

Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986

The medicine is dispensed with a doctor's prescription only

Mesulid® 100
Caplets

Active ingredient:

Each caplet contains: nimesulide 100 mg

For the list of the additional ingredients, see section 6. See also "Important information about some of the medicine's ingredients" in section 2.

Read the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have any further questions, please refer to the doctor or pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is the medicine intended for?

For relief of acute pains, including menstrual pains.

Therapeutic group: nonsteroidal anti-inflammatory drugs (NSAIDs)

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient (nimesulide) or to any of the additional ingredients the medicine contains (for a list of the additional ingredients, see section 6).
- You suffered in the past from an allergic reaction (hypersensitivity) after taking acetylsalicylic acid (aspirin) or other NSAIDs, that can be manifested in one or more of the following symptoms: wheezing, chest tightness, shortness of breath, bronchospasm (asthma); runny nose, nasal polyps, swelling in the nose causing blockage; skin rashes; urticaria; sudden skin or mucosal swelling, such as swelling of the face, of and around the eyes, of the lips, the mouth or the throat, possibly making breathing difficult (angioneurotic edema).
- After previous treatment with nonsteroidal anti-inflammatory drugs (NSAIDs), you suffered from bleeding and/or perforations (holes) in the digestive system (for instance in the stomach, in the intestines).
- You suffer from bleeding or active ulcers in the digestive system, or if you have suffered in the past from ulcers or bleeding in the digestive system (that occurred at least twice).
- You suffer or have suffered in the past from bleeding in the brain (stroke), from other bleeding, or from a blood clotting disturbance.
- You suffer from impaired liver function, severely impaired kidney function or severe heart failure.
- You are taking other medicines that might adversely affect the liver, e.g.: paracetamol, other pain-killers or other nonsteroidal anti-inflammatory drugs (NSAIDs).
- You suffer or have suffered in the past from dependence (addiction) to medicines, drugs or alcohol, or regularly drink large quantities of alcohol.
- You developed in the past side effects in the liver in wake of using this medicine or the use of other similar medicines.
- You are suffering from fever and/or flu symptoms (such as: generally feeling unwell, pains, chills, shivering, fever).
- You are in the last three months of pregnancy or are breastfeeding. See the "Pregnancy, breastfeeding and fertility" section.
- Use in the first or second trimester of pregnancy is not recommended. See the "Pregnancy, breastfeeding and fertility" section.

- Do not use in children under 12 years of age.

Special warnings regarding the use of the medicine:

Before (and during) treatment with the medicine tell the doctor if:

- You suffer from high blood pressure, heart problems (such as heart failure), had a stroke, or if you are at risk to suffer from these conditions (for instance if you have diabetes, high cholesterol or blood fats, or if you smoke). Nonsteroidal anti-inflammatory drugs (NSAIDs) such as Mesulid can be related to a slight increased risk of heart attacks or stroke. The risk of suffering from these conditions is related more to high doses and prolonged treatment. Do not exceed the recommended dose and/or the recommended treatment duration.
- You suffered in the past from an ulcer or bleeding from your stomach or intestines, or from inflammatory conditions of the intestines, such as ulcerative colitis or Crohn's disease.
- You suffer from kidneys or liver problems - see also the "Do not use the medicine if" section.
- You suffer from vascular, blood flow and/or blood clotting problems - see also the "Do not use the medicine if" section.

Additional warnings:

