PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

GOUTEZE® OTC, 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

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

- Keep this leaflet. You may need to read it again.
- Do not share GOUTEZE OTC with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after you have taken the complete course of 12 tablets.

What is in this leaflet

1. What GOUTEZE OTC is and what it is used for

2. What you need to know before you take GOUTEZE OTC

3. How to take GOUTEZE OTC

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1. What GOUTEZE OTC is and what it is used for

The active ingredient in GOUTEZE OTC tablets is colchicine. Colchicine is an anti-gout medicine.

Colchicine helps to reduce the inflammation, tenderness and swelling caused by gout in the joints.

GOUTEZE OTC tablets are used to treat acute attacks of gout in adults.

GOUTEZE OTC is not a painkiller and should not be used to treat other causes of pain.

2. What you need to know before you take GOUTEZE OTC

Do not take GOUTEZE OTC, if you:

- are hypersensitive (allergic) to colchicine or any of the other ingredients of GOUTEZE OTC (listed in section 6)
- are undergoing haemodialysis (a procedure in which a dialysis machine is used to clean your blood)
- suffer from severe liver or kidney impairment
- have blood disorders (low red or white cell count or problems with blood clotting, leukaemia). GOUTEZE OTC may also cause a drop in red and white blood cell counts and platelet count (see **Possible side effects**). Your doctor will want to periodically measure these blood levels.
- are taking pristinamycin (a medicine used to treat bacterial infections)
- have kidney and liver problems and also have to take certain other medicines (see **Other medicines and GOUTEZE OTC**):
  - Ciclosporin (used to prevent organ rejection after a transplant, psoriasis and rheumatoid arthritis)
  - Verapamil and diltiazem (used to treat high blood pressure or angina)

- Quinidine (used to treat abnormal heart rhythms)
- Ritonavir, atazanavir or indinavir (used to treat HIV infection)
- Clarithromycin, erythromycin or telithromycin (so-called macrolide antibiotics, used to treat bacterial infections)
- Ketoconazole or itraconazole (used to treat fungal infections).

- are pregnant, may become pregnant, or breastfeed your baby (see **Pregnancy and breastfeeding**)
- are a women of childbearing age, unless you are using effective contraception.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist or professional healthcare provider.

Warnings and precautions

Take special care with GOUTEZE OTC

- Do not take more than the recommended dose of GOUTEZE OTC. If you experience nausea, vomiting, diarrhoea or stomach pain, stop taking GOUTEZE OTC and contact your doctor.
- If you are an elderly (≥ 65 years) or debilitated patient (a patient with impaired energy or strength), as you may be more prone to the toxicity of GOUTEZE OTC. Your healthcare provider will be monitoring you for toxicity and may decide to temporarily interrupt or discontinue your treatment with GOUTEZE OTC at the first signs of toxicity, such as nausea, vomiting and diarrhoea.

Tell your doctor or healthcare provider before you start taking GOUTEZE OTC tablets:

- if you have problems with your heart, kidneys, liver or digestive system - your dose may need to be reduced if you have kidney or liver problems;
- if you have ulcers or other serious gastrointestinal disorders, as these conditions may worsen when taking GOUTEZE OTC;
- if you take other medicines that may cause muscle pain or damage, such as statins (for high blood cholesterol), as GOUTEZE OTC may worsen these conditions (see **Other medicines and GOUTEZE OTC**);
- if you have a blood disorder, as shown in laboratory tests.

GOUTEZE OTC tablets 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 GOUTEZE OTC 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 **Possible side effects**).

Children and adolescents

These tablets are not for use in children.

Other medicines and GOUTEZE OTC

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

Effects of other medicines on GOUTEZE OTC:

The following medicines may cause toxic concentrations of colchicine in your blood, which can be serious and life-threatening if you have kidney or liver disease (see "**Do not take GOUTEZE OTC**"):

- Clarithromycin, erythromycin, telithromycin, roxithromycin or pristinamycin (antibiotics, used to treat infections)
- Ciclosporin (used to prevent organ rejection after a transplant, psoriasis and rheumatoid arthritis)
- Verapamil and diltiazem (used to treat high blood pressure or angina)
- Quinidine (medicine used to treat irregular heartbeat)
- Ritonavir, atazanavir and indinavir (used to treat HIV infection)
- Disulfiram (used to help treat alcoholism)
- Ketoconazole, itraconazole and voriconazole (used to treat fungal infections)
- Digoxin (medicine to treat irregular heartbeat).

Be careful with the following medicines. Tell your doctor or pharmacist if you are taking any of these:

- Statins e.g. simvastatin, fluvastatin, pravastatin, atorvastatin, bezafibrate (used to lower cholesterol). They may increase your risk of a muscle disease known as 'rhabdomyolysis' (the breakdown of muscle fibre)
- Anti-inflammatory medicines such as ibuprofen, diclofenac (used to treat inflammation) as the risk of side effects may be increased
- Water tablets such as chlorthalidone, hydrochlorothiazide, indapamide (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
- Medicines used in the treatment of cancer, as they may increase the amount of serum uric acid.

Talk to your doctor before taking GOUTEZE OTC tablets if you are uncertain if you are taking any medicines that may possibly damage your kidneys, liver or blood.

Your doctor will adjust your dose of GOUTEZE OTC tablets or stop your treatment with GOUTEZE OTC.

