PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Naproxen EC Tablets 250 mg and 500 mg
Naproxen

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

In this leaflet:

1. What Naproxen is and what it is used for
2. Before you take Naproxen
3. How to take Naproxen
4. Possible side effects
5. How to store Naproxen
6. Further information

1. WHAT NAPROXEN IS AND WHAT IT IS USED FOR

Naproxen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAID). It is a painkiller and antipyretic (reduces fever). Naproxen works by reducing inflammation and relieving pain, swelling and stiffness in the joints and muscles. There are a number of painful conditions that can affect your joints and muscles, which can be helped by taking Naproxen. These conditions include:
- rheumatoid arthritis including childhood rheumatoid arthritis
- osteoarthritis
- ankylosing spondylitis (arthritis in the spine)
- gout
- musculo-skeletal disorders such as sprains, strains and other injuries, such as backache or neckache
- period pain

2. BEFORE YOU TAKE NAPROXEN

Do not take Naproxen
- if you are allergic (hypersensitive) to naproxen or any of the other ingredients in these tablets (these are listed in section 6)
- if you have taken another non-steroidal anti-inflammatory drug before (including Aspirin) and suffered an unpleasant or allergic reaction including asthma, redness and itching of the skin or an itchy, running nose
- if you have a stomach ulcer or know that you have suffered with ulcers in the past
- if you have severe heart failure, a disease of the heart that causes shortness of breath and swelling of the feet or legs due to fluid build up
- if you have recently become pregnant

Warning and precautions

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. Stop using Naproxen and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Take special care with Naproxen

- if you suffer from bronchial asthma or from allergies
- if you have any problems with your stomach or bowel
- if you have problems with your blood not clotting
- if you have problems with your liver or kidneys or have to be careful not to take too much sodium in your diet.

Tell your doctor if any of the above applies to you.

Please note:

It is important that you use the lowest dose that controls your pain and you **should not** take Naproxen for longer than necessary to control your symptoms. Some anti-inflammatory/pain- relieving medicines may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke, especially when used at high doses and in long-term treatment. Although Naproxen (1000mg daily) may be associated with a lower risk, some risk is still possible

- if you have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA") you should discuss this with your doctor before taking Naproxen.
- you should also discuss your treatment with your doctor if you have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker. Your doctor will want to ensure that you take the lowest necessary dose of Naproxen for the shortest period necessary.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, or any of the following:

- Phenytoin to treat or prevent convulsions, anticoagulants to thin your blood, such as Warfarin or sulphonamides to treat infection, as the levels of all these medicines in your blood may increase when you start taking Naproxen
- Aspirin/ acetylsalicylic acid to prevent blood clots.
- Furosemide or other "water tablets", as these may not work as well when you start taking Naproxen
- Lithium to treat mental illness or Methotrexate, for psoriasis, as your body may not be able to clear these as quickly when you start taking Naproxen
- medicines to lower your blood pressure or to treat a heart condition
- Probenecid, for gout, as the dose of Naproxen you will need will be lower than usual
- antibiotics, to treat infection, as side effects may occur if some antibiotics are taken with Naproxen
- Digoxin for your heart; corticosteroids such as Ciclosporin and Prendisolone; Mifepristone or if you are already taking other non-steroidal anti-inflammatory drugs

Taking Naproxen with food and drink

You should swallow Naproxen whole with a glass of water, with or after food**. Do not** crush or chew.

Pregnancy and breast-feeding

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.

Naproxen may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant. Tell your doctor if you are breast-

feeding, as small amounts of Naproxen can pass into breast milk. Ask your doctor or pharmacist for advice before taking any medicine.

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Driving and using machines - Do not drive or operate machinery if you suffer from side effects such as dizziness, drowsiness, fatigue and visual disturbances.

Effects on laboratory tests
If you need to have any tests such as blood tests, urine tests, liver function or adrenal function tests tell the doctor that you are taking Naproxen. You may need to stop taking these tablets before you have the test.

Important information about some of the ingredients of Naproxen
Naproxen 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.
Naproxen contains **soya oil**. If you are allergic to peanut or soya, do not use this medicinal product.

3. HOW TO TAKE NAPROXEN

Always take Naproxen exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Dosage
You should swallow the tablets whole with a glass of water, with or after food. **Do not** crush or chew.
The dose you should take will depend on what you are taking Naproxen for.

