

Package leaflet: Information for the patient
Nabumetone 500 mg film-coated Tablets

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

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

Nabumetone Tablets belong to a group of medicines called non-steroidal anti-inflammatory drugs (known as NSAIDs).

They work by reducing the production of some natural chemicals found in the body. These chemicals (prostaglandins) cause the symptoms of inflammation such as pain and swelling.

Nabumetone Tablets are used to treat the pain, stiffness and swelling of joints which are affected by osteoarthritis or rheumatoid arthritis.

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

Do not take Nabumetone Tablets:

- if you are allergic to nabumetone or any of the other ingredients of this medicine (listed in section 6).
- if you have ever had an allergic reaction like a rash, itchy, runny or bleeding nose, or become short of breath when you have taken aspirin (acetylsalicylic acid) or other NSAID medicines. Such medicines include ibuprofen, diclofenac or naproxen. Some people who have had previous allergic reactions to NSAID medicines have very serious, sometimes fatal, reactions if they take this kind of medicine again.
- if you have, or have ever had a stomach (peptic) ulcer or any perforation or bleeding (haemorrhage) in your digestive system or if you have or have ever had peptic disease.
- if you have serious problems with your heart (severe heart failure).
- if you are currently receiving treatment for a stroke or other internal bleed.
- if you have serious problems with your liver (liver cirrhosis).
- if you have serious problems with your kidneys (kidney failure).
- if you are in the last three months of pregnancy.
- if you are breast-feeding.

If any of the above applies to you, talk to your doctor or pharmacist.

Warnings and precautions

Check with your doctor before taking Nabumetone Tablets if you:

- have, or have ever had asthma
- have, or have ever had stomach problems. This includes Crohn's disease or ulcerative colitis

- have kidney problems
- have liver problems
- have heart problems
- have or have ever had high blood pressure (hypertension)
- have ever had a stroke
- have any signs of water building up in your body, such as swollen ankles
- have a condition called systemic lupus erythematosus (SLE or Lupus for short) or any other autoimmune disease
- are in the first six months of pregnancy
- are trying to, or planning to become pregnant
- have diabetes
- have high cholesterol
- are a smoker
- are over 65 years of age
- have an infection. NSAID medicines such as nabumetone may hide the symptoms of infections such as fever and inflammation.

Children

Do not give Nabumetone Tablets to children.

Medicines such as Nabumetone Tablets may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

Other medicines and Nabumetone Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription.

- Anticoagulants such as warfarin or heparin (to thin your blood)
- Anticonvulsants such as phenytoin (to prevent fits)
- Antidepressants such as selective serotonin reuptake inhibitors (SSRI's) (to treat depression)
- Oral antidiabetics such as chlorpropamide and metformin (to control blood sugar levels)
- Antihypertensives such as ACE inhibitors or angiotensin receptor agonists (to reduce high blood pressure)
- Cardiac glycosides such as digoxin (to manage certain heart conditions)
- Ciclosporin and tacrolimus (to prevent transplanted organs being rejected)
- Corticosteroids (to treat skin conditions)
- Diuretics (water tablets to make you pass more urine)
- Lithium (to treat mental illness)
- Methotrexate (to treat arthritis)
- Mifepristone (used by doctors to terminate pregnancies). If you have taken mifepristone within the last two weeks you should not take Nabumetone Tablets
- Non steroidal anti-inflammatory drugs (NSAIDs or COX-2), including ibuprofen, acetylsalicylic acid, diclofenac, naproxen, clopidogrel or aspirin
- Quinolone (antibiotics to treat infections)
- Zidovudine (to treat HIV)
- Protein-bound drugs such as sulphonamides, sulphonylureas, probenecid, sulfapyrazone or hydantoin (used in medicines to treat bacterial infections, diabetes, oedema, hypertension and gout)
- Bisphosphonates (used in medicines to treat conditions that effect your bones)
- Oxpentifylline (pentoxifylline) (used in medicines to treat the symptoms of intermittent claudication)

Nabumetone Tablets with food, drink and alcohol

Take this medicine with or after a meal.

Do not drink alcohol during treatment with Nabumetone Tablets.

Pregnancy, breast-feeding and fertility

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.

Do not take Nabumetone Tablets 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 Nabumetone Tablets 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, Nabumetone Tablets 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.

Please note: Taking this medicine may make it harder for you to become pregnant. Ask your doctor for advice.

Driving and using machines

Whilst taking Nabumetone Tablets you may feel dizzy, tired, drowsy, confused or notice problems with your eyesight. If any of these symptoms occur, do not drive or operate machinery.

Nabumetone 500mg film-coated Tablets contain sodium

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

3. How to take Nabumetone Tablets

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

Important:

- Only take the amount of this medicine your doctor has prescribed.
- Only take this medicine for the treatment time your doctor has prescribed.

This will stop you getting so many side-effects. This will also reduce any chance of you having a stroke or heart attack.

Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Remember: Always take this medicine with or after a meal. Swallow the tablets whole with water. Do not chew the tablets.

Some patients may need to take another medicine at the same time as taking Nabumetone Tablets. Your doctor will prescribe this if you need it.

Adults

- The usual dose is 1 g taken once a day at bedtime (two 500 mg tablets).
- The label your pharmacist puts on your medicine will tell you exactly how many tablets to take.
- If you need to take more, your doctor will explain how much to take and when to take it.

Elderly (65 years and over)

- The usual starting dose is 500 mg taken once a day at bedtime (one 500 mg tablet).
- The label your pharmacist puts on your medicine will tell you exactly how many tablets to take.
- If you need to take more, your doctor will explain how much to take and when to take it.
- Never take more than 1 g of Nabumetone Tablets each day (two 500 mg tablets).

