

COLCHICINE SEID 1 mg tablets

Read all of this leaflet carefully before you start taking this medicine.

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

What is in this leaflet

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2. What do you need to know before you take COLCHICINE SEID 1 mg
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1. What COLCHICINE SEID 1 mg is and what is it used for

COLCHICINE SEID 1 mg are tablets for oral administration. Each cardboard box contains 40 tablets.

COLCHICINE SEID 1 mg belongs to the group of medicines known as antigout drugs.

COLCHICINE SEID 1 mg is used in 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 COLCHICINE SEID 1 mg

Do not take COLCHICINE SEID 1 mg:

- If you are allergic to colchicine or any of the other ingredients of this medicine.
- Severe renal failure
- Patients undergoing haemodialysis

- Severe hepatic insufficiency
- Severe gastrointestinal disorders
- Stomach ulcer
- Heart disease
- Haematological disorders
- Pregnancy
- If you have recently taken or are taking other medicines (see Use of other medicines).

Special precautions with COLCHICINE SEID 1 mg

- If you have diarrhoea, nausea, vomits or abdominal pain during treatment, tell immediately your doctor because possibly your treatment has to be discontinued or the dose reduced.
- In the elderly, children and weak patients or those who abuse alcohol.
- A dose adjustment may be required in patients with hepatic or renal impairment.
- Severe muscular and renal disorders may appear with chronic treatment.

If you take Colchicine Seid, 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.

Use of other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those without prescription.

Specially tell your doctor before taking colchicine if you have recently taken or are taking medicines containing any of the following active substances, as the elimination of Colchicine Seid from the body can be impaired:

- Medicines used for treatment of infections, as clarithromycin, erythromycin, telithromycin 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 VHI treatment, as indinavir, nelfinavir, ritonavir and saquinavir.

If you take Colchicine Seid 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 vitamine B₁₂ may be affected by chronic administration or high doses of colchicine. Possibly the Vitamine B₁₂ doses may have to be increased.

Use of Colchicine Seid 1 mg with food and drink

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

Pregnancy and breast-feeding

Tell your doctor or pharmacist before taking a 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 to your baby.

Driving and using machines

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

Important information on some of the components of Colchicine Seid 1 mg

This medicine contains lactose. If your doctor has told you that you have an intolerance to certain sugars, ask him before taking it.

This medicine contains methylenecasein. If you are allergic or intolerant to cow milk protein you must not take this medicine.

3. How to take COLCHICINE SEID 1 mg

Always follow the instructions of administration of Colchicine Seid 1 mg as your doctor has told you. Check with your doctor if you are not sure.

The doses below must never be exceeded.

Oral use:

• Adults

– Acute attack of gout:

The recommended dose is 1 tablet at the first sign of the acute attack. If pain relief is not achieved, a second tablet may be



administered 1 or 2 hours after the first dose. Doses higher than 2 tablets in 24 hours must not be administered. Doses higher than 2 tablets per day have not shown better efficacy, but an increase in adverse effects.

Do not take more than 6 tablets in total in 4 consecutive days of treatment. 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.

– **Preventive treatment of gout attacks during initial therapy with allopurinol or uricosuric agents:**

The recommended dose as preventive treatment of gout attacks is 1 tablet per day. Your doctor will tell you how long you should take Colchicine Seid.

– **Periodic disease or familial Mediterranean fever:**

The recommended dose is 1 to 2 tablets 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 Colchicine Seid.

– **Treatment of chronic gout:**

The recommended dose for treatment of chronic gout is 1 tablet per day. Your doctor will tell you how long you should take Colchicine Seid.

• **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.

– **Periodic disease or familial Mediterranean fever:**

The recommended dose in children over 12 years is 1 to 2 tablets per day. This may be divided into two daily doses or taken as a single dose.

If you take more Colchicine Seid 1 mg than you should

Ask immediately your doctor or go immediately to the nearest hospital in case of overdose or accidental massive intake.

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 water and 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 Colchicine Seid 1 mg

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

4. Possible side effects

Like all medicines, Colchicine Seid 1 mg 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.

Occasionally have been detected:

- 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 controlling the muscles, reversible after stopping treatment.
- Muscle disorders such as rhabdomyolysis (breakdown of muscular fibers)

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.

5. How to store COLCHICINE SEID 1 mg

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

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the label.

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

Do not store above 30°C. Protect from moisture and 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. Other information

Composition of Colchicine Seid 1 mg

- The active substance is: Colchicine 1 mg
- The other ingredients are: lactose, microcrystalline cellulose, polyvinylpyrrolidone, methylene casein, magnesium stearate and erythrosine lacquer.

What Colchicine Seid 1 mg looks like and contents of the pack

Pack containing 2 blisters of 20 tablets each of them

Marketing authorisation holder and manufacturing responsible:

SEID, S.A.

Carretera de Sabadell a Granollers, Km. 15

08185 Lliçà de Vall, Barcelona (Spain)

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