

PACKAGE LEAFLET: INFORMATION FOR THE USER

ANDOL GR 100

100 mg, gastro-resistant 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?

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1. WHAT ANDOL GR 100 IS AND WHAT IT IS USED FOR

Andol GR 100 gastro-resistant tablets contain acetylsalicylic acid which, in lower doses, belongs to a group of medicines known as antithrombotics that prevent the accumulation and adhesion of platelets and thereby prevent formation of blood clots. Platelets are blood cells that cause blood clotting, and participate in the creation of a blood clot (thrombosis). If a blood clot develops in an artery, it prevents blood flow and oxygen supply. If this occurs in the heart it may lead to heart attack or angina pectoris (chest pain), and if it occurs in the brain, to a brain stroke.

Andol GR 100 is intended for the reduction of risk of the formation of blood clots, thereby preventing:

- heart problems
- stroke
- cardiovascular problems in patients with stable or unstable angina pectoris.

Andol GR 100 is also applied for the prevention of blood clots after certain operations on the heart, to expand the blood vessels.

This medicine is not recommended for the use in emergency medical conditions, but only in the preventive treatment.

2. BEFORE YOU TAKE ANDOL GR 100

Do not take ANDOL GR 100

- if you are allergic to acetylsalicylic acid or to any of the ingredients of Andol GR 100 (see section 6. "Further information"),
- if you are allergic to other salicylates or nonsteroidal anti-inflammatory drugs, which are often used to treat inflammation of the joints (arthritis) or rheumatism and for pain relief,
- If you have had an asthma attack or the appearance of swelling on some part of the body, for example, on the face, lips, throat or tongue (angioedema) after taking salicylates or NSAIDs,
- if you have or have ever had a stomach or small intestine ulcer, or any kind of bleeding,
- If you have ever had problems with blood clotting,
- If you have serious problems with your liver or kidneys,
- If you are taking methotrexate (a drug for the treatment of cancer or rheumatoid arthritis) at doses higher than 15 mg per week,
- If you are in the last trimester of pregnancy you should not take the dose of Andol GR 100 higher than 100 mg per day (see section "Pregnancy and lactation").

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

- are taking other anticoagulant drugs
- have heart, liver or kidney problems
- have ever had problems with your stomach or small intestine
- have high blood pressure
- have asthma, hay fever, nasal polyps or other chronic diseases of the respiratory system
- have ever had a gout attack
- have heavy menstrual bleeding
- are pregnant, trying to get pregnant or breast-feeding

You should seek immediate medical advice if your symptoms get worse or if you experience serious or unexpected side effects such as abnormal bleeding, serious skin reactions or any other symptoms of severe hypersensitivity reactions (see section "Possible side effects").

Tell your doctor if you have scheduled surgery (even a minor procedure such as tooth extraction) because Andol GR 100 dilutes the blood and thereby increases the risk of bleeding.

Due to the risk of Reye's syndrome Andol is not recommended for the use in children under 16.

You must ensure that you stay hydrated while taking Andol GR 100 (you can feel the thirst and have dry mouth) because the use of acetylsalicylic acid may damage kidney function.

This medicine is not suitable for pain relief or lowering the fever.

If any of the abovementioned applies to you or if you are not sure, consult your doctor or pharmacist.

Taking other medicines

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

Simultaneous use of Andol GR 100 and certain medications can affect the treatment effect.

This applies to medicines for:

- blood-thinning / prevention of the formation of blood clots (warfarin, heparin, clopidogrel)
- prevention of organ rejection after transplantation (cyclosporine, tacrolimus)
- high blood pressure (diuretics and angiotensin-converting)
- regulation of heart rate (digoxin)
- manic depression (lithium),

- relieve of pain and inflammation (non-steroidal anti-inflammatory drugs such as ibuprofen or steroids),
- treatment of gout (probenecid)
- epilepsy (valproate, phenytoin)
- treatment of glaucoma (acetazolamide),
- treatment of cancer or rheumatoid arthritis (methotrexate; at doses less than 15 mg per week),
- diabetes (glibenclamide)
- depression (selective serotonin reuptake inhibitors such as sertraline, or paroxetine),
- use in hormone replacement therapy in the case of reduced function of the pituitary gland or the adrenal gland and in the case of their surgical removal,
- treatment of inflammation, including rheumatic diseases and intestinal inflammation (steroids).

