

SCHEDULING STATUS:

S2

COLNOVA 0,5 mg tablets**Colchicine****Contains sugar (49 mg lactose monohydrate) per tablet****Read all of this leaflet carefully because it contains important information for you**

COLNOVA 0,5 is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use COLNOVA 0,5 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share COLNOVA 0,5 with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

1. What COLNOVA 0,5 is and what it is used for
2. What you need to know before you take COLNOVA 0,5
3. How to take COLNOVA 0,5
4. Possible side effects
5. How to store COLNOVA 0,5
6. Contents of the pack and other information

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

The active ingredient in COLNOVA 0,5 tablets is colchicine and is an anti-gout medicine.

COLNOVA 0,5 is used to treat gout attacks in adults in cases of emergency.

2. What you need to know before you take COLNOVA 0,5

Do not take COLNOVA 0,5:

- if you are hypersensitive (allergic) to colchicine or any of the other ingredients of COLNOVA 0,5 (listed in section 6);
- if you are undergoing haemodialysis;
- if you have severe kidney problems;
- if you have severe liver problems;
- if you have a severe blood disorder as COLNOVA 0,5 can cause a decrease in production of your red blood cells, white blood cells and blood platelets;
- if you are suffering from any severe liver impairment and taking the following medicines:
 - Clarithromycin, erythromycin or telithromycin (used to treat infections).
 - Ciclosporin (used to prevent organ rejection after a transplant, psoriasis and rheumatoid arthritis).
 - Ritonavir, atazanavir or indinavir (used to treat HIV infection).
 - Ketoconazole or itraconazole (used to treat fungal infections).
 - Verapamil and diltiazem (used to treat high blood pressure or angina).
 - Quinidine (used to treat abnormal heart rhythms).
- if you are pregnant or you are breastfeeding your baby;
- if you are a woman of childbearing age, unless you are using effective contraception.

Warnings and precautions

Take special care with COLNOVA 0,5:

- COLNOVA 0,5 can be toxic, so it is important that you do not exceed the dose prescribed by your doctor.
- If you get symptoms such as nausea (feeling sick), vomiting (being sick), stomach pain and diarrhoea, stop taking COLNOVA 0,5 and immediately contact your doctor (see also section 4 'Possible side effects').
- COLNOVA 0,5 can cause a serious decrease in bone marrow function leading to a decrease in certain white blood cells (agranulocytosis), a decrease in red blood cells and pigment (aplastic anaemia) and/or a low blood platelet count (thrombocytopenia). You should have regular blood tests to monitor any changes.

- If you develop symptoms such as fever, inflammation of the mouth, sore throat, prolonged bleeding, bruising or skin problems, stop taking COLNOVA 0,5 and contact your doctor immediately. These could be signs that you have a serious blood problem and your doctor may want you to have blood tests straight away (see also section 4 'Possible side effects').

Talk to your doctor before taking COLNOVA 0,5 if you:

- have problems with your heart, kidneys, liver or digestive system;
- are elderly and weak;
- have a blood disorder.

Other medicines and COLNOVA 0,5

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

When COLNOVA 0,5 are taken together with any of the following medicines, side effects due to colchicine toxicity are more likely and these can be serious and life-threatening:

- Certain anti-biotics such as clarithromycin, erythromycin, telithromycin and azithromycin (used to treat infections);
- Anti-viral medicines such as ritonavir, atazanavir and indinavir (used to treat HIV infection);
- Ciclosporin (used to prevent organ rejection after a transplant, psoriasis and rheumatoid arthritis);
- Anti-fungal medicines such as ketoconazole, itraconazole and voriconazole;
- Certain heart medicines such as verapamil and diltiazem;
- Disulfiram (used to help treat alcoholism).

It is also important to tell your doctor or pharmacist if you are taking any of the following medicines:

- Cimetidine (used to treat stomach problems);
- Tolbutamide (for treating Type 2 diabetes mellitus);

- Digoxin (used to treat certain heart conditions) and ‘fibrates’ (medicines used to lower cholesterol), as they may increase your risk of a muscle disease known as ‘rhabdomyolysis’. Taking COLNOVA 0,5 together with ciclosporin or ‘statins’ also increases your risk of developing this disease.

