

# Colchicine 1mg

OPOCALCIUM

colchicine

**This leaflet should be read carefully before using this drug.**

Keep this leaflet as you should need to read it again.

Should you have any other questions or any doubt, ask your physician or pharmacist for further information. This drug was prescribed to you personally.

Never give it to somebody else even if the symptoms are the same as yours, this could be harmful.

## ■ IDENTIFICATION OF THE MEDICINE

### DENOMINATION

COLCHICINE OPOCALCIUM 1 mg, tablet

### COMPOSITION

Crystallized colchicine ..... 1 mg

Excipients : sucrose, magnesium stearate, polyvidone, erythrosin (E 127), lactose.

For a tablet of 75 mg.

### PRESENTATION FORM

Tablet. Box of 20 under blister.

### PHARMACOTHERAPEUTIC CATEGORY

ANTI-GOUT

Anti-inflammatory

### NAME AND ADDRESS OF THE M.A. HOLDER AND DISTRIBUTOR

Laboratoires Galéniques Vernin - 20, rue Louis-Charles Vernin - 77190 DAMMARIE-LES-LYS - FRANCE

### MANUFACTURER'S NAME AND ADDRESS

Sanofi Winthrop Industrie - 56, route de Choisy au Bac - 60200 COMPIÈGNE - France

## ■ CASES IN WHICH THIS DRUG CAN BE USED

This medicine is indicated for :

- prevention and treatment of gout attacks,
- familial mediterranean fever,
- Behçet disease,
- Other acute attacks of microcrystalline diseases.

## ■ CAUTION !

### CASES IN WHICH THIS DRUG MUST NOT BE USED

DO NOT USE this drug in the following cases :

- Severe renal disease,
- Severe hepatic disease.

*IF YOU HAVE ANY DOUBT, YOU MUST SEEK ADVICE FROM YOUR PHYSICIAN OR PHARMACIST.*

### SPECIAL WARNINGS

Due to lactose, you should not take this medicine in case of galactosemia, of glucose and galactose malabsorption syndrome, or in case of deficit in lactase (rare metabolic diseases).

Due to sucrose, you should not take this medicine in case of fructose intolerance, glucose and galactose malabsorption syndrome, or in case of deficit in sucrose-isomaltase (rare metabolic diseases).

The concomitant intake of colchicine with some antibiotics (see drug interactions) is not recommended.

### PRECAUTIONS FOR USE

In case of long term treatment, check the blood cells count regularly.

In case of hepatic and renal diseases, INFORM YOUR PHYSICIAN.

*IF YOU HAVE ANY DOUBT, YOU MUST SEEK ADVICE FROM YOUR PHYSICIAN OR PHARMACIST.*

## DRUG INTERACTIONS AND OTHER INTERACTIONS

This medication should not be associated with some antibiotics (pristinamycin, telithromy, azithromycin, clarithromycin, dirithromycin, erythromycin, josamycin, midecamycin, roxithromycin, troleandomycin except spiramycin).

IN ORDER TO AVOID POSSIBLE INTERACTIONS BETWEEN SEVERAL DRUGS, SYSTEMATICALLY INFORM YOUR PHYSICIAN OR PHARMACIST OF ANY OTHER CURRENT TREATMENT.

## PREGNANCY - LACTATION

IN CASE OF PREGNANCY OR LACTATION, INFORM YOUR PHYSICIAN.

## LIST OF EXCIPIENTS THAT MUST BE KNOWN TO ALLOW SAFE USE IN SENSITIVE PATIENTS

Lactose, sucrose.

## ■ HOW TO USE THIS MEDICINE

### DOSAGE

#### • Acute attacks of gout :

- 1<sup>st</sup> day : 3 tablets (1 in the morning, 1 in the midday, 1 in the evening),
- 2<sup>nd</sup> and 3<sup>rd</sup> days : 2 tablets (1 in the morning and 1 in the evening),
- 4<sup>th</sup> day and following days : 1 tablet in the evening.

#### • Acute gout attacks of microcrystalline diseases.

#### • Other acute attacks of microcrystalline diseases, familial mediterranean fever, Behçet disease :

1 tablet in the evening.

In any case, strictly comply with your physician's prescription.

## MODE AND ROUTE OF ADMINISTRATION

Oral route.

## FREQUENCY AND TIME OF ADMINISTRATION OF THE DRUG

This drug should preferably be taken during meals.

## ACTION IN CASE OF OVERDOSAGE

In case of overdosage, REFER IMMEDIATELY TO YOUR PHYSICIAN, AN ANTIPOISONING SPECIALIZED UNIT OR INTENSIVE CARE UNIT, even if the patient still seems unchanged.

## ACTION IF ONE OR SEVERAL DOSES HAVE BEEN FORGOTTEN

If a dose has been forgotten, omit the dose and carry on with the scheduled treatment. Do not take double dose.

## ■ ADVERSE REACTIONS

LIKE ANY ACTIVE PRODUCT, THIS DRUG CAN CAUSE MORE OR LESS DISTURBING EFFECTS IN SOME SUBJECTS :

- Digestive disorders (diarrhoea, nausea, vomiting), urticaria, skin rash.
- Exceptional blood disorders (cf. Precautions for use).
- Azoospermia (no spermatozoon in the sperm) and neuro-muscular disorders reversible after drug discontinuation.

INFORM YOUR PHYSICIAN OR PHARMACIST OF ANY ADVERSE REACTION THAT IS NOT MENTIONED IN THIS LEAFLET.

## ■ STORAGE

DO NOT EXCEED THE EXPIRY DATE WHICH IS CLEARLY INDICATED ON THE PACKAGING.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

## SPECIAL PRECAUTIONS OF STORAGE

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

## ■ DATE OF LEAFLET UPDATE

April 2008.