

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Nimulid MD

100 mg orodispersible tablets

NIMESULIDE

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*• 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.*

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*• 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 •*

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### What is in this leaflet?

1. What Nimulid MD is and what it is used for
2. Before you take Nimulid MD
3. How to take Nimulid MD
4. Possible side effects
5. How to store Nimulid MD
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#### 1. WHAT NIMULID MD IS AND WHAT IT IS USED FOR

Nimulid MD is a nonsteroidal anti-inflammatory medicine, which contains nimesulide as an active substance, and is used in the treatment of:

- acute pain
- painful menstruation

Before the doctor prescribes Nimulid MD, 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 NIMULID MD

Inform the doctor if you are taking other medicines, have a chronic disease, a metabolic disorder, you are too sensitive to medicines or have had an allergic reaction to some of them.

***Nimulid MD must not be used:***

- If you are allergic to nimesulide or on some of the auxiliary substances of the medicinal product;
- If you have had an allergic reaction (for example: wheezing, clogged runny nose, hives) after taking aspirin or other nonsteroidal anti-inflammatory medicines;
- If you have had a reaction on nimesulide leading to impaired liver function;
- If you are taking other medicines that are known to affect the liver function, for example paracetamol or non-steroidal anti-inflammatory;
- If you have habit to consume alcohol in larger quantities;
- If you are addicted to medicines or other substances (medicine abuse);
- If you have reduced liver function or increased liver enzymes;
- If you have or have ever had an ulcer in the stomach or duodenum;
- If you have bleeding from the stomach or intestines;
- If you have had a stroke;
- If you have any other problem with bleeding or any problem with blood clotting;
- If you have heart disease or kidney disease (weakened kidney function);
- If you have a fever or flu (if you feel ill, sick, have chills or shivering or have a fever);
- If you are in the last quarter of pregnancy;
- If you are breast-feeding.

**Nimulid MD should not be used in children under the age of 12.*****When you are taking Nimulid MD, take special care:***

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.
- If during treatment with Nimulid MD you notice symptoms of liver damage, you must stop taking medicine and inform your doctor. Symptoms that indicate liver injury include loss of appetite, nausea, vomiting, stomach pain, chronic fatigue, or dark discoloration of urine.
- If you have ever had an ulcer in the stomach, bleeding from the stomach or bowel, ulcerative colitis (inflammation of the large intestine) or Crohn's disease (chronic inflammation of the digestive tract), you need to tell your doctor before you start using Nimulid MD.
- If during treatment with Nimulid MD you notice symptoms of fever and/or symptoms similar to the flu (if you feel ill, sick, have chills or shivering or have a fever), you need to stop treatment and inform your doctor.
- If you have reduced cardiac or renal function, you must tell your doctor before starting treatment with Nimulid MD; kidney function can worsen during therapy with Nimulid MD.

-If you are an older patient, your doctor may request that you occasionally make sure Nimulid MD does not cause problems with the stomach, kidneys, heart, or liver.

- Tell your doctor if you plan to become pregnant, as Nimulid MD might reduce fertility in women.
- In case of dark stool (which may indicate bleeding in the digestive tract) or pain in the abdomen (may indicate abscess), immediately stop taking Nimulid MD and immediately inform a doctor.

***Other medicines***

The following medicines may interact with Nimulid MD:

- anticoagulants (used to prevent blood clotting), for example, warfarin,
- Antiplatelet medicines (used to prevent the formation of thrombi), for example, acetylsalicylic acid,

- antihypertensive medicines or diuretics that are used in the case of cardiac weakness or high blood pressure
- lithium that is used in the treatment of depression and other conditions,
- methotrexate (used for the treatment of cancer),
- cyclosporine (used for the prevention of rejection of the organ or bone marrow transplantation),
- selective serotonin reuptake inhibitors (used in the treatment of depression),
- steroids (used in the treatment of developing process).

Before taking Nimulid MD contact your doctor or pharmacist if you are taking the medicines listed above.

### ***Taking Nimulid MD with food or drinks***

Take Nimulid MD after meals, as well as to avoid consumption of alcoholic beverages during therapy because of the potential damage to the liver.

### ***Pregnancy and breastfeeding***

Before you start taking any medicine, consult your doctor or pharmacist.

#### **Pregnancy**

Nimulid MD must not be used in the last three months of pregnancy, while its use in the first and second trimester of pregnancy is not recommended. From the sixth month of pregnancy YOU MAY NOT UNDER ANY CIRCUMSTANCES take Nimulid MD, because it can cause serious consequences to the heart, lungs and kidneys of your child.

Also, the use of Nimulid MD is not recommended for women who are trying to get pregnant.

#### **Breast feeding**

It is not known whether Nimulid MD is excreted into breast milk. Nimulid MD must not be used during the period of breastfeeding.

### ***Driving and using machines***

There is not enough data on the influence of nimesulide on the psychophysical abilities when managing a motor vehicle and handling machines. However, the patients which experience fainting or dizziness after taking Nimulid MD should not drive or operate machinery.

### ***Important information about some of the ingredients of Nimulid MD***

Nimulid MD contains the following auxiliary substances: aspartame, mannitol, sodium methyl parahydroxybenzoate (E 219) and sodium propyl (E 217).

Aspartame is a source of phenylalanine. It can be harmful for people with phenylketonuria.

Mannitol can act slightly laxative.

Sodium methyl parahydroxybenzoate and sodium propyl can cause allergic reactions, which can even be delayed.

## ***3. HOW TO TAKE NIMULID MD***

If you think that Nimulid MD has too weak or strong effect on your body, consult your doctor, or pharmacist. Always take Nimulid MD as your doctor has prescribed.

The medicine is intended for use in adults and children older than 12.

