

PACKAGE LEAFLET: INFORMATION FOR THE USER

ANDOL 100

100 mg tablet

ACETYLSALICYLIC ACID

• 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 Andol 100 tablets is and what it is used for
2. Before you take Andol 100 tablets
3. How to take use Andol 100 tablets
4. Possible side effects
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1. WHAT ANDOL 100 IS AND WHAT IT IS USED FOR

The active substance in Andol 100 tablets is Acetylsalicylic acid.

According to anatomical - therapeutic - chemical classification (ATC), it belongs to the group B01AC06, which refers to the pharmacotherapeutic group: Antithrombotic drugs, platelet aggregation inhibitors, except for heparin.

Andol 100 is used for the prevention and treatment of myocardial infarction and stroke; additional treatment of unstable angina and short-term disturbances of cerebral circulation. It is also used after surgery on blood vessels in order to maintain their flowability.

2. BEFORE YOU TAKE ANDOL 100

Do not take ANDOL 100

If the answer is YES to any of these questions do not take Andol:

- Have you ever had an allergic reaction to an ingredient of Andol 100 tablet?
- Have you had an allergic reaction to other nonsteroidal anti-inflammatory medicine?
- Do you have bronchial asthma?
- Do you suffer from diseases of the upper digestive system, such as gastritis and gastric and duodenal ulcers?

- Do you have an inherent increased tendency to bleed?
- Do you have a serious kidney or liver disease?
- Do you suffer from gout?
- Are you in the last trimester of pregnancy (daily doses over 100 mg)?
- Do you receive methotrexate at a dose of 15 mg / week or more?

Take special care with ANDOL 100, so you must tell the doctor if you

- are taking other anticoagulant drugs
- have liver or kidney problems
- are suffering from diseases of the digestive system, such as gastritis and gastric and duodenal ulcers
- have bronchial asthma
- have had allergic reactions related to the use of any anti-inflammatory painkillers
- are pregnant, trying to get pregnant or breast-feeding

Taking other medicines

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

Tell your doctor if you are taking:

- antacids (medicines for the neutralization of gastric juice), as they may reduce the effect of Andol 100
- anticoagulant drugs (heparin, ticlopidine, clopidogrel or other anticoagulants), because they may increase tendency to bleed
- uricosurics (eg, probenecid)
- other NSAIDs
- medicines for diabetes (oral hypoglycaemic agents from the group of sulfonylureas), methotrexate, or valproic acid because Andol 100 may enhance their effect
- medicines against transplant rejection (cyclosporine and tacrolimus)
- medicines for high blood pressure (eg, diuretics and ACE-inhibitors)
- methotrexate, corticosteroids, acetazolamide, sodium valproate, phenytoin, digoxin, barbiturates, lithium.

CAUTION!

Avoid alcohol while taking Andol 100 because it enhances the harmful effect of salicylic acid on the lining of the digestive system.

Due to the risk of Reye's syndrome Andol is not recommended for the use in children under 16 who have a fever or other symptoms of viral infections, especially flu or chickenpox.

Andol should be avoided 5 days before surgery, because of possible increased bleeding tendency.

Pregnancy and breast-feeding

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

Pregnancy

Although clinical application, and epidemiological data suggest that Acetylsalicylic acid is safe for use during pregnancy, talk to your doctor about the use of Andol 100 during pregnancy.

Breastfeeding

Patients who are breastfeeding should avoid taking Acetylsalicylic acid.

3. HOW TO TAKE ANDOL 100

Andol 100 tablets should be swallowed with water.

Andol 100 should be taken as instructed.

The usual dose is 1 tablet of Andol 100 per day.

In the case of overdosing it is necessary to urgently contact the doctor, although symptoms can occur up to 24 hours after taking an overdose of the medicine.

Symptoms of overdose may include ringing in ears, dizziness, nausea, vomiting, hyperventilation, disorientation, sweating and tremors. A large overdose can lead to convulsions, hyperthermia, metabolic acidosis, hyper / hypoglycemia, hypokalemia, dehydration, pulmonary edema, rhabdomyolysis and arrhythmia.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ANDOL 100 can cause side effects, although not everybody gets them.

Although Andol 100 is well tolerated, in some people it can cause certain side effects.

The most common are indigestion, abdominal pain, nausea and vomiting. In some people it may cause damage to the gastric mucosa, and possible bleeding from the digestive system.

More rarely, it can cause skin hypersensitivity reactions such as rash, urticaria and pruritus, and other hypersensitivity reactions such as hay fever of allergic origin, angioedema and bronchospasm.

Anemia occurs rarely, most often in patients glucose-6-phosphatase deficiency.

the bleeding is possible (eg. from the nose, gums, or skin).

Reye's syndrome is a very rare but serious side effect, manifested as a damage to the liver and brain.

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 ANDOL 100

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use ANDOL 100 after the expiry date which is stated on the label, 24 months from the date of manufacture.

6. FURTHER INFORMATION

What ANDOL 100 contains

One tablet contains 100 mg of acetylsalicylic acid in a buffered form.

Andol tablets also contain the following ingredients: magnesium oxide; maize starch; gelatin; maize starch, pregelatinised; microcrystalline cellulose; talc.

What ANDOL 100 looks like and contents of the pack

Andol 100 tablets are white to almostwhite, marbled round tablets with the letter P on one side and notch on the other side.

Andol 100 tablets are packed in blisters of 10 tablets, 2 blisters in a box.

Regime of dispensing

The medicine is issued without a doctor's prescription.

Manufacturer

PLIVA Croatia Ltd.

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