

APPROVED PATIENT INFORMATION LEAFLET FOR KOLCRYS

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

KOLCRYS 0,5 mg tablets

Colchicine

Contains sugar (50,80 mg lactose monohydrate per tablet).

Read all of this leaflet carefully because it contains important information for you

KOLCRYS is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use ACRTIN carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share KOLCRYS with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve

What is in this leaflet

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

1. What KOLCRYS is and what it is used for

KOLCRYS is used to treat acute gout attacks in cases of an emergency.

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2. What you need to know before you take KOLCRYS

Do not take KOLCRYS:

- If you are hypersensitive (allergic) to colchicine or any of the other ingredients of KOLCRYS (listed in section 6.1).
- If you are pregnant (see **Pregnancy and breastfeeding**)
- If you have kidney or liver problems.
- If you have any blood disorders.
- If you are on kidney dialysis

Warnings and Precautions

Take special care with KOLCRYS

- If you are an elderly person.

Tell your doctor:

- If you are or become weak, exhausted or worn out.
If you develop problems with your heart, kidneys, liver or digestive system.

Other medicines and KOLCRYS

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently using:

- Clarithromycin, telithromycin, erythromycin (antibiotics used to treat infections).
- Ritonavir, atazanavir (anti-viral medicine, used to treat human immunodeficiency virus (HIV) infections).
- Ciclosporin (used to prevent organ rejection after a transplant, psoriasis and rheumatoid arthritis).

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- Itraconazole, ketoconazole (used to treat fungal infections).
- Verapamil, diltiazem (used to treat high blood pressure or angina).
- Quinidine, digoxin (used to treat abnormal heart rhythms).
- Statins, fibrates (used to treat high cholesterol).
- Hydrochlorothiazide (used to treat high blood pressure).
- Vitamin B12 supplement. (as KOLCRYS may reduce the amount of Vitamin B12 that your body can absorb)
- Cimetidine (used to reduce stomach acid).
- Tolbutamide (used to control blood sugar).

KOLCRYS with food and drink

KOLCRYS can be taken with or without food.

Do not take grapefruit juice while taking KOLCRYS.

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 health care provider for advice before taking KOLCRYS.

Do not take KOLCRYS if you are pregnant.

Driving and using machines

It is not known if KOLCRYS can affect your ability to drive a vehicle and use machines. Take special care before performing tasks requiring your attention, until you know how KOLCRYS will affect you.

KOLCRYS contains lactose monohydrate

KOLCRYS contains a sugar called lactose monohydrate. If you have been told by your doctor that

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you have an intolerance to some sugars consult your doctor before taking KOLCRYS.

3. How to take KOLCRYS

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

Always take KOLCRYS exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual initial dose is 1 or 2 tablets orally, followed by 1 tablet every two hours until pain relief is obtained or until vomiting (being sick) or diarrhoea starts.

You should not take more than 12 tablets as a course of treatment.

You should wait for 3 days before starting another course of KOLCRYS.

If you are an elderly patient or your kidneys are not functioning normally, you will need a lower dose or increased interval between doses.

If you have the impression that the effect of KOLCRYS is too strong or too weak, tell your doctor or pharmacist.

If you take more KOLCRYS than you should

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

KOLCRYS is extremely toxic in overdose, and you are more at risk of toxicity if you have kidney or liver damage, gastrointestinal or heart problems or if you are elderly.

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Symptoms:

Symptoms of overdose may not appear for at least 6 hours.

The first symptoms of toxicity are a feeling of burning and rawness in the mouth and throat, and difficulty in swallowing. This is followed by nausea (feeling sick), vomiting (being sick), and diarrhoea which can be severe or bloody leading to dehydration and low blood pressure (you may feel extremely thirsty or faint). A burning sensation of the stomach and skin may also occur. Very serious vascular (vein and artery) damage and kidney toxicity (e.g. abnormal small amounts of urine) may occur. Multiple organ failure may occur and may present as central nervous system (nerve tissues that control the activity of the body) toxicity, bone marrow depression (fever, prolonged bleeding, bruising or skin problems), liver damage, (yellowing of the skin and whites of the eyes, also called jaundice) muscle damage, (pain, swelling, stiffness, weakness) respiratory distress (fast breathing, shortness of breath, or rapid breathing), heart injury (pain in the chest, back, jaw and other areas of the upper body).

You may develop convulsions (fits), delirium (confused thinking), neuropathy (weakness, numbness and pain from nerve damage, usually in the hands and feet), paralysis or sepsis (condition caused by the body's response to an infection). Hair loss, if you previously had leucocytosis (a condition where you have too many white blood cells) it may return, and stomatitis (inflammation of the mouth and lips) may occur about 10 days after the overdose.

Take this leaflet and the rest of the remaining tablets with you so the doctor will know what you have taken.

4. Possible side effects

KOLCRYS can have side effects.

Not all side effects reported for KOLCRYS are included in this leaflet. Should your general health worsens, or if you experience any untoward effects while taking KOLCRYS,

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please consult your healthcare provider for advice.

If any of the following happens, stop taking KOLCRYS 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 reaction to KOLCRYS. 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:

- Gastrointestinal haemorrhage (loose stool with blood in it).
- Kidney damage (passing less urine than is normal).
- Liver damage (yellowing of the skin and whites of the eyes, also called jaundice).
- Problems with your bone marrow which can lead to fever, prolonged bleeding, bruising or skin problems, fatigue, frequent infections or rapid heart rate.
- A breakdown of muscle tissue which can lead to kidney problems. Symptoms include dark, reddish urine, a decreased amount of urine, weakness and muscle aches.

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

Tell your doctor if you notice any of the following:

Frequent:

- Stomach pain.
- Nausea (feeling sick).

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- Vomiting (being sick).
- Diarrhoea.

Side effects of unknown frequency:

- Weakness, numbness and pain from nerve damage, usually in the hands and feet.
- Hair loss.
- Rash.
- Burning sensation of the skin.
- Muscle weakness.
- Absence of menstrual period or painful menstrual periods.
- Reduced ability to produce sperm, or low or zero sperm count.
- Burning sensation in the throat.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist.

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 KOLCRYS.

5. How to store KOLCRYS

- Store at or below 30 °C.
- Protect from light and moisture.

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- Do not remove blister strips from outer carton until required for use.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the label or the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What KOLCRYS contains

The active substance is 0,5 mg colchicine.

The other ingredients are lactose monohydrate, povidone, pregelatinised starch, stearic acid and talc.

What KOLCRYS looks like and contents of the pack

Round, white to pale yellow coloured tablets, plain on both sides.

Silver Alu/Alu blister strips with 6 tablets per blister strip, provided in outer cartons of 1 x 6 or 2 x 6, therefore a pack of either 6 or 12 tablets.

Holder of certificate of registration

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Colchicine 0,5 mg Tablets
Forrester Pharma (Pty) Ltd

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