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DECEMBER 2025

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SCHEDULING STATUS:

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GOUTRELEFE 0.5

GOUTRELEFE 1.0

Film-coated tablets

Colchicine.

Contains Sugar – lactose monohydrate

GOUTRELEFE 0.5 contains 62,42 mg lactose monohydrate per tablet.

GOUTRELEFE 1.0 contains 124,84 mg lactose monohydrate per tablet.

Read all of this leaflet carefully before you start taking GOUTRELEFE

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

GOUTRELEFE 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

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1. What GOUTRELEFE is and what it is used for

GOUTRELEFE belongs to a group of medicines called anti-gout medicines. GOUTRELEFE is used for the relief of acute attacks of gout in cases of emergency.

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

2. What you need to know before you take GOUTRELEFE

Do not take GOUTRELEFE:

- If you are hypersensitive (allergic) to colchicine or any of the other ingredients of GOUTRELEFE (listed in section 6).
- If you are pregnant.
- If you are breastfeeding your baby.
- If you have blood dyscrasias (disorders) a medical condition (haematologic disorders) that may affect the cellular or plasma components of the blood, the bone marrow, or the lymph tissue. Examples of blood dyscrasias include anaemias (decrease in the production of your red blood cells), cancers such as leukaemias and lymphomas, conditions that cause the blood to clot or bleed too readily, and more. Symptoms of blood disorders include fever, sore throat, bleeding for a longer than usual time, inflammation of your mouth, bruising or abnormal skin rashes and abnormal tiredness (see section 4 Possible side effects)
- If you are a female of childbearing potential, unless you are using effective contraceptive.
- If you have liver problems.
- If you have kidney problems.
- If you are undergoing haemodialysis, a procedure in which a machine filters and cleans your blood instead of your kidneys.
- If you are taking a medicine called pristinamycin for the treatment of bacterial infections.
- If you have kidney or liver problems and you are taking certain medicines (see other medicines and GOUTRELEFE). Examples of these medicines are:
- Medicines used to treat fungal infections such as itraconazole, voriconazole and ketoconazole.
- Medicines used to manage HIV (human immunodeficiency virus) infections such as ritonavir, atazanavir and indinavir.

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- Medicine used to suppress your immune system after an organ transplant such as ciclosporin.
- Medicine used to treat high blood pressure such as verapamil and diltiazem.
- Medicine used to treat alcoholism, disulfiram.
- If you are taking a macrolide antibiotic for the treatment of bacterial infection such as clarithromycin, azithromycin and telithromycin.

Warnings and precautions

You should not take more GOUTRELEFE than prescribed to you as fatal overdoses have been reported with GOUTRELEFE in adults and children. Keep GOUTRELEFE away from children (see If you take more GOUTRELEFE than you should).

Take special care with GOUTRELEFE if you:

- Have problems with your heart, kidneys, liver or digestive system.
- Are elderly (≥ 65 years) and weak.
- Have a blood disorder as GOUTRELEFE can be toxic. It is important that you do not exceed the recommended dose. There is only a slight difference between an effective dose of GOUTRELEFE and an overdose. Therefore, if you get symptoms such as nausea (feeling sick), vomiting (being sick), stomach pain and diarrhoea, stop taking GOUTRELEFE and immediately contact your doctor(see also section 4 'Possible side effects'). GOUTRELEFE 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 GOUTRELEFE and contact your doctor immediately. These could be signs that you that you have a serious blood problem and your doctor may want you to have blood tests straight away (see Possible side effects).
- Are very tired, weak, with impaired energy or strength or run down (debilitated).

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- Start feeling sick, queasy or feel that you are about to vomit (nausea), or if you vomit, feel stomach pain or have loose stools (diarrhoea) after taking GOUTRELEFE then you should stop taking GOUTRELEFE.

- Experience side effects of the digestive system, your healthcare provider will decide either to withdraw GOUTRELEFE or to reduce the dose.
- If you are unsure whether you should take GOUTRELEFE discuss it with your healthcare provider.

Children

There is no experience with the use of GOUTRELEFE in children.

Important information about some of the ingredients of GOUTRELEFE

GOUTRELEFE contains sugar in the form of lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.
Tell your doctor or healthcare professional if you are allergic or intolerant to lactose so that alternate therapy may be recommended.

