

PACKAGE LEAFLET: INFORMATION FOR THE USER

ANDOL C

500 mg + 250 mg effervescent tablet

ACETYLSALICYLIC ACID, ASCORBIC 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 C is and what it is used for
2. Before you take Andol C
3. How to take Andol C
4. Possible side effects
5. How to store Andol C
6. Further information

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

Andol C belongs to a group of medicines called analgesics-antipyretics. These medicines relieve pain and reduce fever.

Andol C is used to relieve the symptoms of colds, flu and other infections of the upper respiratory system (fever, headache, sore throat, aching muscles and joints).

Andol C is also used to lower body temperature in case of other conditions followed by fever.

Andol C relieves mild to moderate pain of various origins: headache (including migraine), musculoskeletal pain (due to arthritis, trauma or overstrain), toothache, pain after surgery.

2. BEFORE YOU TAKE ANDOL C

Tell your doctor if you have any chronic illness, metabolic disorder, or an allergic reaction.

Do not take Andol C

- if you are allergic (hypersensitive) to Acetylsalicylic acid or to any of the other ingredients in this medicine,

- if you have had an allergic reaction to a history of the salicylates or other nonsteroidal anti-inflammatory drugs, including asthma attacks, bronchospasm, angioedema, urticaria, rhinitis,
- if you suffer from diseases of the upper digestive system, such as gastritis and gastric and duodenal ulcers,
- if you have increased tendency to bleed,
- if you have a serious kidney or liver disease,
- if you are under 12 years of age,
- if you have bronchial asthma,
- if you are in the last trimester of pregnancy.

Take special care with Andol C, so you must tell the doctor if you

- have in the past suffered from a stomach ulcer or duodenal ulcer or bleeding from the digestive system,
- The child has a fever due to infection with influenza or chicken pox,
- (Possibility of Reye's syndrome),
- have lost a lot of fluid, eg. Due to vomiting and / or diarrhea,
- suffer from kidney or liver disease,
- suffer from asthma, allergic rhinitis, chronic urticaria or other forms of hypersensitivity,
- suffer from gout or you have elevated levels of uric acid in the blood,
- suffer from lack of glucose-6-phosphate dehydrogenase,
- suffer from iron overload or some form of anemia,
- are on the restricted salt diet,
- need to have a surgery, even if it is a small one (eg, tooth extraction).

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 C and certain medications can affect the effect of some medicines. **Do not consume alcohol during treatment Andol C, because it increases the risk of damage to the digestive system.**

- Other analgesic-antipyretics, or non-steroidal anti-inflammatory drugs (because of the increased risk of damage to the digestive system).
- Methotrexate at low doses (<15 mg / week) (due to the increased risk of methotrexate toxicity).
- Medicines to thin the blood (due to the increased risk of bleeding).
- Medicines that increase the excretion of uric acid (because of the risk of weakening of their impact).
- Medicines to treat high blood pressure (because of the risk of weakening of their impact).
- ACE inhibitors, if you suffer from chronic heart failure (due to the risk of weakening of their impact).
- Thiazide diuretics (because of the risk of weakening of their impact).
- Valproic acid is used for the treatment of epilepsy (increased risk of toxicity of valproic acid).
- Glucocorticoids that are apply systemically (due to the increased risk of damage to the digestive system, because of the risk of toxicity of acetylsalicylic acid after stopping the use of glucocorticoids).
- Medicines to treat depression (tricyclic anti-depressives - because of the risk of their reduced effectiveness; selective serotonin reuptake inhibitors - because of the risk of increased bleeding tendency).
- Digoxin which is used for reinforcement of the heart rate (due to increased risk of digoxin toxicity).
- Antidiabetic agents, medicines for the treatment of diabetes.

Pregnancy and breastfeeding

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

Andol should not be taken during the last trimester of pregnancy because of the increased risk of complications for mother and child before and during birth.

3. HOW TO TAKE ANDOL C

One Andol C tablet should be dissolved in 1 deciliter of water. You should drink freshly prepared solution.

