

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.
- 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 Tillomed are and what they are used for

Nabumetone Tillomed belongs to a group of medicines called non-steroidal anti-inflammatory drugs (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 <product name>

Do not take Nabumetone Tillomed :

- if you are allergic to nabumetone or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- if you have or have had a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach (2 or more episodes).
- if you have ever had an allergic reaction such as a skin rash, or an 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 severe impaired liver or kidney function.
- if you are in the third trimester of pregnancy.
- if you are breast-feeding.
- if you have had bleeding or ulceration of the upper gastrointestinal tract related to NSAID therapy.
- if you have severe heart failure.

Warnings and precautions

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

- have a history of gastrointestinal disease such as Crohn's disease or ulcerative colitis

- had stomach ulcers or inflammatory bowel disease
- have a serious heart condition called congestive heart failure
- have peripheral arterial disease (circulation problems in the limbs, usually in the legs)
- have hyperlipidaemia (high blood level of a type of fat called lipids)
- have ever had a stroke
- have a condition called systemic lupus erythematosus (SLE or Lupus)
- have had bleeding in the brain or other bleeding problems
- have diabetes
- are a smoker
- have or have ever had high blood pressure (hypertension)
- are a woman trying to become pregnant or undergoing investigation for infertility (see 'Pregnancy and breast-feeding' section)
- are over 65 years of age, as you have a higher risk of getting side effects
- have an infection as NSAID medicines such as <product name> may hide the symptoms of infection (such as fever, pain and inflammation).

If you are going to be treated for a long time you should have regular medical tests for side effects and kidney function.

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 of the following medicines, including those obtained without a prescription.

- Anticoagulants such as warfarin or heparin (to thin your blood)
- Selective serotonin reuptake inhibitors (SSRI's) (to treat depression)
- Oral antidiabetics (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 reduce inflammation)
- Aminoglycosides (type of antibiotic)
- Probenecid, sulfinpyrazone (used to treat gout)
- Diuretics or 'water tablets' (to make you pass more water)
- Lithium (to treat mental illness)
- Methotrexate (to treat arthritis)
- Mifepristone (used by doctors to terminate pregnancies). Nabumetone Tillomed should not be used for 8-12 days after mifepristone administration
- Other non steroidal anti-inflammatory drugs (NSAIDs or COX-2) including ibuprofen, acetylsalicylic acid (aspirin), diclofenac, naproxen, clopidogrel
- Quinolone antibiotics (to treat infections)
- Zidovudine (to treat HIV/AIDS)
- Anti-platelet medicines (used to decrease blood clots forming)
- Highly protein-bound drugs such as sulfonamides, sulfonyleureas or hydantoin
- Bisphosphonates (medicines to help strengthen bones, to help prevent or slow bone thinning or reduce the risk of bones breaking)
- Oxpentifylline (pentoxifylline) (medicines to treat intermittent claudication)

Nabumetone Tillomed with food, drink and alcohol

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.

Pregnancy and breast-feeding

Do not take Nabumetone Tillomed 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 Tillomed during the first 6 months of pregnancy or while breast-feeding 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 Tillomed 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.

Fertility

Nabumetone Tillomed may make it more difficult to become pregnant, speak to your doctor if you are having problems.

Driving and using machines

Dizziness, drowsiness, confusion, fatigue and visual disturbances have been reported after taking nabumetone. If any of these symptoms occur, the patient must not drive or operate machinery.

Nabumetone Tillomed contains 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.

Adults

- The recommended dose is 1 g (as two 500 mg tablets), taken as a single night time dose, with or without food.
- For severe or persistent symptoms, or during flare ups, an extra 500 mg to 1 g may be given as a morning dose.

Elderly (65 years and over)

- The recommended starting dose is 500 mg (as one 500 mg tablet) taken as a single night time dose, with or without food.
- The total daily dosage should not be more than 1 g (two 500 mg tablets).

Use in children

Nabumetone Tillomed are not recommended for use in children.

If you take more Nabumetone Tillomed 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 include: feeling or being sick, stomach pain, rarely diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, ringing in the ears (tinnitus), fainting,

headache and occasionally fits (convulsions). In cases of significant overdose, acute kidney failure and liver damage are possible.

If you forget to take Nabumetone Tillomed

Take it as soon as you remember, unless it is time for your next dose. If you miss a dose, **do not** take a double dose to make up for a forgotten dose. Simply take the next dose as planned.

If you stop taking Nabumetone Tillomed

It is important that you keep taking Nabumetone Tillomed for as long as your doctor has told you to.

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 notice:

- signs of an allergic reaction: itching or rash (especially affecting your whole body), swelling of the eyelids, face, lips, throat or tongue, difficulty breathing or swallowing
- 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)
- 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)
- fever, general ill feeling, itching, joint aches, multiple skin lesions (erythema multiforme)
- 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. Peptic ulcers (ulcer in your stomach or duodenum), or stomach or intestinal bleeding, sometimes fatal, particularly in the elderly may occur.

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

- Ringing in the ears (tinnitus) or ear disorders
- Increase in blood pressure
- Diarrhoea, constipation, feeling sick, inflammation of the stomach, stomach ache, wind
- Rash, itchy skin (pruritus)
- Fluid retention which causes swelling of parts of the body (oedema)

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

- Confusion, nervousness, anxiety
- Difficulty sleeping
- Tiredness, dizziness, headache, tingling or numbness in the hands or feet (paraesthesia)
- Problems with your sight or eyes
- Breathing difficulties
- Nose bleeds
- Upset stomach, being sick
- Mouth ulcers, dry mouth
- Increased skin sensitivity to sunlight (photosensitivity), skin rashes with the formation of wheals (urticaria)
- Sweating
- Muscle weakness (myopathy)

- Problems with the urinary tract
- General weakness (asthenia), fatigue
- Abnormal liver enzymes

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

- Low numbers of blood platelets (thrombocytopenia)
- Inflammation of the lungs causing shortness of breath and a dry cough (interstitial pneumonitis)
- Inflammation of the pancreas (pancreatitis)
- Liver failure
- Yellowing of the skin and the whites of the eyes (jaundice)
- Loss of hair (alopecia)
- A skin disorder called pseudoporphyria which causes skin sensitivity and blisters
- Kidney failure, protein in the urine (nephrotic syndrome)
- Heavy or unusually prolonged periods (menorrhagia)

Not known (frequency cannot be estimated from the available data)

- 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
- Skin rash caused by small blood vessels bleeding into the skin (purpura)
- Inflammation of the kidney (interstitial nephritis)
- A general feeling of being unwell (malaise)
- Blood disorders which can cause weakness, bruising or make infections more likely (neutropenia, agranulocytosis, leucopenia, aplastic anaemia and haemolytic anaemia)

Other side effects

High blood pressure (hypertension) and heart failure have been reported in association with NSAID treatment.

NSAID medicines such as Nabumetone Tillomed (particularly at high doses and in long term treatment), may be associated with an 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 national reporting system](#) listed in [Appendix V*](#). 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 date which is stated on the label after “EXP”. The expiry 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

Each film-coated tablet contains 500mg of the active ingredient 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

MIAS Pharma Limited

Suite 2, Stafford House, Strand Road

Portmarnock, Co. Dublin

Ireland

Tillomed Malta Limited

Malta Life Sciences Park

LS2.01.06 Industrial Estate

San Gwann, SGN 3000, Malta

^[1]Only the actual release site will be listed on the marketed product.

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

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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