

Package leaflet: Information for the patient

Clopasa 0.5 mg tablets

(colchicine)

Read all of this leaflet carefully before you start using 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. See section 4.

What is in this leaflet

1. What Dexketoprofen-Tchaikapharma is and what it is used for
2. What you need to know before you use Dexketoprofen-Tchaikapharma
3. How to use Dexketoprofen-Tchaikapharma
4. Possible side effects
5. How to store Dexketoprofen-Tchaikapharma
6. Contents of the pack and other information

1. What Clopasa 0,5 mg is and what is it used for

Clopasa belongs to the group of medicines known as antigout drugs.

Clopasa is used for the treatment of acute gout attacks and chronic gout, prophylaxis of acute attacks when starting treatment with other medicines decreasing uric acid in blood and urine, and periodic disease (Familiar Mediterranean Fever).

2. What do you need to know before you take Clopasa:

Do not use Clopasa:

- If you are allergic to colchicine or any of the other ingredients of this medicine (included in section 6);
- If you have kidney injury;
- If you are patients undergoing haemodialysis;
- If you have severe hepatic insufficiency;
- If you have severe gastrointestinal disorders;
- If you have stomach ulcer;
- If you have heart disease;
- If you have haematological disorders;
- If you are pregnancy;
- If you have recently taken or are taking other medicines (see "Use of Clopasa with other medicines").

Warnings and precautions

Talk to your doctor or pharmacist before using Clopasa:

- If you experience symptoms like diarrhea, nausea, vomiting or abdominal pain during the treatment immediately inform your physician because treatment may need to be stopped or the

- dose to be reduced;
- If used by elderly patients, children, patients with low body weight or patients abusing alcohol;
 - A dose adjustment may be required in patients with hepatic or renal impairment;
 - Severe muscular and renal disorders may occur during chronic treatment.

If you take Clopasa, the potential side effects of this medicine on blood have to be monitored (decrease in white blood cells, platelets and red blood cells). Possibly your doctor will prescribe you regular blood tests in order to control these adverse effects.

Other medicines and Clopasa

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

Tell your doctor or pharmacist before taking colchicine if you have recently taken or are taking medicines that containing any of the following active substances. These active substances can affect the elimination of colchicine from the body:

- Medicines used for treatment of infections, as clarithromycin, erythromycin, telithromycin, azithromycin and other antibiotics of the Macrolides' group;
- Medicines used for treatment of fungal infections, as itraconazole and ketoconazole;
- Medicines used for hypertension, as verapamil and diltiazem;
- Medicines used for HIV treatment, as indinavir, nelfinavir, ritonavir and saquinavir.

If you take Clopasa with medicines used for decreasing cholesterol and triglycerids levels, as atorvastatin, simvastatin, pravastatin, fluvastatin, gemfibrozil, fenofibrate, fenofibric acid or bezafibrate, with medicines used for treatment of heart diseases as digoxine, or with immunosuppressors as ciclosporin, it may promote the appearance of muscular problems. Tell your doctor before using colchicine.

The absorption of vitamin B12 may be affected by chronic administration or high doses of colchicine. Possibly the Vitamin B12 doses may have to be increased.

Use of Clopasa with food and drink

Clopasa must not be combined with grapefruit intake, as colchicine elimination from the body may be reduced and thus be harmful for the patient.

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.

Do not take this medicine if you are pregnant.

The administration of colchicine is not recommended during breast-feeding because colchicine can pass into breast milk.

Driving and using machines

It is highly unlikely that Clopasa affects your ability to drive and using machines.

3. How to use Clopasa

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure how to take this medicine.

Doses listed below should not be exceeded.

Adults

- **Acute attack of gout**

The recommended dose is 2 tablets (1 mg of colchicine) at the first sign of the acute attack. If pain relief is not achieved, 1-2 more tablets (0,5 mg to 1 mg of colchicine) may be administered 1 or 2 hours after the first dose. Doses higher than 4 tablets (2 mg of colchicine) in 24 hours must not be administered. Doses higher than 4 tablets (2 mg of colchicine) per day have not shown better efficacy, but an increase in adverse effects.

