

Benlek 500 mg/ 38,75 mg / 50 mg tablets

metamizole sodium/ thiamine hydrochloride/ caffeine



Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor, or pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3-5 days.

What is in this leaflet

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1. What Benlek is and what it is used for

Benlek tablets are white or almost white, round, flat, with a score line on one side.

Benlek is a combination medicine composed of three active substances: metamizole, Vitamin B1 and caffeine.

Benlek has a marked pain relieving and antipyretic (fever reducing) effects, moderate anti-inflammatory action and spasmolytic activity due to metamizole.

Caffeine has a stimulating effect on the nervous system; it constricts blood vessels and lowers the intracranial pressure; it enhances the effect of metamizole by penetrating into the brain tissue.

Vitamin B1 exerts a favourable effect on the inflammatory processes in the nervous system, the conduction of the nerve impulses, and improves metabolism.

Benlek is used for the symptomatic treatment of pains of different origin:

- Headache (tension type, migraine) and toothache;
- Inflammatory and degenerative diseases of the locomotor system (rheumatic pains);
- Post-operative and post-traumatic conditions;
- Peripheral nervous system diseases (radiculitis, plexitis, neuritis, neuralgia, polyneuritis, polyneuropathies)
- Menstrual cramps.

You must talk to a doctor if you do not feel better or if you feel worse after 3-5 days.

2. What you need to know before you take Benlek

Do not take Benlek tablets:

- if you are allergic to the active substances (metamizole, caffeine, vitamin B1) or other pyrazolone derivatives, or any of the other ingredients of this medicine (listed in section 6).
- If you have a low white blood cell count (leukopenia),

low platelet count (thrombocytopenia), anemia, hepatic porphyria ;

- If you suffer from bronchial asthma; acute liver and/or kidney failure;
- If you have congenital glucose-6-phosphate-dehydrogenase deficiency

Benlek should not be used during pregnancy and lactation, or given to children under the age of 12 years.

Warnings and precautions

Talk to your doctor or pharmacist before taking Benlek if you have or have had any health problems, particularly some of the following:

- food, drug or another type of allergy;
- impaired kidney and/or liver function;
- active ulcer disease;
- glaucoma;
- rhythm disorders;
- insomnia;
- severe headache of unclear origin;
- hypertension.

Frequent or continuous use of Benlek would require blood count monitoring .

Benlek should not be taken at least 12 hours prior to administration of tests using adenosine or dipyridamole because the drug component caffeine may influence the test results.

Benlek should not be used concomitantly with other non-steroidal anti-inflammatory drugs and metamizole.

Children

The tablets should not be given to children under the age of 12 years.

Other medicines and Benlek

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Caution is required if you combine Benlek with other medicines due to metamizole content which interferes with the metabolism of some drugs.

The use of Benlek with other pain relieving, fever reducing and anti-inflammatory medicines may increase the risk of allergic reactions.

There is a risk of white blood cell reduction if Benlek is concomitantly administered with blood cell formation depressants.

Some medicines belonging to the group of neuroleptics and tranquilizers, enhance the analgesic effect of Benlek. Concomitant administration with chlorpromazine may precipitate a sudden drop in body temperature.

Some oral contraceptives and antidepressants delay the degradation of metamizole, thus increasing Benlek toxicity. Use of Benlek is not recommended in tissue transplant recipients due to the property of metamizole to decrease the blood concentration of cyclosporin A in the blood.

Concomitant administration with sympathomimetics may cause central nervous system excitation. Metamizole should not be co-administered with other non-steroidal anti-inflammatory drugs.

Benlek with food, drink and alcohol

There are no restrictions about the use of this medicinal product with food and drink .

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This medicinal product should not be given to pregnant women.

If the use of Benlek is required, breastfeeding should be discontinued as some of the drug components are excreted in breast milk.

Driving and using machines

Benlek has no influence on the ability to drive and use machines.

Benlek contains wheat starch, therefore it should not be used by patients with celiac disease (gluten enteropathy). Patients with allergy to wheat (other than celiac disease) should not use this product.

3. How to take Benlek

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Benlek is administered orally, with a sufficient amount of liquid.

The recommended dose for *adults* is: 1 tablet 3 times daily. The maximum dose for *adults* is 6 tablets/ 24 hours.

Use in children and adolescents

Children and adolescents aged from 12 to 16 years:

The recommended dose is: ½ to 1 tablet 3 times/ day.

Maximum dose for *children and adolescents aged from 12 to 16 years* is 4 tablets/ 24 hours.

The tablet can be divided into equal doses.

Treatment should not continue for longer than 3 to 5 days unless advised by a doctor.

If you take more Benlek than you should

If you take more than the recommended dose, seek immediate medical advice.

No overdose symptoms are observed if you adhere to the recommended dosing regimen. When too much of a drug is accidentally taken, the following symptoms may be observed: nausea, vomiting, excitation, insomnia, headache, vertigo, tinnitus, low urine output or no urine output in more severe cases, seizures, anemia, sudden onset of low white blood cell count.

Treatment: gastric lavage, activated carbon, laxatives. If required, symptomatic treatment may be administered. No specific antidote. Treatment should be carried out in a hospital. *If overdose symptoms occur, seek immediate medical advice.*

If you forget to take Benlek

Do not take a double dose to make up for a forgotten tablet. Take the medicine at the time for your next dose without increasing the dose.

4. Possible side effects

Side effects are listed by frequency, as follows: very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$); not known (cannot be estimated from available data).

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may occur:

Immune system disorders: skin allergic reactions (skin rash, itching, redness), in very rare cases: difficulty breathing, allergic shock or other anaphylactic reactions.

Blood and lymphatic system disorders: low white blood cell and/or platelet count ; in very rare cases: bleeding into the skin appearing as small dots, anemia.

Nervous system disorders: vertigo, increased excitability , insomnia

Cardio-vascular disorders: fast heart rate, awareness of one's own heartbeat.

Gastrointestinal disorders: loss of appetite, nausea, vomiting, decrease in bile flow, jaundice.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Benlek

Keep this medicine out of the sight and reach of children.

Store below 25°C.

Do not use Benlek after the expiry date which is stated on the carton.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Benlek contains

The active substances are:

Metamizole sodium

Thiamine hydrochloride

Caffeine

The other ingredients are: microcrystalline cellulose, wheat starch, povidone, talc, magnesium stearate, gelatin, silica gel, colloidal anhydrous .

What Benlek looks like and contents of the pack

Benlek is packaged in aluminium and plastic foil blister packs x 10 tablets/blister pack.

Two blister packs with a package leaflet are packaged in a carton box.

Marketing Authorisation Holder and Manufacturer

Acipharm EAD

130, Simeonovsko shosse Blvd., Sofia 1700, Bulgaria

This leaflet was last revised in

January, 2014