PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

COLCHICINE 0,5 mg ACTIVO

0,5 mg Colchicine tablets

COLCHICINE 0,5 mg ACTIVO contains sugar: 50,80 mg lactose monohydrate per tablet

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

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

- Keep this leaflet. You may need to read it again.
- Do not share COLCHICINE 0,5 mg ACTIVO 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 3 days.

What is in this leaflet

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2. What you need to know before you take COLCHICINE 0,5 mg ACTIVO
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1. What COLCHICINE 0,5 mg ACTIVO is and what it is used for

Colchicine, the active ingredient in COLCHICINE 0,5 mg ACTIVO is an anti-gout preparation used for emergency treatment of acute gout attacks.

COLCHICINE 0,5 mg ACTIVO is not a painkiller and should not be used to treat other causes of pain.

2. What you need to know before you take COLCHICINE 0,5 mg ACTIVO

Do not take COLCHICINE 0,5 mg ACTIVO:

- if you are hypersensitive (allergic) to colchicine or any of the other ingredients of COLCHICINE 0,5 mg ACTIVO listed in section 6.
- if you are undergoing haemodialysis (a procedure in which a dialysis machine is used to clean your blood).
- if you have severe liver or kidney problems.
- if you have kidney or liver problems and are taking certain medicines (see 'Other medicines and COLCHICINE 0,5 mg ACTIVO').
- if you are taking certain antibiotics (such as erythromycin, clarithromycin).
- if you are taking a medicine called pristinamycin for treatment of bacterial infections.
- if you have a severe blood disorder, such as certain types of anaemias or cancers.
- if you are pregnant or breastfeeding.
- if you are a woman of childbearing age, unless you are using effective contraception.

Warnings and precautions

Special care should be taken with COLCHICINE 0,5 mg ACTIVO because:

- COLCHICINE 0,5 mg ACTIVO can be toxic, so it is important that you do not exceed the dose prescribed by your doctor.

There is only a slight difference between an effective dose of COLCHICINE 0,5 mg ACTIVO and an overdose. Therefore, if you get symptoms such as nausea (feeling sick), vomiting (being sick), stomach pain and diarrhoea, stop taking COLCHICINE 0,5 mg ACTIVO and immediately contact your doctor (see also section 4 'Possible side effects').

Take special care with COLCHICINE 0,5 mg ACTIVO if you:

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

  COLCHICINE 0,5 mg ACTIVO 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 COLCHICINE 0,5 mg ACTIVO 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').

Children and adolescents

There is no experience with the use of COLCHICINE 0,5 mg ACTIVO in children.

Other medicines and COLCHICINE 0,5 mg ACTIVO:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines, because when used together with COLCHICINE 0,5 mg ACTIVO side effects due to colchicine toxicity are more likely and these can be serious and life-threatening:

- certain antibiotics such as clarithromycin, erythromycin or telithromycin (used to treat infections)
- ciclosporin (used to prevent organ rejection after a transplant, psoriasis and rheumatoid arthritis)
- anti-viral medicines such as ritonavir, atazanavir or indinavir (used to treat HIV infections)
- itraconazole or ketoconazole (used to treat fungal infections)
- certain heart medicines such as verapamil and diltiazem (used to treat high blood pressure or angina) or quinidine (used to treat abnormal heart rhythms) or digoxin (used to treat irregular heartbeat)

If you are taking any of the above medicines, your doctor may want to adjust your dose of COLCHICINE 0,5 mg ACTIVO or temporarily stop your treatment with COLCHICINE 0,5 mg ACTIVO. If you have liver or kidney problems and you are taking any of the above medicines, you should not take COLCHICINE 0,5 mg ACTIVO.

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

- anti-inflammatory medicines e.g. ibuprofen, diclofenac (used to treat inflammation), as the risk of side effects may be increased.
- anticoagulants such as warfarin used to thin blood, as there is an increased risk of bleeding.
- medicines that can cause blood disorders like antibiotics e.g. chloramphenicol and cotrimoxazole, anti-psychotics e.g. clozapine and olanzapine, anti-thyroid medicines

e.g. carbimazole and anti-epileptics e.g. lamotrigine, phenytoin, valproic acid and carbamazepine, as the side effects related to blood disorders may be increased.

- medicines used in the treatment of cancer, as they may increase the levels of colchicine.
- vitamin B12 – COLCHICINE 0,5 mg ACTIVO may reduce the amount of vitamin B12 that your body can absorb through your gut.
- statins and fibrates e.g. simvastatin (used to lower cholesterol) as they may increase your risk of a muscle disease known as ‘rhabdomyolysis’ (abnormal muscle breakdown which can lead to kidney problems).
- water tablets (used to treat high blood pressure).
- cimetidine (used to reduce stomach acid), as it may increase the amount of colchicine in your blood.
- tolbutamide (used to control blood sugar), as it may increase the amount of colchicine in your blood.

Taking COLCHICINE 0,5 mg ACTIVO with food and drink:

Alcohol consumption while taking COLCHICINE 0,5 mg ACTIVO may increase the risk of digestive problems and should therefore be avoided.

Grapefruit juice may increase the amount of colchicine in your blood. Therefore, you should not drink grapefruit juice while you are taking COLCHICINE 0,5 mg ACTIVO.

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 COLCHICINE 0,5 mg ACTIVO.