Andol C should not be used more than 3 days to lower fever without consulting a doctor.
Andol C should not be used more than 10 days in adults, or more than 5 days in children to suppress pain without consulting a doctor.

Adults

The usual single dose is 1 to 2 tablets, and it can be repeated every 4 to 6 hours up to a maximum total daily dose of 8 tablets (4 grams of acetylsalicylic acid).

Children over the age of 12

The usual single dose for children older than 12 years is 1 tablet, and it can be repeated every 6 hours up to a maximum total dose of 4 tablets a day (2 grams of acetylsalicylic acid), or the total daily dose of 60 mg / kg of body weight divided into four to six daily administrations (single dose of 15 mg / kg or 10 mg / kg).

If you take more Andol C than you should

Immediately consult your doctor or pharmacist! Single intake of 20 effervescent tablets or more, can be life threatening, especially for the elderly and children, and patients with kidney disease. Repeating a single dose of 10-15 effervescent tablets can cause chronic poisoning with acetylsalicylic acid. Typical symptoms of overdose are burning sensation and pain in the abdomen after taking the medicine, and then, after a few hours without disturbances, occur restlessness, dizziness, tremors, confusion, disorientation, vision problems and speech, mania, hallucinations, increase in body temperature, convulsions like epilepsy and loss of consciousness. Typical signs of chronic poisoning are tinnitus, hearing loss, blurred vision, headache, dizziness, confusion, excessive sweating and thirst, rapid breathing and heartbeat, nausea, vomiting and sometimes diarrhea.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, **ANDOL C** can cause side effects, although not everybody gets them.
Side effects are listed according to the following categories of frequency:

Very common: more than 1 treated person of 10
Common: 1 to 10 treated persons of 100
Uncommon: 1 to 10 treated persons of 1000
Rare: 1 to 10 treated persons of 10000
Very rare: less than 1 treated person of 10000
Not known: frequency cannot be estimated from the available data

The most common side effects during treatment with Andol C are disorders of the digestive system. The risk of their occurrence is greater with long-term use of high doses. Typically these side effects are less severe abdominal pain, heartburn, sometimes nausea, vomiting and rarely, visible (in the vomit or stool) or concealed hemorrhage (can cause anemia). With the short term administration of the recommended doses the formation of stomach or duodenum ulcers is extremely rare.

Other possible side effects include an increased tendency to bleed, but with the short term administration of the recommended doses this occurs very rarely.

It is possible for patients to experience moderate and transient elevation of liver transaminases.
Hypersensitivity reactions such as asthmatic attack (difficulty breathing, shortness of breath, cough), nasal congestion with increased discharge or swelling of the lips and / or cheeks, tongue and trachea, and skin changes (urticaria) are rare in otherwise healthy people. However, in asthmatic patients, and those that are prone to allergies, allergic rhinitis, idiopathic urticaria, or hypersensitivity are more common.

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 C

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use **ANDOL C** after the expiry date which is stated on the label.

Shelf life: 3 years.

Tablets are best used within 12 months after the first opening of the tube.

Tube should be well closed after taking the tablet.

6. FURTHER INFORMATION

What ANDOL C contains

The active substance: 1 effervescent tablet contains 500 mg of acetylsalicylic acid and 250 mg of ascorbic acid (vitamin C).

Other ingredients are citric acid, anhydrous, sodium bicarbonate, sodium carbonate, anhydrous sodium dihydrogen citrate, sodium citrate, povidone K-30, mannitol, sodium docusate, simethicone, sodium cyclamate, saccharin sodium, lemon flavor "KS" 145.

1 effervescent tablet contains 381.04 mg of sodium.

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What ANDOL C looks like and contents of the pack

Round, white tablets with a smooth surface, with a break-line on one side.

Regime of dispensing

The medicine is issued without a doctor's prescription.

Manufacturer

PLIVA d.o.o. Croatia, Access Baruna Filipovića 25, Zagreb, Croatia

Manufacturer of the medicinal product

PLIVA d.o.o. Croatia, Access Baruna Filipovića 25, Zagreb, Croatia