

PACKAGE LEAFLET: INFORMATION FOR THE USER

NIMESIL

100 mg, granules for oral suspension

NIMESULIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Nimesil is and what it is used for
2. Before you take Nimesil
3. How to take Nimesil
4. Possible side effects
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1. WHAT NIMESIL IS AND WHAT IT IS USED FOR

Nimesil is a non• steroidal anti• inflammatory medicine (NSAID) for the removal of pain. It is used for the treatment of acute pain, as well as for the treatment of menstrual pain.

Before the doctor prescribes Nimesil, he/she will assess the benefit that you can have from this medicine as well as the possibility of a side effect.

2. BEFORE YOU TAKE NIMESIL

Do not use Nimesil:

- If you are hypersensitive (allergic) to nimesulide or any of the other ingredients of the medicine Nimesil (a list of ingredients is in section 6, at the end of this leaflet);
- If you have had an allergic reaction (for example, wheezing, a runny nose or stuffy nose, rashes or hives) after taking aspirin or other non• steroid anti• inflammatory medicine;
- If you have had a reaction to nimesulide that affected the liver;
- If you are taking other medications known to affect the liver, eg. acetaminophen, or any other medications for pain or any of NSAIDs,

- If you are addicted to medicines or if you have a predisposition for addiction to medicines or other substances,
- If you drink a lot of alcohol;
- If you have problems with your liver or have elevated levels of liver enzymes;
- If you have sores in the digestive tract (ulcers in the stomach or duodenum) now or have had it in the past;
- If you have had bleeding in the stomach or intestines;
- If you have had bleeding in the brain (stroke);
- If you have any other problem with the bleed or problems due to decreased blood clotting;
- If you have serious heart problems in terms of the blood circulation (heart failure), or kidney failure (weak kidney function), or any disorder of the liver;
- If you have fever or flu (feeling of weakness, pain, sweating, cold, high temperature);
- If you are in the last three months of pregnancy;
- If you are breast
- feeding.

Do not give to the child under 12 years.

Warning

Medications, such as Nimesil can cause a slight increase in risk of heart attack (myocardial infarction) or stroke. The risk is higher when using high - dose in long -term therapy. That's why you should not exceed the recommended dose and duration of therapy.

If you have heart problems, if you have had a stroke, or you are at risk (for example, you suffer from high blood pressure, diabetes, high cholesterol, or if you smoke), contact your doctor, or pharmacist to check whether the therapy is suitable for you.

If you have had a serious allergic reaction, you should stop using Nimesil after you notice the first signs of skin rash, damage to the soft tissues (mucous lesions), or any other sign of allergies contact your doctor.

You should stop using it immediately in the case bleeding in the digestive tract (the dark stool), or if you notice symptoms of ulcers in the digestive tract (manifested as pain in the abdomen).

Pay special attention when using the medicine Nimesil:

- If you have intolerance of certain sugars consult your doctor before you start taking Nimesil granules;
- Tell your doctor if you are taking any medicines which may interact with Nimesil granules:
 - medicines that help prevent blood clots (anticoagulants, aspirin or other derivatives of salicylic acid),
 - medicines that enhance the formation of urine and its secretion– diuretics, which are used with heart disease or high blood pressure
 - lithium, used in the treatment of depression and other similar conditions,
 - methotrexate,
 - Cyclosporine;
- If you notice symptoms suggestive of liver problems (loss of appetite, nausea, vomiting, abdominal pain, fatigue, dark urine color) during therapy with nimesulide, stop taking the medicine Nimesil and contact your doctor immediately;
- If you have had an ulcer in the digestive system, bleeding from the stomach or bowel, ulcerative colitis or Crohn's disease, tell your doctor before you start taking Nimesil;
- If you experience fever or cold• like symptoms (pain in the body, feeling cold, shivering) while taking the medicine Nimesil, stop taking the medicine and tell your doctor;
- If you have heart disease, high blood pressure, problems with circulation, or kidney disease, tell your doctor before you start using Nimesil. Nimesil can weaken the function of the kidney;
- If you are an older patient, your doctor may request that you occasionally make sure Nimesil does not cause problems with the stomach, kidneys, heart, or liver.
- If you are planning to get pregnant, contact your doctor because Nimesil can reduce fertility.

Taking other medicines with Nimesil 100 mg granules for oral suspension

You should make sure your doctor or pharmacists know if you are taking any of the following medicines, before you start taking Nimesil:

- Corticosteroids (medications used to treat inflammatory conditions),
- Anticoagulants like warfarin or medicines that affect platelets, for example, aspirin (medicines that help prevent blood clots),
- selective serotonin reuptake inhibitors (medicines used to treat depression),
- Antihypertensive medicines or diuretics (medications to control blood pressure and heart disease),
- Lithium (a medicine used to treat mood disorders),
- Methotrexate (a medicine for the treatment of rheumatoid arthritis and cancer),
- Cyclosporine (a medicine used after organ transplants or for the treatment of disorders of the immune system)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines without a prescription.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before taking Nimesil or any other medicine.

- You should not take Nimesil during the last 3 months of pregnancy; it can cause problems to the child, or during childbirth.
- If you are planning to get pregnant, you must inform your doctor because Nimesil might reduce fertility,
- If you are in the first or second trimester of pregnancy, you may not exceed the dose and duration of treatment, which is prescribed by a doctor.

