

Package leaflet: Information for the patient
Nabumetone 500mg 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:

- 1. What Nabumetone tablets are and what they are used for**
- 2. What you need to know before you take Nabumetone tablets**
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1. What Nabumetone tablets are and what they are used for

Nabumetone belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which are used to reduce inflammation and pain in joints and muscles.

Nabumetone tablets are for diseases of the joints such as rheumatoid arthritis or osteoarthritis.

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

Do not take Nabumetone tablets if you:

- are in the **last three months of pregnancy** or **breastfeeding**.
- are **allergic to nabumetone** or any of the other ingredients of this medicine (listed in section 6). Carmoisine aluminium lake (E122) may cause allergic reactions.
- are **allergic to aspirin or other non-steroidal anti-inflammatory medicines** (NSAIDs), or have had difficulty breathing due to narrowing of the airways, swelling of the face, lips, throat or tongue, runny nose or a skin rash which has pale or red irregular raised patches with severe itching, when taking these medicines.
- have or have had a **peptic ulcer** (ulcer in your stomach or duodenum) or **bleeding in your stomach** (2 or more episodes).
- have had **bleeding or ulceration of the upper gastrointestinal tract** related to NSAID therapy.
- have **severely impaired liver** or **kidney** function.
- have **severe heart failure** or severely impaired heart function.
- are taking any other **non-steroidal anti-inflammatory medicines (NSAIDs), COX II inhibitors** or **aspirin**.
- have an uncorrected **blood clotting disorder**.

Medicines such as nabumetone 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.

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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nabumetone tablets if you have:

- **low blood pressure** or **water retention**.
- had **high blood pressure** or **heart failure**.
- or have had **asthma**.
- or have a **history of gastrointestinal disease** such as ulcerative colitis or Crohn’s disease.
- had **stomach and intestinal problems**.
- impaired **kidney** function.
- an **infection**. Nabumetone may mask symptoms of infections such as fever and inflammation.
- **systemic lupus erythematosus (SLE)** or **other connective tissue disorders**.
- your **thyroid hormone levels** or **thyroid function monitored**. Nabumetone can lower blood levels of thyroid hormone and can affect thyroid function test results.

if you are:

- a woman trying to **become pregnant** or undergoing investigation for infertility (see ‘Pregnancy and breast feeding’ section).
- **elderly**. If you are elderly, you have a higher risk of getting side effects.

If you experience any **skin reactions** or **rash** when you first start taking Nabumetone please stop using it and talk to your doctor.

Other medicines and Nabumetone tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Especially:

- medicines which thin the blood or which prevent blood clotting, such as warfarin
- drugs used to treat high blood pressure such as:
 - ACE inhibitors e.g. captopril
 - angiotensin II receptor antagonists e.g. candesartan or losartan
- cardiac glycosides such as digoxin (used to treat some heart conditions)
- lithium (used for depression)
- ciclosporin (used to suppress the immune system)
- mifepristone (used for termination of pregnancy), Nabumetone tablets should not be taken within 8-12 days of taking mifepristone.
- other non-steroidal anti-inflammatory drugs (NSAIDs) including aspirin
- corticosteroids e.g. prednisolone
- antibiotics such as quinolones (used to treat infections)
- selective serotonin re-uptake inhibitors (e.g. paroxetine), venlafaxine or moclobemide (used for depression)
- sulfonylureas (e.g. gliclazide) (used in diabetes)
- bisphosphonates e.g. alendronic acid (used in bone disorders)
- methotrexate (used to treat some types of cancer, Crohn's disease, psoriasis or rheumatoid arthritis)
- clopidrogel (an anti-platelet drug)
- pentoxifylline (used to treat blood vessel disease)
- probenecid or sulfinpyrazone(used to treat gout)

Pregnancy and breast-feeding

You should not take Nabumetone tablets if you are pregnant, especially in the last 3 months, plan to become pregnant or are breast-feeding. Ask your doctor for advice before taking any medicine. Nabumetone may make it more difficult to become pregnant, speak to your doctor if you are having problems.

Driving and using machines

Nabumetone may make you feel dizzy and confused. Make sure you are not affected before you drive or operate machinery.

Nabumetone tablets contain Carmoisine aluminium lake (E122)

Nabumetone tablets contain Carmoisine aluminium lake (E122) which may cause allergic reactions.

Tests

If you have impaired liver or kidney function or a history of high blood pressure or congestive heart failure, your doctor may want to monitor you by carrying out tests.

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.

Speak to your doctor before drinking **alcohol** with Nabumetone tablets, as there may be an increased risk of getting certain side effects.

Swallow tablets with water **with or after food**, this will reduce the risk of side effects on the stomach and intestines.

