

Colchicine 1mg

OPOCALCIUM
colchicine

Please read this leaflet carefully before taking this medication.

- Keep this leaflet as you may need to read it again.
- If you have any further questions or any doubt, ask your physician or pharmacist for more information.
- This medication has been prescribed for you personally. Never give it to anyone else, even if that person has the same symptoms, as it could be harmful.
- If you experience any side effects which become serious or which are not mentioned in this leaflet, refer to your physician or pharmacist.

In this leaflet:

1. What is COLCHICINE OPOCALCIUM 1 mg tablet and what is it used for ?
2. What do you need to know before taking COLCHICINE OPOCALCIUM 1 mg tablet ?
3. How do you take COLCHICINE OPOCALCIUM 1 mg tablet ?
4. What are the possible side effects ?
5. How do you store COLCHICINE OPOCALCIUM 1 mg tablet ?
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1. WHAT IS COLCHICINE OPOCALCIUM 1 mg, tablet AND WHAT IS IT USED FOR ?

ANTI-GOUT / Anti-inflammatory

This medication is indicated for :

- the treatment and prevention of gout attacks,
- other acute microcrystalline attacks,
- familial Mediterranean fever,
- Behçet's disease.

2. WHAT DO YOU NEED TO KNOW BEFORE TAKING COLCHICINE OPOCALCIUM 1 mg tablet ?

If your physician has advised you have an intolerance to certain sugars, contact him/her before taking this medication.

Never take COLCHICINE OPOCALCIUM 1 mg tablet in the following cases :

- Severe renal disease,
- Severe hepatic disease,
- Treatment with antibiotics such as pristinamycin or those of the macrolides family (telithromycin, azithromycin, clarithromycin, dirithromycin, erythromycin, josamycin, midecamycin, roxithromycin, troleandomycin, spiramycin).

IF IN DOUBT, IT IS ESSENTIAL TO ASK FOR ADVICE FROM YOUR PHYSICIAN OR PHARMACIST.

Be careful with COLCHICINE OPOCALCIUM 1 mg tablet.

Special warnings:

The use of this medication is not recommended in patients with a fructose or galactose intolerance, a Lapp lactase deficiency or a glucose or galactose malabsorption syndrome or a sucrose/isomaltase deficiency (rare hereditary diseases).

Concomitant use of Colchicine with certain antibiotics (see "Taking or using other medications") is contraindicated.

Precautions for use:

In the case of long term treatment, check the haemogram regularly.

In the event of hepatic or renal disease, CONSULT YOUR PHYSICIAN.

IF IN DOUBT, DO NOT HESITATE TO ASK FOR ADVICE FROM YOUR PHYSICIAN OR PHARMACIST.

Taking or using with other medications: If you are taking or have recently taken a different medication including those obtained without a prescription, discuss this with your physician or pharmacist especially if it is one of the following: macrolides, pristinamycin, oral anticoagulants, ciclosporine, inhibitors of HMG-CoA reductase, verapamil or protease inhibitors.

Pregnancy and breastfeeding: IF YOU ARE PREGNANT OR BREASTFEEDING, CONSULT YOUR PHYSICIAN. Seek advice from your physician or pharmacist before taking any medication.

Excipients with known effects: lactose and sucrose.

3. HOW DO YOU TAKE COLCHICINE OPOCALCIUM 1 mg tablet ?

Dosage :

Acute attacks of gout:

Dosage should be adapted to take into account efficacy results and tolerability levels.

Dosage regimen: doses of no more than 1 mg (1 tablet) should be divided into several separate daily doses.

1st day: 3 mg of colchicine (3 tablets) per day. Colchicine achieves optimal results when taken early (within 12 hours of onset). In this case, a lower dose of 2 mg of colchicine should be sufficient.

2nd and 3rd days: 2 mg of colchicine (2 tablets) per day.

4th and subsequent days: 1 mg of colchicine (1 tablet) per day.

Do not exceed maximum dose: 3 mg on the 1st day, 2 mg on the 2nd and 3rd day.

If diarrhoea develops, the dose should be decreased.

Prophylaxis for acute attacks of gout: 1 mg per day.

Other acute microcrystalline attacks, familial Mediterranean fever, Behçet's disease: 1 mg per day.

In all other cases, strictly comply with your physician's prescription.

Mode and route of administration : Oral route.

Administration frequency: This medication should preferably be taken at meal times.

If you have taken more COLCHICINE OPOCALCIUM 1 mg tablet than you should have:

in case of an overdose, CONSULT YOUR PHYSICIAN, A POISONS CENTRE OR AN EMERGENCY CARE CENTRE IMMEDIATELY, even if the state of the patient does not seem to have changed.

If you have forgotten to take your COLCHICINE OPOCALCIUM 1 mg tablet:

If you have forgotten, ignore the missing dose and continue the treatment as prescribed. Do not take a double dose

4. WHAT ARE THE POSSIBLE UNDESIRABLE SIDE-EFFECTS ?

Like all medications, COLCHICINE OPOCALCIUM 1 mg tablet may have undesirable side-effects which may not affect everyone.

- Digestive disorders (diarrhoea, nausea, vomiting), urticaria, skin rashes.
- Exceptionally : blood disorders (see "Be careful with COLCHICINE OPOCALCIUM 1 mg tablet").
- Azoospermia (absence of spermatozooids in the sperm) and neuro-muscular disorders which are reversible after cessation of treatment.

If you notice any side-effects not mentioned in this leaflet or if some undesirable side-effects become serious, please inform your physician or pharmacist.

5. HOW DO YOU STORE COLCHICINE OPOCALCIUM 1 mg tablet ?

Keep out of reach and sight of children.

Do not use COLCHICINE OPOCALCIUM 1 mg tablet after the expiry date which is stated on the box.

The expiry date refers to the last day of the month.

Store at a temperature below +25 °C and protected from light.

Medication should not be flushed down the toilet or discarded with other household waste. Ask your pharmacist how to dispose of unused medication. These steps will help to protect the environment.

6. ADDITIONAL INFORMATION

What does COLCHICINE OPOCALCIUM 1 mg tablet contain ?

The active substance is :

Crystallized Colchicine..... 1.000 mg.

For one tablet.

The other components are :

Sucrose, magnesium stearate, polyvidone, erythrosine food colouring (E127), lactose.

What does COLCHICINE OPOCALCIUM 1 mg tablet look like and what is contained in the outer packaging ?

This medication is a tablet. Box of 20 tablets.

Marketing authorization holder/owner: Laboratoires Galéniques Vernin

20 rue Louis-Charles Vernin - 77 190 DAMMARE LES LYS

Manufacturer: Sanofi Winthrop Industrie - 56 route de Choisy-au-Bac - 60 205 COMPIEGNE

The last date on which this leaflet was approved: June 2011.

Detailed information on this medication is available on Afsaps website (France).