Adults
Rheumatoid Arthritis, Osteoarthritis and Ankylosing Spondylitis: The usual dose is 500 mg to 1 gram Naproxen daily, divided into two doses and taken 12 hours apart.
Gout: The usual dose is 750 mg Naproxen at once when an attack occurs, then 250 mg every 8 hours until the attack has gone.
Period Pain and Musculo-Skeletal Disorders (sprains etc): The usual dose is 500 mg to start, then one 250 mg tablet every 6 – 8 hours as needed.

Elderly If you are elderly the dose you take will be similar to other adults but should be the lowest dose that is effective. If you notice any signs of bleeding in your stomach or gut (e.g. black, tarry stools or if you vomit blood) stop taking Naproxen and tell your doctor straight away.

Children *Juvenile Rheumatoid Arthritis (children over 5 years of age):* The dose is worked out depending on the weight of your child. The usual dose is 10 mg Naproxen/kg bodyweight/day, divided into two doses (morning and evening). Children under 16 years old **should not** take Naproxen for any other use.

If you take more Naproxen than you should - If you take more Naproxen than you should, contact your doctor or nearest hospital emergency department immediately. Symptoms of overdose include drowsiness, heartburn, indigestion, feeling and being sick. Take the container and any remaining tablets with you.

If you forget to take Naproxen - If you forget to take Naproxen take it as soon as you remember unless it is almost time for your next dose. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Naproxen - Do not stop taking Naproxen without talking to your doctor, even if you feel better. It is important that you take the full course of Naproxen prescribed by your doctor.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Naproxen can cause side effects, although not everybody gets them. Side effects are more likely in elderly patients.

If any of the following happen, **stop taking Naproxen and tell your doctor immediately or go to your nearest hospital emergency department:**

- 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.
- 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
- if you have severe stomach pain
- if you pass black, tarry stools
- if you vomit any blood or dark particles that look like coffee grounds
- if you have an allergic reaction causing difficulty in breathing, tightness of the chest, swelling of the face, throat or tongue, sore dry itchy skin, or severe skin rashes
- if you notice sensitivity of the skin to sunlight, red spots or rash on the skin or unusual bruising or bleeding of the skin
- if your skin or the whites of your eyes become yellow

Other possible side effects are:

- indigestion or heartburn
- abdominal pain (pains in your stomach) or other abnormal stomach symptoms
- feeling unusually tired and pale, feverish, sore throat
- liver problems which may cause dark urine, pale stools
- change in urinary function such as difficulty or pain in passing urine or blood in the urine
- swollen ankles and breathlessness.

Less frequent side effects that may occur include vertigo, feeling drowsy or tired, sleeplessness, tingling of the arms and legs, headache, feeling dizzy, confused or generally unwell, lack of concentration, hallucinating, ringing in the ears, fits, depression, changes in eyesight, blurred or loss of vision, loss of hearing, mouth ulcers, sore swollen mouth, severe stomach upset (gastritis), high levels of potassium in the blood, a mild form of meningitis (causing headache, neck stiffness, fever, confusion, feeling or being sick). Rarely swollen red sore skin (vasculitis).

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

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

5. HOW TO STORE NAPROXEN

Keep out of the reach and sight of children. Do not use Naproxen after the expiry date, which is shown on the label or carton. The expiry date refers to the last day of that month. Do not store above 25°C. Keep the tablets in the original container. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Naproxen contains - The active substance is naproxen The other ingredients are lactose, see section 2 'Important information about some of the ingredients of naproxen' monohydrate, maize starch,

povidone, crospovidone, talc, colloidal anhydrous silica, magnesium stearate, cellacephate, diethylphthalate, acetone, shellac (E904), iron oxide black (E172), N-Butyl alcohol, soya lecithin (E322), see section 2 'Important information about some of the ingredients of naproxen' antifoam and industrial methylated spirit.

What Naproxen looks like and contents of the pack - Your medicine comes as white enteric-coated tablets containing either 250 mg or 500 mg of naproxen. The 250 mg tablets are marked with 'NX 250' on one side. The 500 mg tablets are marked with 'NX 500' on one side. Naproxen is available in blisters of 5, 7, 10, 14, 15, 20, 21, 25, 28, 30, 56, 60, 84, 90, 100, 112, 120, 168 and 180 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
The Marketing Authorisation Holder is:
Viatris,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom.

The Manufacturer is:
Gerard Laboratories
Grange Road
Dublin 13.

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