Doses

Your doctor should prescribe the lowest effective dose for the shortest amount of time. This will reduce any side effects you may have.

- **Adults:** The usual dose is 1g (two tablets) taken as a single dose at bedtime. If your pain is severe, persistent or worsens suddenly, your doctor may prescribe you an extra 500mg-1g (one or two tablets) to be taken in the morning.
- **Elderly:** If you are elderly, the maximum dose is 1g (two tablets) a day, 500mg (one tablet) a day may give you enough relief. Your doctor may monitor you for 4 weeks after you start taking Nabumetone tablets.
- **Children:** Not recommended.

If you take more Nabumetone tablets than you should

It is important not to take too many tablets. If you have taken more than you should, contact your doctor, pharmacist or nearest hospital casualty department immediately. **Symptoms of overdose** are headache, feeling or being sick, stomach pain, bleeding in the stomach or intestines, diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, ringing or buzzing in the ears, fainting, fits, kidney failure and liver damage.

If you forget to take Nabumetone tablets

If you forget to take your tablets, take your next dose as soon as you remember, unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose.

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.

Do not take if you have or have had a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach

Stop taking Nabumetone tablets and contact your doctor immediately if:

You notice signs of stomach or intestinal bleeding, ulceration or perforation, such as: blood in your faeces (stools/motions), black tarry stools, blood or dark particles that look like coffee grounds in your vomit, or abdominal pains (pains in your stomach) or other abnormal stomach symptoms, indigestion or heartburn.

Severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (toxic epidermal necrolysis), Severe form of skin rash with flushing, fever, blisters or ulcers (Stevens Johnsons syndrome) or Widespread skin rash – circular, irregular red patches on the skin of the hands and arms (erythema multiforme)

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 tablets if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

Contact your doctor immediately if you notice signs of an allergic reaction: itchy skin rash, swelling of the face, lips, throat or tongue, or difficulty breathing or swallowing.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Blood: changes in the numbers and types of your blood cells. If you notice increased bruising, nosebleeds, sore throats, infections, excessive tiredness, breathlessness on exertion or abnormal paleness of the skin, you should tell your doctor who may want you to have a blood test.

Immune system: skin reactions including large raised spots on the skin, small blisters or red, flaky and peeling skin, itching, rash, pale or red irregular raised patches with severe itching (hives).

Psychiatric: confusion, hallucinations, difficulty sleeping, nervousness.

Nervous system: headache, dizziness, sedation, tiredness, ‘pins and needles’ or tingling, 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.

Eye: abnormal vision, problems with your sight or with your eyes.

Ear: ringing or buzzing in the ears, problems with your hearing or your ears.

Heart: high blood pressure.

Airways: nosebleeds, breathing difficulties, inflammation of the lungs causing coughing or wheezing.

Stomach and intestines: diarrhoea, indigestion, dry mouth, feeling or being sick, constipation, stomach pain, wind, inflammation of the stomach lining, mouth ulcers, colitis, Crohn’s disease, worsening of existing colitis or Crohn’s disease, inflammation, perforation or narrowing of the food pipe, ulceration of the food pipe with or without bleeding, stomach problems, inflammation of the mouth.

Liver: liver failure, disease of the liver causing yellowing of the skin or whites of the eyes (jaundice).

Skin: hair loss, rash, itching, sensitivity to sunlight or artificial light (e.g. sun beds), itchy skin rash caused by allergic reaction-pale or red irregular raised patches with severe itching (hives), swollen face, lips, throat or tongue, sweating.

Muscles: weakness.

Kidneys: kidney failure, protein in your urine, urinary tract problems.

Reproductive system: impaired female fertility, heavy periods.

General disorders: water retention (causing swelling in a specific area of the body), weakness or loss of strength, tiredness

Investigations: abnormal liver enzymes as seen in a blood tests

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 out of the sight and reach of children.

Store in the original container.

Do not use this medicine after the expiry date which is stated on the carton. The expiry 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 (the ingredient that makes the tablets work) is nabumetone. Each tablet contains 500mg nabumetone.
- The other ingredients are microcrystalline cellulose 101 (E460), hydroxypropylmethylcellulose (E464), sodium lauryl sulfate, sodium starch glycollate, colloidal silica, magnesium stearate, propylene glycol, purified talc (E553), carmoisine aluminium lake (E122), indigo carmine aluminium lake (E132), titanium dioxide (E171).

What Nabumetone tablets look like and contents of the pack

Nabumetone tablets are maroon, oval, biconvex, film-coated tablets.

Pack size is 56.

Marketing Authorisation Holder and Manufacturer

Actavis, Barnstaple, EX32 8NS, UK.

This leaflet was last revised in August 2018.