Talk to your doctor before taking COLNOVA 0,5 if you are taking any medicines that may possibly damage your kidneys, liver or blood. Check with your doctor if you are not sure.

COLNOVA 0,5 may reduce the amount of vitamin B12 that your body can absorb through your gut.

COLNOVA 0,5 with food, drink and alcohol

Grapefruit juice may increase the amount of colchicine in your blood.

Therefore, you should not drink grapefruit juice whilst you are taking COLNOVA 0,5.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking COLNOVA 0,5.

Do not take COLNOVA 0,5 if you are pregnant or breastfeeding your baby.

Driving and using machines

No details are available regarding the influence of COLNOVA 0,5 on the ability to drive and use machines.

It is not always possible to predict to what extent COLNOVA 0,5 may interfere with your daily activities. You should not drive, use machinery or perform any tasks that require concentration until you are certain that COLNOVA 0,5 does not adversely affect your ability to do so safely.

COLNOVA 0,5 contains sugar (lactose monohydrate).

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking COLNOVA 0,5.

3. How to take COLNOVA 0,5

Do not share medicines prescribed for you with any other person.

Always take COLNOVA 0,5 exactly as described in this leaflet or as your doctor or pharmacist have told you.

COLNOVA 0,5 tablets are for oral use only. Swallow the tablet whole with water.

The usual dose is one (1) or two (2) COLNOVA 0,5 tablets to start, followed by one (1) COLNOVA 0,5 tablet every 2 hours until pain is relieved or gastrointestinal symptoms such as vomiting, or diarrhoea occur.

Do not take more than twelve (12) COLNOVA 0,5 tablets as a course of treatment.

After completion of a course of COLNOVA 0,5, you should not start another course for at least three days.

If you take more COLNOVA 0,5 than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Early symptoms of overdose may include nausea, vomiting, stomach pain, bloody diarrhoea and low blood pressure. Treatment with COLNOVA 0,5 should be discontinued if one of these symptoms occur.

If you forget to take COLNOVA 0,5

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

4. Possible side effects

COLNOVA 0,5 can have side effects.

Not all side effects reported for COLNOVA 0,5 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking COLNOVA 0,5, please consult your healthcare provider for advice.

If any of the following happens, stop taking COLNOVA 0,5 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to COLNOVA 0,5. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequency unknown:

- symptoms such as fever, inflammation of the mouth, sore throat, prolonged bleeding, bruising or skin problems. These could be signs that you have a serious blood problem as a result of bone marrow depression.
- deficiency of all blood cell types: red blood cells, (white blood cells, and platelets).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- stomach pain;
- nausea;
- vomiting;
- diarrhoea;
- hair loss.

Less frequent side effects:

- inflammation of the nerves which can cause pain, weakness, tingling or numbness;
- throat burning;
- gastrointestinal bleeding;

- burning of the skin;
- hives;
- macular lesions that are red and usually 2–10 mm in diameter but may be confluent in places, in an adult it is usually due to a medicine;
- abnormal muscle breakdown which can lead to kidney problems (rhabdomyolysis);
- pain in the muscle;
- condition of a man whose semen contains no sperm.

Side effects with unknown frequency:

- nerve damage;
- lowered blood pressure;
- liver damage;
- kidney damage;
- absence of menstrual periods;
- painful periods;
- reduced ability to produce sperm (low sperm count).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of COLNOVA 0,5.

5. How to store COLNOVA 0,5

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C. Keep the tablets in the blisters until required for use.

Do not use COLNOVA 0,5 after the expiry date which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What COLNOVA 0,5 contains

The active substance is colchicine. Each tablet contains 0,5 mg of colchicine.

The other ingredients are lactose monohydrate, magnesium stearate, microcrystalline cellulose and sodium starch glycolate.

What COLNOVA 0,5 looks like and contents of the pack

Off-white to light yellow coloured, round shaped, biconvex uncoated tablets debossed with 'C' on one side and '0.5' on the other side.

COLNOVA 0,5 tablets are packaged in white opaque PVC film - Aluminium foil blister.

COLNOVA 0,5 tablets packed in above blister will be further packed in a pre-printed carton.

Blister pack sizes: 12's: containing 2 blisters of 6 tablets each.

Holder of Certificate of Registration

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