Children

Nabumetone Tablets are not recommended for use in children.

Medical check-ups

When you are taking this medicine, your doctor may ask you to come for check-ups which may include:

- Checking your kidneys to make sure they are working properly. Your doctor may want to do some tests before you start taking Nabumetone Tablets and then re-check your kidney function once you have been taking the medicine for a few weeks.
- Checking your liver is working properly.
- Checking you are not getting any problems with swelling of any part of your body. Your doctor may want to give you some medicine to help with these symptoms.
- If you are elderly you will need to go for check-ups during the first four weeks of taking the medicine. This is to make sure that the medicine is working properly and that the dose you are taking is right for you.

If you take more Nabumetone Tablets than you should

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department immediately for advice. Remember to take this leaflet or any remaining tablets with you.

Symptoms of overdose may include: feeling or being sick, stomach pain, diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, ringing in the ears (tinnitus), fainting and occasionally have fits (convulsions). In cases of significant overdose, kidney failure and liver damage are also possible.

If you forget to take Nabumetone Tablets

Do not take a double dose to make up for a forgotten dose. Simply take the next dose as planned.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking this medicine and seek immediate medical help if you have any of the following symptoms:

- You have difficulty breathing
- Your face or throat swells
- You have a severe rash that may blister
- You have chest pains or sudden numbness and confusion
- You have blood in your faeces (stools). They may look black and tarry
- You vomit blood or dark particles that look like coffee granules.

Stop taking this medicine and tell your doctor if you have any of the following symptoms:

This is especially important if you are elderly.

- You have indigestion or heartburn
- You have severe pains in your stomach
- You have any other abnormal stomach symptoms.

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 or drug hypersensitivity syndrome). Stop using Nabumetone 500mg film-coated Tablets if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

The following side effects have been reported:

Common side effects: (may affect up to 1 in 10 people)

- Ringing in your ears or problems with the ears
- Increase in blood pressure (you may feel dizzy and have a headache)
- Diarrhoea, constipation, feeling sick, inflammation of the stomach lining, stomach ache, wind
- Rash, itchy skin
- Fluid retention which causes swelling e.g. swollen ankles

Uncommon side effects: (may affect up to 1 in 100 people)

- Confusion, nervousness, problems sleeping
- Tiredness, dizziness, headache, “pins and needles” or tingling feelings, anxiety
- Problems with your sight or with your eyes
- Breathing difficulties, nose bleeds
- Upset stomach, being sick
- Mouth ulcers, dry mouth
- Increased skin sensitivity to sunlight or artificial light, red, raised patches on the skin, sweating
- Problems with your muscles
- Problems with your urinary tract
- Loss of strength or energy, fatigue
- Abnormal liver enzymes

Very rare side effects: (may affect up to 1 in 10,000 people)

- Low numbers of blood platelets
- Inflammation of the lungs causing shortness of breath and a dry cough
- Yellowing of your skin and the whites of your eyes (jaundice), liver failure
- Severe skin eruptions where the skin reddens, peels and swells and looks severely burnt, or a severe skin rash with flushing, fever, blisters and ulcers or a widespread skin rash with circular irregular red patches on the hands and feet
- Skin hives, loss of hair
- A disorder called pseudoporphyria which causes skin blisters, stomach pains and nervous system problems
- Kidney problems such as blood in the urine, kidney failure
- Heavy or unusually prolonged menstrual periods
- Inflammation of the pancreas (pancreatitis)

Other possible side effects where the frequency is not known

- Depression, hallucinations
- Aseptic meningitis (stiff neck, headache, feeling or being sick, fever, disorientation) especially in patients who already have an autoimmune disorder such as systemic lupus erythematosus or mixed connective tissue disorder
- Vertigo, drowsiness

- Asthma or worsening of existing asthma
- Red or purple skin patches
- A problem with the kidneys known as interstitial nephritis. The symptoms include fever, rash, enlarged kidneys, lower back pain, problems when passing urine
- A general feeling of being unwell or “out of sorts”
- Changes in the numbers and types of blood cells. You may get ill more often with a sore throat, fever, chills, anaemia or abnormal bruising
- Worsening of existing stomach conditions such as Crohn’s disease or ulcerative colitis

Important: Medicines such as Nabumetone Tablets may be associated with a small increased risk of heart attack (myocardial infarction) or stroke.

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 directly 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 Nabumetone Tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry (EXP) date which is stated on the label. The expiry (EXP) date refers to the last day of that month.

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 Nabumetone Tablets contain

The active substance is nabumetone. Each film-coated tablet contains 500 mg nabumetone. The other ingredients are: **Core:** Cellulose microcrystalline, Sodium starch glycolate (TYPE A), Silica colloidal anhydrous, Hypromellose, Sodium lauril sulfate and Magnesium stearate. **Coating:** Hypromellose, Titanium dioxide (E171) and Macrogol 6000.

What Nabumetone Tablets look like and contents of the pack

Nabumetone Tablets are white, modified capsule shaped, film coated tablets, 17.60 mm x 8.10 mm, debossed with "HP" on one side and "370" on the other side. The tablets come in a HDPE bottle containing 56 film-coated tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Tillomed Laboratories Ltd
220 Butterfield
Great Marlings
Luton, LU2 8DL
United Kingdom

Manufacturer¹

¹ Only actual batch release site listed on printed leaflet

Tillomed Laboratories Ltd
220 Butterfield
Great Marlings
Luton, LU2 8DL
United Kingdom

MIAS Pharma Limited
Suite 2, Stafford House,
Strand Road, Portmarnock,
Co. Dublin,
Ireland

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