- If you develop severe allergic reactions or severe skin reactions (that sometimes might be life-threatening) discontinue the use upon the appearance of the first symptom and refer to the doctor. The symptoms can include skin rash, lesions in soft tissues (mucosal wounds) and any other sign suspected as allergy. See also the "Side effects" section.
- Do not take the medicine, and in any case do not do so without consulting a doctor if, after taking Mesulid (or another medicine containing the active ingredient nimesulide), you have ever developed a skin reaction manifested in round or oval patches of redness and swelling of the skin, blistering, urticaria/hives and itching. The reaction is called fixed drug eruption.
- Nonsteroidal anti-inflammatory drugs (NSAIDs) might cause severe side effects in the digestive system that can at times be life-threatening (especially in the elderly) and include bleeding, ulcers and perforations. Discontinue use immediately if you notice bleeding (causing tar-colored stools) or ulcers in your digestive system (causing abdominal pain). See also the "Side effects" section.
- In rare cases the medicine may cause severe side effects in the liver, which can be life-threatening in very rare cases. If during treatment with Mesulid you develop symptoms that may suggest liver problems, such as: lack of appetite, nausea, vomiting, abdominal pain, persistent tiredness, dark urine; abnormal liver function test results - stop taking the medicine and refer to the doctor immediately. See also the "Side effects" section.
- If during the treatment with Mesulid you develop fever and/or flu-like symptoms (feeling generally unwell, pains, chills, shivering), stop using it and refer to the doctor.
- The elderly may be more sensitive to the side effects of nonsteroidal anti-inflammatory drugs such as Mesulid. The doctor may want to perform medical monitoring to make sure that the medicine is not causing stomach, kidneys, liver or heart problems.
- The medicine should be used with the minimal effective dose and for the minimal time period required to control the symptoms, as determined by the doctor, in order to reduce the risk of side effects.
- If you think there is no improvement in your condition, refer to the doctor.
- Consult the doctor on the need to concomitantly take medicines intended for the protection of the digestive system.
- If you are to undergo surgery (including dental) inform the doctor you are taking this medicine.
- The medicine serves as second-line treatment after the doctor's assessment of the benefit from its use in relation to the risk.

Children and adolescents: This medicine is not intended for children under 12 years of age.

Drug interactions:

If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell the doctor or pharmacist. Especially inform the doctor or pharmacist if you are taking the following medicines (it should be noted that the following list indicates the active ingredients in the medicines. If you are unsure whether you are using one of these medicines, please consult with the doctor or pharmacist):

- Corticosteroids, methotrexate, cyclosporin.
- Blood thinners, such as: anticoagulants (e.g. warfarin), antiplatelet medicines, acetylsalicylic acid (aspirin) or other salicylates.
- Medicines for treating high blood pressure, such as: ACE inhibitors or angiotensin II receptor blockers, diuretics (such as furosemide).
- Lithium, medicines of the SSRIs group (to treat depression).
- Do not use Mesulid if you are taking other medicines that might adversely affect the liver, e.g.: paracetamol, other pain-relievers or other nonsteroidal anti-inflammatory drugs (NSAIDs).

Use of the medicine and food

Take the medicine after a meal.

Use of the medicine and alcohol consumption

Do not drink alcohol during the treatment period with this medicine.

Pregnancy, breastfeeding and fertility

Do not use the medicine without consulting the doctor if you are pregnant, are planning a pregnancy, think you are pregnant or if you are breastfeeding.

- If you are planning a pregnancy, tell the doctor, since the medicine may impair fertility.
- Do not use Mesulid in the last three months of the pregnancy since this might harm the baby and also endanger the mother during childbirth. It can cause kidney and heart problems in the unborn baby. It may affect the mother's and the baby's tendency to bleed and cause labour to be later or longer than expected.
- Use in the first or second trimester of pregnancy is not recommended unless absolutely necessary and advised by your doctor. If you need treatment with Mesulid during this period in the pregnancy or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If the medicine is taken for a period of more than a few days from 20 weeks of pregnancy onward, there is a risk of a possible side effect of kidney damage in the unborn baby and low levels of amniotic fluid that surrounds the unborn baby (oligohydramnios) or narrowing of a blood vessel in the heart of the unborn baby. It is recommended to avoid using medicines from the NSAIDs group starting from the 20th week of pregnancy and to consult a healthcare professional if necessary. If you need treatment with the medicine from the 20th week of pregnancy and onward for longer than a few days, the doctor may recommend additional monitoring, such as ultrasound. If the doctor decided on the need to take the medicine, do not exceed the dosage and duration of treatment recommended by the doctor.
- Do not use Mesulid during the breastfeeding period.

Driving and use of machinery: If you feel dizziness, vertigo or drowsiness during the use of the medicine, do not drive or operate machinery.

Important information about some of the medicine's ingredients

Each caplet contains approximately 153 mg of lactose. If you have intolerance to certain sugars, consult the doctor before taking the medicine.

The caplet contains hydrogenated castor oil which may cause abdominal pain and diarrhea.

3. How to use the medicine?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are unsure about the dosage and the manner of treatment with the medicine. The dosage and manner of treatment will be determined by the doctor only.

The standard dosage is usually:

Adults over 12 years of age: one caplet twice daily after a meal.

Do not exceed the recommended dose.