The medicine should be dissolved in your mouth, not swallowed.

The usual dose is one oral dispersible tablet of Nimulid MD twice a day, after meals.

Use Nimulid MD during a shorter period of time and for no more than 15 days as an individual therapy.

***If you have taken more Nimulid MD than you should***

If you have taken a higher dose of Nimulid MD than you should, speak with your doctor or pharmacist.

The most common symptoms of an overdose with Nimulid MD are lack of interest, sleepiness, nausea, vomiting, and pain in the upper part of the stomach, which are disappearing after you stop taking the medicine.

Rarely you may experience elevated blood pressure, acute damage of the kidney, respiratory depression and coma.

There are no specific antidotes, and active coal and inducing vomiting can be applied.

***If you forget to take Nimulid MD***

If you miss a dose, take the next dose at the usual time and continue to take the medicine as instructed by a doctor.

Do not take a double dose to make up for a forgotten dose.

***If you suddenly stop taking Nimulid MD***

Do not use Nimulid MD longer than 15 days during one treatment.

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Nimulid MD can cause side effects, although not everybody gets them.

Side effects are classified according to the following frequency:

**Very common** (more than 1 in 10 patients who take the medicine)

**Common** (1-10 of 100 patients who take the medicine)

**Uncommon** (1-10 of 1,000 patients taking the medicine)

**Rare** (at 1-10 in 10,000 patients who take the medicine)

**Very rare** (rarer than 1 in 10,000 patients who take the medicine)

**Unknown** (frequency cannot be estimated)

If any of the following occurs stop taking the medicine and inform your doctor, because these may be symptoms of the rare serious side effects that require immediate medical intervention:

- an unpleasant sensation or pain in the abdomen, bleeding from the stomach or intestines, or black stools,
- changes of the skin in the form of a rash or redness,
- dry cough or difficulty breathing,
- skin or the whites are yellow,
- an unexpected change in the amount or appearance of urine,
- swollen face, feet or legs
- loss of appetite, general malaise, vomiting, abdominal pain, or a feeling of tiredness

Side effects that may occur while taking Nimulid MD are:

**Common:**

Diarrhea, nausea, vomiting, mild changes in blood relating to the function of the liver (increased liver enzyme).

**Uncommon:**

Shortness of breath, dizziness, increased blood pressure, constipation, bleeding from the stomach or intestines, bloating of stomach, ulcers in the intestine or stomach duodenum and perforation of ulcer, itching, rash, increased sweating, swelling (edema).

**Rare:**

Anemia (anemia), increase of certain white cells (Eosinophilia), hyper-sensitivity (increased sensitivity of the organism), unstable blood pressure, discomfort while urinating, or cessation of urination, blood in the urine (urine), increasing the value of potassium in the blood, a feeling of anxiety or nervousness, nightmares, blurred

vision, rapid cardiac work, hemorrhage, hot flushes, redness of the skin (erythema), skin inflammation (dermatitis), general feeling of weakness, fatigue.

**Very rare:**

Reduction in the number of white blood cells, anaphylaxis (severe allergic reaction), serious problems with the skin (known as erythema multiform, Stevens-Johnson's syndrome, Toxic Epidermal Necrolysis), gastritis (inflammation of the lining of the stomach), hives, abnormal kidney function, or inflammation (nephritis), decreased urination, abnormal functions of the brain (encephalopathy), Ray's syndrome (a disease that is characterized by the emergence of a fatty liver and damage of brain function), headache, sleepiness, reduction in the number of blood platelets-Blood platelet, subcutaneous bleeding or bleeding in other parts of the body, vomiting blood, worsening colitis (inflammation of the colon) and the programme of disease (chronic inflammation of the digestive tract), inflammation of the liver (hepatitis) sometimes very seriously (fulminant hepatitis, sometimes fatal), jaundice (yellow skin and sclera) or cessation of secretion of bile, allergies, including severe reactions with collapsing and difficult breathing, asthma, bronchospasm (reflex spasm of the bronchi), a drop in body temperature (hypothermia), abnormal vision, vertigo (dizziness), pain in the stomach, digestive disorder, painful sores in the mouth (stomatitis), rash, swelling of the face and soft tissues.

**Unknown:**

Cardiac insufficiency (weakness of the heart).

**Reporting of side effects**

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

**5. HOW TO STORE NIMULID MD**

Keep out of reach and sight of children.

Store at temperature up to 25 ° C, in original package, protected from light and moisture.

Medicines should not be disposed of via sewer, or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to preserve the environment.

Unused medicine will be destroyed in accordance with the applicable regulations.

**Shelf life**

3 years.

It should not be used after the expiration date indicated on the package.

**6. FURTHER INFORMATION**

**What does Nimulid MD contain?**

One oral dispersible tablets of Nimulid MD contains:

Active substance: nimesulide, 100 mg.

Auxiliary substances:

Mannitol;

Croscarmellose sodium-sodium;

Magnesium stearate;

Aspartame;

Silicon dioxide, colloidal anhydrous;

Sodium Starch Glycolate;

Sodium methyl parahydroxybenzoate (E219);

Sodium propyl (E 217);

Potassium sorbate;

The aroma of Orange Blossom (Trusil Orange Special).

***What it looks like and contents of the pack***

Round, biconvex, flavored, uncoated tablets, pale yellow in color.

Ten tablets in PVC-foil blister.

Blister with 10 tablets in a cardboard box.

***Regime of dispensing***

The medicine is issued on doctor's prescription

***Manufacturer***

PANACEA BIOTEC Ltd

Mathura Road, New Delhi, India

***Manufacturer of the medicinal product***

PANACEA BIOTEC Ltd

Malpur Baddi, Tehsil Nalagarh, Distt. Solan (H.P.)- 173205, India