop using Naproxen Tablets and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Other medicines and Naproxen Tablets

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
- medicines that prevent blood clotting such as aspirin/ acetylsalicylic acid, warfarin, heparin, clopidogrel or ticlopidine.
- diuretics (water tablets) such as furosemide
- medicines to treat high blood pressure such as propranolol, enalapril, cilazapril
- a ‘cardiac glycoside’ used to treat heart problems, such as digoxin

- a steroid used to treat swelling and inflammation, like hydrocortisone, prednisolone and dexamethasone
- probenecid, a medicine to treat gout
- certain medicines used to treat mental illness, such as lithium or ‘SSRIs’ like fluoxetine or citalopram
- medicines used to treat epilepsy, such as phenytoin and hydantoin
- An ‘ACE inhibitor’ or any other medicine for high blood pressure like cilazapril, enalapril or propranolol.
- sulfonamide medicines, like hydrochlorothiazide, acetazolamide, indapamide and sulfonamide antibiotics used to treat infections
- a ‘quinolone antibiotic’ used to treat infections, such as ciprofloxacin or moxifloxacin
- A sulfonylurea (for diabetes), like glimepiride or glipizide
- An angiotensin-II receptor antagonist, like candesartan, eprosartan or losartan.
- ciclosporin or tacrolimus, medicines used to prevent transplant rejection after surgery
- methotrexate, a medicine used to treat skin conditions, rheumatoid arthritis and cancer
- colestyramine, a medicine used to reduce cholesterol
- zidovudine, a medicine used to treat AIDS and HIV infections
- mifepristone, a medicine 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 Naproxen Tablets. Please note that the above medicines may be known to you by other names, often the brand names. In this section only the active ingredient or therapeutic group of the medicine is given, and not the brand name. Always thoroughly check the pack and information leaflet of the medicines you are already using for the active ingredient or therapeutic group of that medicine.

It may still be all right for you to take Naproxen tablets and your doctor will be able to decide what is suitable for you.

Pregnancy, breast-feeding and fertility

Do not take naproxen 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 naproxen 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.

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.

Naproxen 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

Naproxen 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.

Naproxen Tablets contain 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.

Naproxen Tablets contain sodium

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

3. How to take Naproxen Tablets

Always take Naproxen Tablets exactly as your doctor has told you. Medicines such as Naproxen Tablets may be 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 take more than the recommended dose or exceed the duration (length) of the treatment.** Check with your doctor or pharmacist if you are not sure.

Method of administration:

Naproxen Tablets should be swallowed whole with a glass of water, with or after food. Take your tablets at the same time each day.

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

While you are taking Naproxen Tablets 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.

The recommended doses are:

Adults Muscle, joint or tendon problems and period pain

The usual starting dose is 500 mg, followed by one 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 half the dose may be taken twice a day.

Gout

The usual starting dose is 750 mg, followed by one 250 mg tablet every 8 hours as needed.

Elderly and patients with liver and kidney problems

The doctor will decide the right dose for you, it will usually be lower than for other adults.

Children over 5 years, rheumatoid arthritis

The usual dose is 10 mg per kilogram of body weight each day. The total daily dose is split into two doses, to be given 12 hours apart.

If you take more Naproxen Tablets than you should

If you take too many Naproxen Tablets, talk to your doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Naproxen Tablets

If you have missed a dose, continue in accordance with your doctor's prescription. Never take a double dose of Naproxen Tablets to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Naproxen Tablets can cause side effects, although not everybody gets them. Medicines such as Naproxen may be associated with a small increased risk of heart attack ('myocardial infarction') or stroke.

Important side effects to look out for (Serious side effects): Stop taking Naproxen and tell your doctor straight away if any of the following side effects happen. You may need urgent medical treatment:

Allergic reactions, signs include:

- sudden swelling of your throat, face, hands or feet
- difficulty breathing, tightness in your chest
- skin, rashes, blisters or itching.

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, seen as upset stomach, stomach pain, fever, feeling or being sick
- problems with your pancreas, seen as severe stomach pain which spreads to your back
- worsening of ulcerative colitis or Crohn's disease, seen as pain, diarrhoea, vomiting and weight loss.

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
- blistering of skin 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.
- Not known: frequency cannot be estimated from the available data
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 (hepatitis) and problems, 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, which may only be on one side of your body
- a sudden altered sense of smell, taste, hearing, vision or 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 Naproxen and tell your doctor straight away.

Other possible side effects:

- heartburn, indigestion, constipation, stomach ache, feeling sick or being sick, gaseous bowels
- blood problems, like anaemia or changes to the numbers of white blood cells
- high levels of blood potassium which can cause abnormal heart rhythm
- difficulty sleeping or changes in your patterns of dreaming
- depression
- confusion or seeing and possibly hearing things that are not there (hallucinations)
- headache
- fits or seizures, feeling dizzy, light-headed or sleepy
- pins and needles or numbness of your hands and feet
- difficulty with your memory or concentration
- 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
- 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.
- Difficulty breathing, including shortness of breath, wheezing or coughing.
- pneumonia or swelling of your lungs
- bruising, itching, sweating, skin being more sensitive to the sun or hair loss
- blood in your urine or kidney problems
- 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.

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 the side effects you can help provide more information on the safety of this medicine

5. How to store Naproxen Tablets

Keep this medicine out of the sight and reach of children

Do not use Naproxen Tablets after the expiry date, which is stated on the carton after EXP. The expiry date refers to the last date of that month.

Store in a dry place below 25°C. Protect from light. Keep container tightly closed.

Do not use Naproxen Tablets if you notice any visible signs of deterioration.

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 Naproxen Tablets contain

- The active substance in Naproxen 250 mg and Naproxen 500 mg Tablets is naproxen. Each Naproxen 250 mg tablet contains 250 mg (milligrams) of naproxen. Each Naproxen 500 mg tablet contains 500 mg (milligrams) of naproxen.
- The other ingredients are lactose, maize starch, povidone (E1201), sodium starch glycollate, magnesium stearate (E470b) and quinoline yellow (E104).

What Naproxen Tablets look like and contents of the pack

Naproxen Tablets BP 250 mg are yellow coloured, round shaped, flat bevelled edge uncoated tablets with score line between 'NPY' and '250' embossed on one side and plain on the other side.

Naproxen Tablets BP 500 mg are yellow coloured, capsule shaped uncoated tablets with score line between 'NPY' and '500' embossed on one side and plain on the other side.

Naproxen Tablets are available in packs of 28, 30, 56, 60, 84, 100, 250, 500 and 1000 tablets.

Not all pack sizes may be marketed.

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