Do not take more than 12 tablets in total in 4 consecutive days of treatment (6 mg of colchicine). If necessary, due to persistence of gout attack pain, the regime described above may be repeated after a 3 day treatment-free “wash-out” period.

- **Recommended dose for the prevention of a gout attacks, in initial therapy with allopurinol or uricosuric agents**

The recommended dose as preventive treatment of gout attacks is 1 or 2 tablets (0,5 mg to 1 mg of colchicine) per day. Your doctor will tell you how long you should take Clopasa.

- **Familial Mediterranean Fever**

The recommended dose is 2 to 4 tablets (1 mg to 2 mg of colchicine) per day. This may be divided into two daily doses or taken as a single dose. Your doctor will tell you how long you should take Clopasa.

- **Treatment of chronic gout**

The recommended dose for treatment of chronic gout is 1 or 2 tablets (0,5 mg to 1 mg of colchicine) per day. Your doctor will tell you how long you should take Clopasa.

Children and adolescents under 18 years of age

- **Acute attack of gout, prevention of gout attacks and chronic gout**

There are insufficient data to establish recommendations in this group of age.

- **Familial Mediterranean Fever**

The recommended dose in children over 12 years is 2 to 4 tablets per day. This may be divided into two daily doses or taken as a single dose.

The scoreline is only to split the tablet if you find it difficult to swallow it whole.

If you take more Clopasa than you should

If you accidentally receive more than the required dose of Clopasa ask immediately your doctor or go immediately to the nearest hospital indicating the medicine and the amount taken.

If you take doses above the recommended by your doctor, you may suffer intoxication. The overdose intoxications by colchicine are very serious.

There is no specific antidote for colchicine.

Treatment of intoxication by high intake of tablets must include the use of oral activated charcoal, gastric lavage and replacement of electrolytes intravenously.

The signs of overdose usually appear within the 24 hours after taking the medicine, but sometimes

may be delayed up to one week. Therefore, if you suspect an overdose, even without apparent signs, you must seek immediate specialised medical care.

The more frequent symptoms of toxicity are burning and discomfort in the mouth and throat; swallowing and respiratory difficulties; digestive disorders such as diffuse abdominal pain, nausea, vomiting, severe diarrhoea occasionally bloody; confusion; alopecia (loss of hair) and hypotension (decrease in blood pressure).

If you forget to take Clopasa

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

The more frequent adverse reactions are:

- Nausea, vomiting, abdominal pain and diarrhoea.
High doses can cause skin rash, severe diarrhoea, gastrointestinal bleeding and renal or hepatic disorders.

Other side effects that may be observed (with an unknown frequency) are:

- In prolonged treatment, haematological disorders as decrease in white blood cells (leucopenia), decrease in neutrophils (neutropenia), decrease in platelets (thrombocytopenia).
- Azoospermia (absence of spermatozooids)
- Alopecia (loss of hair)
- Disorders in the nerves, reversible after stopping treatment.
- Muscle disorders such as rhabdomyolysis (breakdown of muscular fibers)
- Liver damage

If any of the side effects gets serious, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via national reporting system:

Bulgarian Drug Agency
8 Damyan Gruev Str., 1303 Sofia
Tel.: +359 2 8903417
website: www.bda.bg

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Clopasa 0,5 mg

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

Do not use this medicine after the expiry date which is stated on the carton and on the label. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions. Keep in the original package in order to protect from light.

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

Composition of Clopasa

- The active substance is colchicine. Each tablet contains 0,5 mg of colchicine.
- The other ingredients (excipients) are: magnesium stearate, calcium hydrogen phosphate dihydrate, microcrystalline cellulose, silicon dioxide, colloidal anhydrous.

What the product looks like and contents of the pack

Clopasa 0.5 mg tablets are white, round, biconvex tablets with a scoreline. The scoreline is only to facilitate breaking for ease of swallowing, not to divide into equal doses.

PVC/Al blister. Packages of 20, 25, 30, 40, 50, 60 and 100 tablets.
All types of packaging cannot be put on sale.

Marketing Authorisation Holder and Manufacturer

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