1.3.2 Patient Information Leaflet

SCHEDULING STATUS

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PATIENT INFORMATION LEAFLET

CHOLDIX 0.5 mg (tablets)

Colchicine 0,5 mg

Contains sugar: 49,00 mg lactose monohydrate.

Read all of this leaflet carefully before you take CHOLDIX 0.5 mg

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist, nurse or other health care provider.
- **CHOLDIX 0.5 mg** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What **CHOLDIX 0.5 mg** is and what it is used for
2. What you need to know before you take **CHOLDIX 0.5 mg**
3. How to take **CHOLDIX 0.5 mg**
4. Possible side effects
5. How to store **CHOLDIX 0.5 mg**
6. Contents of the pack and other information

1. What CHOLDIX 0.5 mg is and what it is used for

CHOLDIX 0.5 mg belongs to a group of medicines of gout medicines and is used to control a gout attack.

In gout, the concentration of uric acid in the blood is increased. This allows uric acid crystals to precipitate in the fluid of joints. Colchicine stops the resulting inflammatory response.

2. What you need to know before you take CHOLDIX 0.5 mg

Do not take CHOLDIX 0.5 mg:

- If you are hypersensitive (allergic) to colchicine or any of the ingredients of **CHOLDIX 0.5 mg** (listed in section 6)
- If you are pregnant
- If you have serious blood count abnormalities
- If you have to have haemodialysis (mechanical removal of waste products from the blood)
- If you have kidney or liver disease and are also taking any of the following medications:
  - Ciclosporin – an immunosuppressant used in conditions such as rheumatoid arthritis, Crohn's disease, psoriasis and organ transplants
  - Verapamil and quinidine – used in heart conditions
  - Ritonavir, atazanavir and indinavir – used in the treatment of HIV/AIDS
  - Clarithromycin and telithromycin – used to treat bacterial infections and pneumonia
  - Itraconazole and ketoconazole – used to treat fungal infections
- If you have severe renal impairment.
- If you have severe liver dysfunction.
- If you are a woman of child-bearing age, unless pregnancy is excluded, for example through effective contraception

Warnings and precautions

Tell your doctor or healthcare professional before being given **CHOLDIX 0.5 mg**:

- If you have disorders of the liver or kidneys.
- If you have any cardiovascular diseases.
- If you have gastrointestinal disorders.
- If you have been told you have blood count abnormalities or have the following symptoms - fever, inflammation of the mouth, sore throat or prolonged bleeding occur. Treatment must be stopped immediately and you need to have blood tests done.

Special care should be taken with **CHOLDIX 0.5 mg** and let your doctor know:

- If after taking **CHOLDIX 0.5 mg** you have a burning sensation in the mouth or throat, nausea, vomiting, abdominal pain and diarrhoea. There is a very small difference between the effective dose and the dose at which symptoms of poisoning occur. Stop taking **CHOLDIX 0.5 mg** immediately;
- If after taking **CHOLDIX 0.5 mg** you get any skin abnormalities. You will need to have blood tests to check your blood cell count.

CHOLDIX 0.5 mg can cause a serious decrease in bone marrow function (disappearance of certain white blood cells from the blood (agranulocytosis), platelet deficiency (thrombocytopenia), decrease of red blood cells due to lack of production of red blood cells (aplastic anaemia). Aplastic anaemia in particular has a high risk of death.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before being given this medicine.

Children and adolescents

CHOLDIX 0.5 mg has not been studied in children or adolescents and therefore should not be used in this patient population.

Other medicine and CHOLDIX 0.5 mg:

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

The use of **CHOLDIX 0.5 mg** with these medicines may cause undesirable interactions.

In particular tell your doctor if you are using the following medicines:

- certain antibiotics - which prevent / control certain bacterial infections (such as erythromycin and clarithromycin) as they can lead to poisoning by **CHOLDIX 0.5 mg**
- antifungals such as ketoconazole, itraconazole, and voriconazole
- antiviral for the treatment of HIV (ritonavir)
- anti-immune response medicines (ciclosporin)
- medicines for certain heart conditions (verapamil and diltiazem)
- medicines used to lower cholesterol (such as simvastatin, fluvastatin or pravastatin) and fibrates
- cimetidine (a medicine for gastrointestinal ulcers)
- tolbutamide (a blood sugar lowering medicine).
- vitamin B_{12} (cyanocobalamin) as its absorption from the gastrointestinal tract can be reduced by **CHOLDIX 0.5 mg**
- digoxin (medicine against heart failure and cardiac dysrhythmias)

Do not drink grapefruit juice while taking **CHOLDIX 0.5 mg**. Grapefruit juice can increase the effect of **CHOLDIX 0.5 mg**, causing it to be toxic.

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 this medicine.

Do not take **CHOLDIX 0.5 mg** if you are pregnant or breastfeeding your baby as it may be harmful to your baby.

If you are taking **CHOLDIX 0.5 mg** use effective contraception to avoid falling pregnant.

Driving and using machines

CHOLDIX 0.5 mg might cause drowsiness and dizziness. Do not drive or operate tools or machines if you experience such side effects.

