

PACKAGE LEAFLET: INFORMATION FOR THE USER

ANDOL 300

300 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 300 tablets is and what it is used for
2. Before you take Andol 300 tablets
3. How to take use Andol 300 tablets
4. Possible side effects
5. How to store Andol 300 tablets
6. Further information

1. WHAT ANDOL 300 IS AND WHAT IT IS USED FOR

The active substance in Andol 300 tablets is Acetylsalicylic acid.

It belongs to the group N02BA01 which comprises general analgesics and antipyretics (Salicylic acid and derivatives). Andol 300 is used for the treatment of moderately strong pain of various causes (headache, toothache, nerve inflammation, ischialgia, inflammatory rheumatic diseases, muscle pain, pain after surgery, injury or burns, painful menstruation). It is also used for the treatment of fever caused by flu and colds.

2. BEFORE YOU TAKE ANDOL 300

Do not take ANDOL 300

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 300 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 (except in very limited indications, approved by a specialist)?
- Is the patient under 6 years (risk of accidental inhalation the tablet)?

Take special care with ANDOL 300, 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 heavy and prolonged menstrual bleeding
- are using intrauterine contraceptive devices
- are taking other anticoagulants together with salicylates in high doses
- 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 300
- 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 300 may enhance their effect
- medicines against transplant rejection (cyclosporine and tacrolimus)
- medicines for high blood pressure (eg, diuretics and ACE-inhibitors)

CAUTION!

Avoid alcohol while taking Andol 300 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 300 during pregnancy.

Breastfeeding

Patients who are breastfeeding should avoid taking Acetylsalicylic acid.

3. HOW TO TAKE ANDOL 300

Andol 300 tablets should be swallowed with water.

Andol 300 mg tablet is taken if necessary.

Adults

The usual dose is 1 to 2 tablets, and it may be repeated every 4 to 6 hours.

The maximum daily dose of acetylsalicylic acid is 3 g.

Children

Children weighing between 30 and 50 kg (around 9 to 15 years of age): The recommended daily dose of acetylsalicylic acid is around 60 mg / kg, divided into 4 to 6 doses, ie. around 15 mg / kg every 6 hours or 10 mg / kg every 4 hours.

Andol 300 mg tablets should not be given to children younger than 16 years without the doctors' recommendations.

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 Fever, hyperventilation, ketosis, respiratory alkalosis, metabolic acidosis, coma, cardiovascular shock, respiratory failure, severe hypoglycemia. Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ANDOL 300 can cause side effects, although not everybody gets them.

Although Andol 300 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 300

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use ANDOL 300 after the expiry date which is stated on the label, 24 months from the date of manufacture.

6. FURTHER INFORMATION

What ANDOL 300 contains

One tablet contains 300 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; silica, colloidal anhydrous.

What ANDOL 300 looks like and contents of the pack

Andol 300 tablets are white to almostwhite, marbled round tablets with the inscription PLIVA on one side.
Andol 300 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.

Manufactuer

PLIVA Croatia Ltd.

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