Effect of GOUTEZE OTC on other medicines:

- Warfarin. GOUTEZE OTC may increase the effect of oral blood thinners. Your doctor may want to change your dose of warfarin.
- GOUTEZE OTC may reduce the amount of vitamin B12 that your body can absorb through your gut. You may need to increase your vitamin B12 dose.

Before you begin using any medicine (prescription or non-prescription), get advice from your doctor, pharmacist or healthcare provider.

GOUTEZE OTC with food, drink and alcohol

- Alcohol is a known trigger of gout; you should not take alcohol during an acute attack of gout. Having alcohol while taking GOUTEZE OTC may also increase the risk of gastrointestinal side effects.
- Grapefruit juice may increase the amount of colchicine in your blood. Therefore, you should not drink grapefruit juice while you are taking GOUTEZE OTC.

Pregnancy and breastfeeding

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.

Do not take GOUTEZE OTC if you are pregnant or of childbearing potential (unless you are on effective contraception) (see **Do not take GOUTEZE OTC**).

Colchicine passes into breastmilk. If you are breastfeeding, do not take GOUTEZE OTC.

Driving and using machines

GOUTEZE OTC is not expected to have an influence on your ability to drive or use machinery. It is not always possible to predict to what extent GOUTEZE OTC may interfere with your daily activities. You should not drive or use machines until you are aware of the measure to which GOUTEZE OTC affects you.

GOUTEZE OTC contains lactose

GOUTEZE OTC contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking GOUTEZE OTC tablets.

3. How to take GOUTEZE OTC

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

Always take GOUTEZE OTC exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are not sure.

Do not exceed the prescribed dose of GOUTEZE OTC as it is toxic in overdose.

The usual dose is:

It is very important that you strictly follow your doctor or pharmacist's advice on the dose and for how long to take it.

The usual dose is 0,5 mg to 1 mg (1 to 2 tablets) to be taken immediately, followed by 0,5 mg (1 tablet) every 2 hours until the pain is relieved, or if you develop nausea or diarrhoea. Do not take more than a total of 6 mg (12 tablets) per attack.

Do not repeat the dose before 3 days (preferably 7 days) have passed.

GOUTEZE OTC tablets should be swallowed whole with a glass of water.

If you are elderly, or have kidney problems, you may need a lower dose and you should be carefully monitored for side effects. Do not take GOUTEZE OTC tablets if you have severe kidney or liver problems.

GOUTEZE OTC is not a painkiller and should not be used to treat pain from other causes.

If you have the impression that GOUTEZE OTC is too strong or too weak, you should talk to your doctor or pharmacist.

If you take more GOUTEZE OTC than you should

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

If you take more GOUTEZE OTC tablets than you are supposed to (or if you think a child has accidentally swallowed any), **contact your doctor or nearest hospital's emergency department immediately.** Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

At too high a dose GOUTEZE OTC tablets can be very toxic, even fatal. Early symptoms of overdose include nausea, vomiting, stomach pain, bloody diarrhoea and low blood pressure.

If you forget to take GOUTEZE OTC

Take the missed dose as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and take only your next regularly scheduled dose.

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

4. Possible side effects

GOUTEZE OTC can have side effects.

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

If any of the following happens, stop taking GOUTEZE OTC 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.
- Pale red, raised, itchy bumps (hives) on the skin.

These are all very serious side effects. If you have them, you may have had a serious reaction to GOUTEZE OTC. 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 the following:

- Nausea (feeling sick), vomiting (being sick), stomach pain and severe diarrhoea (see also section 2, **Warnings and precautions**). These may be signs of toxicity.
- Stomach pain with blood in stools and /or vomiting bright red blood. This may be due to intestinal bleeding (See **Take special care with GOUTEZE OTC**).
- 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).
- Yellow colour of the skin and whites of the eyes, nausea, loss of appetite, fatigue, diarrhoea, swollen abdomen. These may be signs of liver problems (liver damage).
- Rhabdomyolysis (muscle breakdown). Some signs are muscle pain, muscle weakness or trouble moving arms and legs, dark red or brown urine or decreased urination. See **Take special care with GOUTEZE OTC.**
- Pain in the back and problems urinating which may be caused by kidney damage.

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Burning of the throat

Side effects of unknown frequency:

- Dizziness (you may have low blood pressure)
- Numbness and tingling in fingers and toes
- Burning of the skin, skin rashes, hair loss (alopecia)
- Muscle weakness (myopathy)
- Lack of fluids (dehydration)
- In men, the sperm count may temporarily be very low or may be completely absent during ejaculation
- Absence of menstruation, pain during menstruation
- A severe decrease in blood cells which can cause weakness, bruising or make infections more likely (aplastic anaemia).

If you notice any side effects not listed 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. 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 GOUTEZE OTC.

5. How to store GOUTEZE OTC

Store all medicines out of reach of children.

Store at or below 30 °C in the original packaging. Keep blisters in the carton until required for use.

Do not store in a bathroom.

Do not use GOUTEZE OTC after the expiry date printed on the blister strip/ carton.

Return all unused or expired medicine to your pharmacist for safe disposal.

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

6. Contents of the pack and other information

What GOUTEZE OTC contains

The active substance is colchicine.

Each GOUTEZE OTC tablet contains 0,5 mg colchicine.

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

What GOUTEZE OTC looks like and content of the pack

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

GOUTEZE OTC tablets are packed in a cardboard carton containing silver OPA/Al/PVC - Aluminium foil blisters with 6 or 12 tablets.

Not all pack sizes may necessarily be marketed.

Holder of Certificate of Registration

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