Pregnancy

COLCHICINE 0,5 mg ACTIVO should not be taken during pregnancy. Effective contraception must be used by women of child-bearing age. Contact your doctor immediately if you become pregnant while taking COLCHICINE 0,5 mg ACTIVO.

Breastfeeding

Colchicine passes into breastmilk, therefore COLCHICINE 0,5 mg ACTIVO should not be taken if you are breastfeeding a baby. Ask your doctor or pharmacist for advice before taking any medicine whilst breastfeeding.

Driving and using machines

COLCHICINE 0,5 mg ACTIVO is not expected to influence your ability to drive. It is not always possible to predict to what extent COLCHICINE 0,5 mg ACTIVO may interfere with your daily activities. You should not drive or use machines if you are affected by these symptoms or until you are aware of the measures to which COLCHICINE 0,5 mg ACTIVO affects you.

COLCHICINE 0,5 mg ACTIVO contains lactose.

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

3. How to take COLCHICINE 0,5 mg ACTIVO

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

Always take COLCHICINE 0,5 mg ACTIVO exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. You should check with your doctor, pharmacist or nurse if you are unsure.

The usual dose for acute attacks of gout in adult patients is:

Take 0,5 mg to 1 mg (1 to 2 tablets) immediately, followed by 0,5 mg (1 tablet) 2 hourly until pain is relieved or until vomiting or diarrhoea occur.

The tablet should be swallowed whole with a glass of water.

The maximum dosage of 6 mg (twelve tablets) must not be exceeded.

A minimum of 3 days, but preferably 7 days, should elapse between courses of gout treatment with COLCHICINE 0,5 mg ACTIVO to avoid cumulative toxicity.

If you have severe kidney problems, you should not take COLCHICINE 0,5 mg ACTIVO.

COLCHICINE 0,5 mg ACTIVO is not an analgesic medication and should not be used to treat pain from other causes.

If you have the impression that the effect of COLCHICINE 0,5 mg ACTIVO is too strong or too weak, tell your doctor or pharmacist.

If you take more COLCHICINE 0,5 mg ACTIVO than you should

Fatal overdoses have been reported with colchicine in adults and children.

Early symptoms of overdose may include nausea, vomiting, stomach pain, bloody diarrhoea and low blood pressure.

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

If you forget to take a dose of COLCHICINE 0,5 mg ACTIVO:

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a forgotten individual dose.

4. Possible side effects

COLCHICINE 0,5 mg ACTIVO can have side effects.

Not all side effects reported for COLCHICINE 0,5 mg ACTIVO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking COLCHICINE 0,5 mg ACTIVO, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- swelling of the hands, feet, ankles, face, lips and 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 COLCHICINE 0,5 mg ACTIVO. 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:

- fever with or without chills; sores, ulcers, or white spots on the lips or in the mouth, sore throat as this can be an indication of bone marrow depression with agranulocytosis (lowered white blood cells),

- unusual bleeding or bruising, black tarry stool, blood in urine or stools, pinpoint red spots on the skin as this can be an indication of thrombocytopenia (lowered blood platelets),
- nausea, vomiting, stomach pain and diarrhoea as this can be signs of toxicity,
- nausea, loss of appetite, fatigue, diarrhoea, swollen abdomen, yellow colour of the skin and whites of the eyes as these may be signs of liver problems (liver damage),
- abnormal urine colour (dark, red, or cola coloured), decreased urine production, general weakness, muscle stiffness or aching, muscle tenderness, weakness of the affected muscles as this can be an indication of rhabdomyolysis,
- vomiting and/or diarrhoea, nausea, weight loss, nocturnal urination (night time urination), more frequent urination as these may be signs of renal problems (renal damage).

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

- Nausea, vomiting, abdominal pain and diarrhoea.

Less frequent side effects

- Burning of the throat.

Side effect with unknown frequency

- Decrease in blood cells that can cause weakness, bruising or make infections more likely (aplastic anaemia) or a decrease in white blood cells.
- Numbness in the fingers and toes.
- Low blood pressure.

- Excessive diarrhoea and bleeding from the intestines.
- Burning of the skin and rash, hair loss.
- Muscle weakness.
- Dehydration (loss of body fluids).
- Inhibition of sperm production, absence of menstrual periods and painful periods.

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, 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 COLCHICINE 0,5 mg ACTIVO.

5. How to store COLCHICINE 0,5 mg ACTIVO

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Store at or below 30 °C in the original container.
- Do not use after the expiry date printed on the label or 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 COLCHICINE 0,5 mg ACTIVO contains

The active substance is colchicine.

Each COLCHICINE 0,5 mg ACTIVO tablet contains 0,5 mg colchicine.

COLCHICINE 0,5 mg ACTIVO contains sugar (lactose monohydrate).

The other ingredients include isopropyl alcohol, lactose monohydrate, povidone, pregelatinised starch, purified water, stearic acid and talc.

What COLCHICINE 0,5 mg ACTIVO looks like and contents of the pack

Pack sizes of 30 or 50 tablets are packed in white opaque round HDPE container with child resistant cap containing polyester fiber and a silica gel canister inside.

COLCHICINE 0,5 mg ACTIVO tablets can also be packed in a white opaque Alu/Alu foil base film with a plain 25 µ Aluminium Foil with 6-8 gsm HSL lidding foil blister strips. The blister strip is packed in an outer carton.

Not all pack sizes may be marketed.

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