Use this medicine at set times as determined by the attending doctor.

Mesulid is intended for short-term treatment. Use the medicine for the shortest time period possible and up to 15 days only.

Manner of use:

There is no information on crushing/chewing of the caplet.

The caplet may be halved according to the scored line.

Swallow the medicine with water.

If you have accidentally taken a higher dosage, or if you are not sure whether you have taken a higher dosage, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or a hospital emergency room and bring the package of the medicine with you. Overdose symptoms can include: drowsiness, apathy, nausea, vomiting, abdominal pain, stomach or digestive system bleeding, breathing difficulties. In rare cases, anaphylactic reactions, high blood pressure, acute kidney failure, respiratory depression and coma may occur.

If you forgot to take the medicine: Do not take a double dose to make up for the forgotten dose.

Adhere to the treatment as recommended by the doctor. Even if there is an improvement in your state of health, do not stop the treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions concerning the use of the medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of Mesulid may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

Stop taking the medicine and refer to the doctor immediately if the following symptoms appear which could indicate rare and severe side effects requiring immediate treatment (such as: allergic reaction or severe skin reaction, liver problems, bleeding or ulcers in the digestive system - see also "Warnings" section):

- Stomach discomfort or pain, lack of appetite, nausea, vomiting, bleeding from the stomach or bowel, black stools.
- Skin disorders, such as rash or redness.
- Wheezing or shortness of breath.
- Yellowing of the skin and/or whites of the eyes (jaundice).
- Unexpected change in the amount or color of urine.
- Swelling of the face, legs or feet.
- Persistent tiredness.

Side effects (including frequencies):

Common side effects (appear in 1-10 users out of 100):

Diarrhea, nausea, vomiting, minor changes in liver function blood tests (increase in liver enzymes).

Uncommon side effects (appear in 1-10 users out of 1,000):

Shortness of breath, dizziness, high blood pressure, constipation, wind, stomach inflammation, itchiness, rash, sweating (increased sweating), swelling (accumulation of fluids, edema), bleeding from the digestive system, intestinal and/or stomach ulcers and/or perforation.

Rare side effects (appear in 1-10 users out of 10,000):

Anemia, decrease in white blood cells, increase in a certain type of white blood cells (eosinophils), blood pressure changes, bleeding, pain and discomfort in passing urine, difficulty in passing urine, blood in the urine, increase in potassium in the blood, feeling of anxiety or nervousness, nightmares, blurred vision, accelerated pulse (tachycardia), flushing, hot flushes, reddening of the skin, skin inflammation, feeling generally unwell, tiredness.

Very rare side effects (appear in less than 1 user out of 10,000):

Severe skin reactions, such as: erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis causing blisters and feeling generally very unwell; urinary retention, small amount of urine, kidneys failure or kidney inflammation; impairment of brain functioning (encephalopathy and Reye's syndrome), decrease in blood platelets causing bleeding under the skin or in other parts of the body; decrease in blood cells (white, red, platelets), black stools due to bleeding; liver inflammation that may sometimes be very severe and cause jaundice and stoppage of bile flow; allergic reactions (including anaphylactic reaction) that can include severe reactions with cardiovascular collapse and wheezing; bronchospasm, asthma; decrease in body temperature; spinning sensation (vertigo), headaches, sleepiness; abdominal pain; digestion difficulties; inflammation/sores in the mouth; itchy rash (urticaria/hives); swelling of the facial area, angioneurotic edema, visual disturbances.

Side effects of unknown frequency (effects whose frequency has not yet been determined):

A reaction called fixed drug eruption: manifested in round or oval patches of redness and swelling of the skin, blistering, urticaria/hives and itching.

Additional side effects related to the use of medicines such as Mesulid:

Worsening of inflammatory bowel diseases, vomiting blood, heart failure, slight increase in risk of heart attack or stroke - also see "Warnings".

If a side effect appears, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: store below 25°C.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Lactose, cellulose microcrystalline, sodium starch glycolate, hydrogenated castor oil, docusate sodium, magnesium stearate, hydroxypropyl cellulose.

What does the medicine look like and what does the package contain?

White caplets with a scored line.

The caplets are packaged in blister packs of 10, 20 or 30 caplets per box. Not all package sizes may be marketed.

Manufacturer and registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.

Medicine registration number in the National Medicines Registry of the Ministry of Health: 0682727431

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