Other medicines and GOUTRELEFE

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
Also see Do not take GOUTRELEFE above for medicines that should not be taken together with GOUTRELEFE:
Tell your doctor if you are taking any of the following, as they may increase the blood levels of GOUTRELEFE and you might need to change the dose of GOUTRELEFE.
Medicines used to treat bacterial infections such as clarithromycin, erythromycin, telithromycin and pristinamycin.

Medicines used to treat fungal infections such as itraconazole, voriconazole and ketoconazole.

Medicines used to manage HIV (human immunodeficiency virus) infections such as ritonavir, atazanavir and indinavir.

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- Medicine used to suppress your immune system after an organ transplant such as ciclosporin.
- Medicine used to treat high blood pressure such as verapamil and diltiazem.
- Medicine used to treat alcoholism, disulfiram.

Tell your doctor if you are taking any of the following:

- Anti-inflammatory medicines called Non-steroidal anti-inflammatory drugs (NSAIDs) (medicines used to treat inflammation) e.g. ibuprofen, diclofenac. These may cause increased side effects when taken with GOUTRELEFE.
- Medicines used to treat neoplasms or cancer (abnormal growths of tissue) as concomitant use may increase the concentration of acid in your blood and decrease the effect of gout therapy.
- GOUTRELEFE can cause muscle weakness (myopathy) and the breakdown of muscle fibre (rhabdomyolysis) when co-administered with:
- Medicines used to treat high cholesterol, referred to as statins and fibrates e.g. simvastatin, fluvastatin, pravastatin, atorvastatin, bezafibrate.
- Digoxin (used to treat certain heart conditions).
- You should report any muscle pain or weakness to your doctor immediately (see section 4).
- Oral blood thinning medications as more frequent INR checks are required. Possible modification of the dosage of the blood thinning treatment is required with GOUTRELEFE and for 8 days after its cessation may be required.
- Cimetidine (used to reduce stomach acid), as it may increase the amount of colchicine, as contained in GOUTRELEFE, in your blood.
- Tolbutamide (used to control blood sugar), as it may increase the amount of colchicine in your blood.
- Talk to your doctor before taking GOUTRELEFE if you are taking any medicines that may possibly damage your kidneys, liver or blood.
- GOUTRELEFE may reduce the amount of vitamin B12 that your body can absorb through your gut.
- Water tablets such as chlorthalidone, hydrochlorothiazide, indapamide used in the

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management of high blood pressure, as they may interfere with the way GOUTRELEFE works and reduce its effectiveness.

GOUTRELEFE with food and 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 GOUTRELEFE.
- Do not consume alcohol while taking GOUTRELEFE.

Pregnancy, breastfeeding and fertility

You must not take GOUTRELEFE if you are pregnant or breastfeeding your baby. 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 GOUTRELEFE.

Driving and using machines

GOUTRELEFE is not expected to influence your ability to drive or operate machinery.

It is not always possible to predict to what extent GOUTRELEFE may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which GOUTRELEFE affects you (see section 4).

GOUTRELEFE contains lactose

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

3. How to take GOUTRELEFE

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

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

DO NOT EXCEED THE RECOMMENDED DOSE (see Warnings and precautions)

In acute gout the initial dose is 0,5 mg to 1 mg (one 1 mg tablet to 2 of the 0,5 mg tablets) by mouth

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immediately, followed by 0,5 mg (1 tablet) every 2 hours until pain relief is obtained or gastrointestinal symptoms like vomiting or diarrhoea occur. **Do not take more than 6 mg (12 of the 0,5 mg tablets or 6 of the 1 mg tablets). Do not repeat the course within 3 days. Wait at least 7 days before you take another course of GOUTRELEFE to avoid toxic doses of colchicine in your blood.**

GOUTRELEFE should be swallowed whole with a glass of water.

GOUTRELEFE is not a pain medication and should not be used to treat pain from other causes.

If you have the impression that the effect of **GOUTRELEFE** is too strong or too weak, talk to your doctor or pharmacist.

If you take more GOUTRELEFE than you should

If you take more GOUTRELEFE than you should it can be serious, toxic and even fatal. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you have kidney, liver, digestive tract or heart diseases, or are a very young or an elderly patient you are at particular risk to develop GOUTRELEFE toxicity.

There is often a delay of up to 6 hours before signs of overdose are seen; some features may be delayed up to 1 week or longer. Early features (which occur up to 1 day after ingestion but 3 hours on average) include:

- Nausea, vomiting, abdominal pain, low blood pressure, and diarrhoea which may be bloody. Diarrhoea can cause severe loss of fluids which can lead to an emergency condition in which severe blood and fluid loss make the heart unable to pump enough blood to the body.