Taking Andol GR 100 with food and drink

Alcohol may increase the risk of bleeding in the digestive system and prolong the bleeding time.

Pregnancy and breast-feeding

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

- Pregnant women should not take acetylsalicylic acid, unless they have been advised by a doctor.
- Andol GR 100 must not be taken if you are in the third trimester of pregnancy unless you have been advised by a doctor, and even then the daily dose should not exceed 100 mg.
- Regular use of this product, as well as the use of higher doses in late pregnancy, can cause serious complications for the mother and child.

Breastfeeding

Patients who are breastfeeding should avoid taking Acetylsalicylic acid.

Driving and using machines

Andol GR 100 should not affect your ability to drive and use machines.

3. HOW TO TAKE ANDOL GR 100

If you are not sure how to take the medicine, ask your doctor or pharmacist for advice.

Adults

Preventing heart problems:

The recommended dose is 1 tablet, once a day.

Preventing stroke:

The recommended dose is 1 tablet, once a day.

Preventing cardiovascular problems in patients with stable or unstable angina pectoris:

The recommended dose is 1 tablet, once a day.

Preventing blood clots after certain heart surgeries:

The recommended dose is 1 tablet, once a day.

Elderly patients

The dosage is the same as in adults. Generally, Andol GR 100 should be used with caution in elderly patients who are more prone to develop side effect. The course of treatment should be monitored at regular intervals.

Children

Andol GR 100 mg tablets should not be given to children younger than 16 years without the doctors' recommendations.

Method of administration

For oral use.

The tablet should be swallowed whole with a sufficient amount of liquid.

The tablets have gastro-resistant coating that prevents stomach irritation, and therefore should not be crushed, broken or chewed.

If you take more Andol GR 100 than you should

If you (or someone else) accidentally take too many tablets, immediately tell your doctor or go to the nearest emergency room. Take the remaining tablets or the packaging so you can show it to the doctor.

Symptoms of overdose may include ringing in ears, hearing problems, headaches, dizziness, confusion, nausea and abdominal pain. A large overdose can lead to shortness of breath, fever, sweating, restlessness, convulsions, hallucinations, drop in blood sugar levels, coma and shock. Talk to your doctor or pharmacist if you have any additional questions.

If you forget to take Andol GR 100

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.

4. POSSIBLE SIDE EFFECTS

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

If you notice any of the following serious side effects, stop taking the medicine and consult a doctor immediately:

- sudden wheezing, swelling of the lips, face or body, rash, fainting or difficulties in swallowing (severe hypersensitivity reaction)
- redness of the skin with blistering or peeling, followed by fever and joint pain; these symptoms may indicate conditions such as polymorphic erythema, Stevens-Johnson syndrome or Lyell's syndrome
- unusual bleeding, such as coughing out blood, vomiting blood, blood in the urine or stool (dark stool).

Other possible side effects:

Common:

- indigestion
- increased bleeding tendency

Uncommon:

- rash
- runny nose
- difficulty breathing

Rare:

- bleeding in the stomach or intestines, bleeding in the brain, altered blood counts
- nausea and vomiting
- asthma
- inflammation of blood vessels
- bruising or purple stain (skin bleeding)
- erythema polymorphic
- Stevens-Johnson syndrome and Lyell's syndrome
- hypersensitivity reactions
- unusually abundant or prolonged menstrual bleeding

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 GR 100

Keep out of the reach and sight of children.

Do not store above 25 °C.

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

6. FURTHER INFORMATION

What ANDOL GR 100 contains

One tablet contains GR 100 mg of acetylsalicylic acid.

Other ingredients: microcrystalline cellulose; maize starch; silica, colloidal anhydrous; stearic acid; Eudragit L 30 D-55 (methacrylic acid / ethyl acrylate copolymer 1: 1, polysorbate 80, sodium lauryl sulfate); triethylcitrate; talc.

What ANDOL GR 100 looks like and contents of the pack

Andol GR 100 gastro-resistant tablets are white, round, biconvex film-coated tablets.

Andol GR 100 is available in packs of 30 gastro-resistant tablets in blisters (3 blisters of 10 tablets) in a box.

Regime of dispensing

The medicine is issued without a doctor's prescription.

Manufacturer

PLIVA Croatia Ltd.

Access Baruna Filipovića 25, Zagreb, Croatia