Nimesil must not be used during breastfeeding.

Driving and using machines:

Do not drive or operate machinery if you feel sleepy or dizzy after taking the medicine Nimesil.

Important note about some of the ingredients of the medicine Nimesil

Nimesil contains sugars. If you have intolerance to some sugars, contact your doctor before you start taking Nimesil.

3. HOW TO TAKE NIMESIL

Always take Nimesil exactly as your doctor has instructed. If you are not sure, consult with your doctor or pharmacist.

The usual dose is one sachet of 100 mg twice daily after meals. The granules should be dissolved in a sufficient amount of water and drunk immediately after dissolution.

Use Nimesil for the shortest possible time and not longer than 15 days as the maximum length of an individual treatment. The risk of side effects may be reduced by taking the lowest effective dose for the shortest possible duration.

If you take more Nimesil 100 mg granules than you should

If you have taken, or you think that you have taken more Nimesil 100 mg granules than you should, talk to your doctor or contact the nearest hospital. Take the remaining medicine with you. In the event of an overdose, you

are likely to experience one or more of the following symptoms: drowsiness, nausea, stomach pain, bleeding in the stomach or wheezing.

If you forget to take Nimesil 100 mg granules

Do not take a double dose to make up for the missed dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Nimesil 100 mg granules can cause side effects, although not everybody gets them.

If any of the following occurs, immediately stop taking the medicine and tell your doctor because these could be rare side effects that require immediate medical attention:

- pain or discomfort in the stomach, loss of appetite, nausea, vomiting or bleeding from the stomach or intestines, or the emergence of black stool,
- disorders of the skin as well as redness or a rash,
- sizzle when breathing or shortness of breath,
- yellow color of the skin or whites of the eyes (jaundice),
- sudden change the amount of, or the color of urine,
- swelling of the face, feet, or legs,
- constant feeling of tiredness.

Unwanted effects of non steroidal anti inflammatory medicines (NSAIDs)

The use of individual NSAIDs can lead to a slight increase in the risk of arterial thrombosis such as heart attack (myocardial infarction) or stroke when using high dose during long term therapy.

During the therapy, NSAIDS may cause the appearance of edema (fluid retention), high blood pressure (hypertension) and heart failure.

The most common side effects involving the digestive tract are:

- peptic or duodenal ulcer (ulcer in the stomach and the duodenum);
- perforation of intestinal walls or bleeding in the digestive tract (can be fatal, especially in older people)

Side effects that may occur during treatment with Nimesil 100 mg granules are:

- common (more than one person in 100): diarrhea, nausea, vomiting, increased liver enzymes in the blood;
- uncommon (affecting up to 1 in 100 people): shortness of breath, dizziness, high blood pressure, constipation, flatulence, inflammatory changes of the stomach • gastritis, itching, rash, sweating, swelling (edema), bleeding in the stomach or intestines, ulcers in the stomach and duodenum;
- rare (affecting less than one person in 1,000): anemia, a decrease in the number of white blood cells, boosting the number of certain white blood cells (Eosinophilia), changes in blood pressure, bleeding, problems urinating, blood in the urine, increase in the level of potassium in the blood, the feeling of restlessness or nervousness, nightmares, blurred vision, rapid pulse, flush skin, redness of the skin, inflammatory reaction of the skin (dermatitis), generally poor condition, fatigue.
- very rare (affecting up to 1 in 10.000 people): severe skin reactions (also known as erythema multiform, Stevens Johnson Syndrome and Toxic Epidermal Necrolysis) that lead to the appearance of the blisters on the skin and is generally very poor condition; failure or inflammation of the kidneys (nephritis); disorder of brain function (encephalopathy), a reduction in the number of platelets in the blood with a consequent subcutaneous haemorrhage or bleeding in other parts of the body; black stools due to bleeding; bleeding from the stomach or intestines; inflammation of the liver (hepatitis), which can be very severe and cause jaundice and liver bile flow stasis; allergies, including severe reactions with possibility of collapse and the squeaking of audible breathing problems; asthma; the reduction in body temperature; dizziness, headache, drowsiness; stomach pain; poor digestion; dry

mouth; a rash that is itching (hives); swelling of the face and the surrounding areas of the body, disorders of vision.

Medicines such as Nimesil 100 mg granules can be linked with increased risk of heart attack (myocardial infarction) or stroke.

If any of the side effects gets serious, or if you notice side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE NIMESIL

Keep out of reach and sight of children.

Store at temperature up to 30 ° c.

Nimesil must not be used after the expiry date which is stated on the carton. The expiration date indicates the last day of the month.

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 Nimesil granules for oral suspension contain

Each sachet of Nimesil granules for oral suspension contains 100 mg of nimesulide.

Auxiliary substance are sucrose; the aroma of orange blossom, citric acid, maltodextrin, MACROGOL cetostearyl ether.

How Nimesil 100 mg granules for oral suspension look like and contents of the pack

Granules for oral suspension are available in paper/aluminium/polyethylene bags. Bags and instructions for the patient are packaged in the carton box. Each pack contains 9, 15 or 30 bags. Each bag contains 2 g of granules (100 mg of nimesulide).

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer

Berlin – Chemie AG

(Menarini group)

Glienicker Weg 125, 12489 Berlin,

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Manufacturers of the medicinal product Laboratorios Menarini S.A.

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