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Symptoms occurring after 1 to 7 days include:

- Confusion
- Decreased heart output, the heart may beat too fast or too slow and difficulty in breathing may be experienced
- Kidney or liver problems
- Problems with breathing
- Extreme elevation of body temperature
- Bone marrow depression, e.g. low white blood cell count.

Also see section 4 Possible side effects.

If you forget to take GOUTRELEFE

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

4. Possible side effects

GOUTRELEFE can have side effects.

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

If any of the following happens, stop taking **GOUTRELEFE** 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 GOUTRELEFE. You may need urgent medical attention or hospitalisation.

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

- Diarrhoea, nausea, vomiting, burning of the throat and stomach pain as this can be signs of toxicity.
- Muscle weakness, low urine output, fatigue, muscle stiffness or soreness/aching/tenderness, bruising, dark, tea-coloured urine, infrequent urination, a fever. As these may be symptoms of damage to muscles (rhabdomyolysis).
- Unusual bleeding or bruising, black tarry stools, blood in urine or stools, pinpoint red spots on the skin as this can be an indication of thrombocytopenia (lowered blood platelets).
- Mild numbness in fingers and toes.
- Weakness, bruising or signs of infection such as fever, chills, sore throat. This may indicate a severe decrease in blood cells (aplastic anaemia).
- Unusual tiredness or weakness, headache, difficulty in breathing (usually associated with increased physical activity).
- 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).
- A reduced amount of urine, swelling of your legs, ankles, and feet from retention of fluids caused by the failure of the kidneys to eliminate water waste, unexplained shortness of breath, excessive drowsiness or fatigue as these may be symptoms of kidney damage.
- Profuse diarrhoea with blood in stools.
- Yellowing of the whites of the eyes and skin accompanied by nausea, severe stomach pain and swelling of the legs as this can be a sign of liver damage (hepatotoxicity).

Tell your doctor if you notice any of the following:

Frequent

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- Nausea,
- vomiting,
- abdominal pain and
- diarrhoea.

Less frequent

- Burning of the throat
- Redness of the skin, rash

Frequency unknown:

- Pins and needles, numbness
- Lowered blood pressure
- Burning of the skin, skin rashes, hair loss (alopecia);
- Muscle damage and pain
- lack of fluids (dehydration)
- absence of menstrual periods;
- painful periods;
- reduced ability to produce sperm (low or zero sperm count).

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

  Should your general health worsen or if you experience any untoward effects while taking **GOUTRELEFE**, please consult your healthcare provider for advice.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Macleods Pharmaceuticals SA (Pty) Ltd. at safety@macleodspharma.com. By reporting side effects,

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you can help provide more information on the safety of **GOUTRELEFE.**

5. How to store GOUTRELEFE

Store at or below 30 °C.

KEEP OUT OF THE REACH OF CHILDREN.

Store in the original package / container.

Keep the blisters in the carton until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the blister /label/carton bottle.

Return all unused medicine to your pharmacist.

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

6. Contents of pack and other information

What GOUTRELEFE contains

The active ingredient is colchicine.

Contains sugar - lactose monohydrate

The other ingredients are:

Microcrystalline cellulose,

Lactose monohydrate,

Crospovidone,

Magnesium stearate,

Instacoat universal brown.

What GOUTRELEFE looks like and contents of the pack

GOUTRELEFE 0.5 : Each film-coated tablet contains 0,5 mg colchicine

GOUTRELEFE 1.0 : Each film-coated tablet contains 1,0 mg colchicine

Contents of the pack: VR

Tablets are packed in aluminium foil laminated with 6 - 8 gsm heat seal lacquer coating on one side and laminated to clear PVC/PVdC on the other side. Pack sizes include 6, 12 and 10 tablets for colchicine 0,5 mg and 1,0 mg tablets.

Not all pack sizes may be marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION

MACLEODS PHARMACEUTICALS SA (PTY) LTD

Ground Floor, Block 1,

Bassonia Estate Office Park (East),

1 Cussonia Drive,

Bassonia Rock Ext 12

Alberton

Gauteng

This leaflet was last revised in

25/11/2025

Registration numbers

GOUTRELEFE 0.5: 57/3.3/0424

GOUTRELEFE 1.0: 57/3.3/0425

Access to the corresponding Professional Information

The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169

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