

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

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 or nurse.
- 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 or nurse. 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 Tillomed are and what they are used for

Nabumetone Tillomed 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 Tillomed 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 Tillomed

Do not take Nabumetone Tillomed:

- 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 or other NSAID medicines. Such medicines include ibuprofen, acetylsalicylic acid, 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 Tillomed 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 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 Tillomed may hide the symptoms of infections such as fever and inflammation.

Medicines such as Nabumetone Tillomed 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 Tillomed

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

- Anticoagulants such as warfarin (to thin your blood)
- Anticonvulsants such as phenytoin (to prevent fits)
- Antidepressants such as selective serotonin reuptake inhibitors (SSRI's) (to treat depression)
- Antidiabetics (taken by mouth to control blood sugar levels)
- Antihypertensives such as ACE inhibitors or angiotensin receptor agonists (to control 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 or 'water tablets' (to make you pass more water)
- Lithium (to treat mental problems)
- 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 Tillomed.
- Non steroidal anti-inflammatory drugs (NSAIDs or COX-2). These include 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, sulfinpyrazone 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)
- Any other medicine, including medicines obtained without a prescription

Nabumetone Tillomed with food, drink and alcohol

Take this medicine with or after a meal.

Do not drink alcohol during treatment with Nabumetone Tillomed.

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.

You should not take Nabumetone Tillomed during the last 3 months of pregnancy.

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

Driving and using machines

Whilst taking Nabumetone Tillomed you may feel dizzy, tired, drowsy, confused or notice problems with your eyesight. If this happens, do not drive or operate machinery. Your doctor may arrange for you to have an eye examination, if your eyesight is affected whilst you are taking this medicine.

Nabumetone Tillomed 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 Tillomed

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 Tillomed. Your doctor will prescribe this if you need it.

Adults

- The recommended dose is 1 g taken once a day at bedtime (as 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 recommended starting dose is 500 mg taken once a day at bedtime (as 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 Tillomed each day (two 500 mg tablets).

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

Children

Nabumetone Tillomed are not recommended for 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 Tillomed 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 Tillomed than you should

Do not take more Nabumetone Tillomed than you should. If you accidentally take too much of your medicine, immediately tell your doctor or go to the nearest hospital casualty department.

Taking too many Nabumetone Tablets may make you feel or be sick, be dizzy or faint, develop a headache or have fits (convulsions).

If you forget to take Nabumetone Tillomed

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:

- if you notice signs of an allergic reaction: itchy skin rash, swelling of the face, lips, throat or tongue, or difficulty breathing or swallowing.
- 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).
- chest pains or sudden numbness and confusion
- 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.

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 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
- Inflammation of the optic nerve
- 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 water
- 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
- Heart (cardiac) failure

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 Tillomed 500mg film-coated Tablets if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

Important: Medicines such as Nabumetone Tillomed 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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; email: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nabumetone Tillomed

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.

This medicinal product does not require any special storage conditions.

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 Tillomed contain

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

What Nabumetone Tillomed look like and contents of the pack

Nabumetone Tillomed 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 Pharma GmbH
Mittelstraße 5/5a
12529 Schönefeld
Germany

Manufacturer¹

Tillomed Laboratories Limited
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Great Marlings
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United Kingdom

¹ Only actual batch release site listed on printed leaflet

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Luton
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Dublin
Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom (Northern Ireland)	Nabumetone 500 mg Film-coated Tablets
Belgium	Nabumetone Tillomed 500 mg comprimés pelliculés Nabumetone Tillomed 500 mg Filmomhulde tabletten Nabumetone Tillomed 500 mg Filmtabletten
Ireland	Nabumetone Tillomed 500 mg Film-coated Tablets

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