

COLCINE

Colchicine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about COLCINE. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What COLCINE is used for

COLCINE contains colchicine as the active ingredient.

COLCINE is used for the relief of pain in acute attacks of gout. It is not an analgesic and does not provide relief from other types of pain.

COLCINE has a preventative effect that helps to reduce the incidence of acute attacks. It will not reduce the amount of uric acid in the body.

COLCINE belongs to a group of medicines called antigout drugs.

Ask your doctor if you have any questions about why COLCINE has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is only available with a doctor's prescription.

There is no evidence that it is addictive.

How COLCINE works

- Colchicine decreases leucocyte chemotaxis and phagocytosis and thereby inhibits the formation and release of a chemotactic glycoprotein that is produced during the phagocytosis of urate crystals.
- Colchicine also inhibits urate crystal deposition, which is enhanced by a low pH in the tissues, probably by inhibiting oxidation of glucose and subsequent lactic acid production in leucocytes.

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There is no evidence that it is addictive.

Before you take COLCINE

When you must not take it

Do not take COLCINE if you have an allergy to:

- any medicine containing colchicine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips or tongue; skin rash, itching or hives.

Do not give this medicine to children.

This medication may be dangerous to children. It is important that it is kept out of reach of children at all times.

Do not take COLCINE if you have:

- combined kidney and liver disease
- serious kidney or liver disease
- serious heart disease
- severe stomach disorder
- a blood disorder.

Do not take this medicine after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take this medicine if the bottle shows signs of having been tampered with.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines or any foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- stomach problems
- kidney or liver disease
- heart disease
- alcoholism.

Tell your doctor if you are pregnant or plan to become pregnant.

COLCINE may affect your developing baby if you take it during pregnancy.

Tell your doctor if you are breast-feeding or plan to breastfeed.

Your doctor will discuss the risks and benefits of you taking COLCINE when breast-feeding.

If you have not told your doctor about any of the above, tell them before you start taking COLCINE.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with COLCINE.

These include:

- cyclosporin - a medicine used to suppress the immune system
- erythromycin, clarithromycin and telithromycin - antibiotics used to treat bacterial infection
- protease inhibitors, including atazanavir, indinavir, nelfinavir, ritonavir and saquinavir, used to treat HIV and other viral infections
- ketoconazole and itraconazole, used to treat certain fungal infections
- nefazodone, used to treat depression
- acidifying and alkalising agents, such as ammonium chloride, ascorbic acid (vitamin C), sodium bicarbonate
- medicines to help you sleep
- alcohol
- NSAIDs or aspirin - anti-inflammatory drugs used to treat pain

- medicines used to treat cancer including radiation therapy
- vitamin B12
- anticoagulants such as coumarin, heparin
- antithyroid medicines.

These medicines may be affected by COLCINE or may affect how well it works. You may need to take different amounts of your medicines or you may need to take different medicines. Your doctor or pharmacist has a more complete list of medicines to be careful with or avoid while taking COLCINE.

How to take COLCINE

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much COLCINE to take.

Do not take more than your doctor tells you to.

The maximum recommended dose for treatment of gout flares is 1.5 mg over a one hour period. Do not repeat the course within 3 days.

How to take COLCINE

Swallow the tablet whole with a full glass of water.

When to take COLCINE

COLCINE may be taken before or after food.

How long to take COLCINE for

Continue taking your medicine for as long as your doctor tells you.

This will depend on your condition and your response to the treatment.

COLCINE helps to control your condition but does not cure it.

Immediately stop taking COLCINE at the first sign of stomach pain, nausea, vomiting or diarrhoea. Do this even if your symptoms have not been relieved.

If you forget to take COLCINE

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much COLCINE (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have taken too much COLCINE. Do this even if

there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

- severe nausea, vomiting, stomach pain and diarrhoea
- burning feeling or rawness in the mouth and throat
- difficulty in breathing or swallowing
- fever
- muscle weakness
- mental confusion, delirium, convulsions.

While you are taking COLCINE

Things you must do

Immediately stop taking COLCINE at the first sign of stomach pain, nausea, vomiting or diarrhoea. Do this even if your symptoms have not been relieved.

Remember to take note of the number of tablets you took before the onset of these symptoms so that you can take fewer tablets during subsequent attacks.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking this medicine, especially if you are being started on any new medicines.

Tell your doctor, surgeon or anaesthetist that you are taking COLCINE if you are about to undergo surgery or an operation.

Tell your doctor immediately if you become pregnant while taking COLCINE.

If you are about to have any blood tests remind your doctor that you are taking COLCINE.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take COLCINE to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how COLCINE affects you.

Check with your doctor or pharmacist before drinking alcohol while you are taking COLCINE.

If you drink alcohol while taking this medicine, you may develop stomach problems.

This medication may be dangerous to children. It is important that it is kept out of reach of children at all times.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking COLCINE.

This medicine helps most people with gout, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

If you are elderly you may have an increased chance of getting side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Immediately stop taking COLCINE at the first sign of stomach pain, nausea, vomiting or diarrhoea. Do this even if your symptoms have not been relieved.

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- loss of appetite
- loss of hair.

The above list includes more serious side effects which may require medical attention.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following symptoms:

- burning feeling in the stomach or throat
- severe stomach pain, nausea, vomiting
- severe diarrhoea with bloody or black tarry stools
- itchy skin, skin rash, hives, unusual bleeding or bruising under the skin
- difficulty in passing urine or blood in urine
- confusion, convulsions
- fever
- muscle weakness
- numbness or weakness in the fingers and toes.

These are all very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Some people may get other side effects while taking COLCINE. Some of these side effects (e.g. changes in thyroid function or in the blood) can only be found when your doctor does tests from time to time to check your progress.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking COLCINE

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C. Protect from light.

Do not store COLCINE or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking COLCINE or the expiry date has passed,

ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

COLCINE Round, off white coloured biconvex, uncoated tablets embossed "C5" on one upper side and plain on the bottom face.

COLCINE available in a

- Al/Al blister pack containing 30 tablets & 100 tablets
- HDPE bottle of 30 tablets.

Ingredients

Active ingredient:

COLCINE

Each uncoated tablets contain 500 microgram of colchicine as the active ingredient.

Inactive ingredients:

- pregelatinised maize starch
- microcrystalline cellulose
- lactose monohydrate
- sodium starch glycollate
- magnesium stearate

This medicine contains lactose

Sponsor

COLCINE is supplied in Australia by:

Pharmacor Pty Ltd.

CHATSWOOD, NSW 2067,

Australia

www.pharmacor.com.au

Australian Registration Numbers

COLCINE 500 MICROGRAM

bottle pack– AUSTR 335430

Blister pack-AUSTR 335431

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