It is not always possible to predict to what extent **CHOLDIX 0.5 mg** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **CHOLDIX 0.5 mg** affects them

CHOLDIX 0.5 mg contains sugar

CHOLDIX 0.5 mg contains 49,00 mg of lactose monohydrate per tablet.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **CHOLDIX 0.5 mg**.

3. How to take CHOLDIX 0.5 mg

Do not share medicines prescribed for you with any other person. Always take **CHOLDIX 0.5 mg** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Dosage in an acute gout attack:

The usual dose for adults is 0,5 mg to 1 mg (1 to 2 tablets) taken immediately by mouth.

You can then take 0,5 mg (1 tablet) every 2 hours until you have pain relief or you have side-effects such as vomiting and diarrhoea.

DO NOT TAKE MORE THAN 6 MG (12 TABLETS) PER TREATMENT PERIOD.

DO NOT TAKE ANOTHER TREATMENT COURSE WITHIN 3 DAYS OF A PREVIOUS COURSE.

Take the tablets by mouth with a glass of water.

Contact your doctor if you have an upset stomach.

Your doctor will tell you how long your treatment with **CHOLDIX 0.5 mg** will last.

If you have the impression that the effect of **CHOLDIX 0.5 mg** is too strong or too weak, tell your doctor or pharmacist.

If you take more CHOLDIX 0.5 mg than you should

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

When you take a dose which is too high of **CHOLDIX 0.5 mg**, the first symptoms only appear after a few hours. You may experience a burning sensation in the throat, stomach and skin, nausea, vomiting, abdominal cramps, bloody diarrhoea which can lead to a low pH value of the blood, dehydration, drop in blood pressure and shock. Contact your doctor immediately or go to the hospital emergency.

The following life-threatening complications can occur a while after ingestion: consciousness disorder with possible delusions (delirium), coma, paralysis, suppression of breathing, cardiac arrest, fluid accumulation in the lungs, damage to the kidneys and a lack of blood.

A temporary increase in white blood cells (leukocytosis) and hair loss may occur about 10 days after ingestion.

If you forget to take CHOLDIX 0.5 mg

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

4. Possible side effects

CHOLDIX 0.5 mg can have side effects.

Not all side effects reported for **CHOLDIX 0.5 mg** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **CHOLDIX 0.5 mg**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **CHOLDIX 0.5 mg** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- A burning sensation in the throat, stomach and skin, nausea, vomiting, abdominal cramps, bloody diarrhoea, skin rashes

These are all very serious side effects. If you have them, you may have had a serious reaction to **CHOLDIX 0.5 mg**. You may need urgent medical attention or hospitalisation.

Treatment with **CHOLDIX 0.5 mg** can very commonly cause nausea, vomiting, diarrhoea, and stomach pain.

Tell your doctor if you notice any of the following:

<u>Frequent side effects:</u>

- Stomach pain
- Nausea
- Vomiting
- Diarrhoea

<u>Less frequent side effects:</u>

- Nervous system disease (neuropathy), nerve inflammation associated with pain, sensory disturbances and sometimes impaired nerve function (peripheral neuritis)
- Changes in the bone marrow (bone marrow depression), which can cause a change in the blood count such as a lack of white blood cells (agranulocytosis)

accompanied by a sudden high fever, severe sore throat and mouth sores and anaemia (aplastic anaemia).

- Hair loss
- Skin rash.
- Reddish brown discoloration of the urine (rhabdomyolysis).
- Muscle disease (myopathy), muscle pain, fatigue.
- Absence of menstrual periods, pain and / or cramps during menstruation (dysmenorrhea), a decrease in the number of sperm in the seminal fluid (oligospermia) and complete absence of sperm in the sperm (azoospermia).

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 via https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **CHOLDIX 0.5 mg**.

5. How to store CHOLDIX 0.5 mg

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store **CHOLDIX 0.5 mg** at or below 25 °C.

Keep the container or blister in the outer carton in order to protect from light.

Do not use after the expiry date stated on the blister pack and the container.

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 CHOLDIX 0.5 mg contains

The active substance is colchicine

Each tablet contains 0,5 mg of colchicine.

Each tablet contains 49,00 mg of sugar (lactose monohydrate).

The other ingredients of **CHOLDIX 0.5 mg** are

cellulose microcrystalline

sodium starch glycolate

magnesium stearate

What CHOLDIX 0.5 mg looks like and contents of the pack

CHOLDIX 0.5 mg is an off-white to light yellow coloured, round shaped, biconvex uncoated tablet debossed with 'C' on one side and "0.5" on the other side.

CHOLDIX 0.5 mg is packed in printed 250 micron white opaque PVC film as the forming material and 25 µ aluminium foil as the lidding material. The blisters are packed in pre-printed cartons with package leaflet.

Pack sizes:

12’s – 2 blisters of 6 tablets each

50’s – 5 blisters of 10 tablets each

CHOLDIX 0.5 mg is packed in round wide mouth white opaque 30 ml HDPE container closed with white opaque 28 mm - 400 polypropylene child resistant closures with wad having induction sealing liner. The HDPE container is packed in a pre-printed carton with package leaflet.

Pack sizes: 12’s and 50’s

Not all packs and pack sizes are necessarily marketed.

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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