

**PATIENT INFORMATION LEAFLET FOR  
CITROGRAN**

**Scheduling Status**

**S0**

**CITROGRAN (Effervescent granules)**

**Each (4 g) contains:**

**Sodium citrate 0,613 g**

**Sodium bicarbonate 1,716 g**

**Citric acid anhydrous 0,702 g**

**Tartaric acid 0,858 g**

**Contains sugar (liquid glucose) 0,252 mL**

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share CITROGRAN 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 after 5 days.

**What is in this leaflet**

1. What CITROGRAN is and what it is used for
2. What you need to know before you take CITROGRAN

3. How to take CITROGRAN
4. Possible side effects
5. How to store CITROGRAN
6. Contents of the pack and other information.

## **1. What CITROGRAN is and what it is used for**

CITROGRAN belongs to a group of medicines acting on the genito-urinary system.

CITROGRAN is used to relieve gastric acidity as well as for its urinary alkalinising properties.

CITROGRAN can be used to relieve symptoms of inflammation of the bladder, including prevention of crystals forming in the urine due to the use of sulphonamides.

## **2. What you need to know before you take CITROGRAN**

Do not take CITROGRAN:

- if you are hypersensitive (allergic) to sodium citrate, sodium bicarbonate, citric acid anhydrous and tartaric acid or any of the other ingredients of CITROGRAN (listed in **Section 6**).
- if you have severe kidney problems. Please discuss this with your doctor.
- If you have metabolic disturbances with alkalosis (rise in the level of alkali in blood resulting in feeling of weakness or cramp, hypocalcaemia (deficiency of calcium in the bloodstream) or hypochlorhydria (an abnormally low level of hydrochloric acid in the stomach).
- If you are currently taking any of the following medicines:
  - Urinary tract antiseptics which require acid urine, such as methanamine mandelate and methanamine hippurate.
- Should be used with care in patients suffering from renal insufficiency.

## **Warnings and Precautions**

Take special care with CITROGRAN:

Before using CITROGRAN you should speak to your doctor if you:

- Are currently taking other medicines, as CITROGRAN may interact with these medicines and cause unwanted or adverse effects.
- Suffer from kidney insufficiency/ problems. You may have to go for blood tests to determine if your kidneys are functioning properly.
- Are taking other antacids and you have compromised kidney function, as this may result in the absorption of dangerously high amounts of aluminium.
- Are suffering from congestive heart failure and high blood pressure.
- Are suffering from an ulcer of the stomach or gut
- Have cirrhosis (a chronic disease of the liver caused by alcoholism or inflammation of the liver).
- Have swelling of the feet, hands or ankles (peripheral oedema).
- Have been diagnosed with pulmonary oedema (fluid accumulating in the lungs).
- Are pregnant and suffering from eclampsia (seizures in pregnant women with high blood pressure).
- Are on a sodium-restricted diet, as you should not take CITROGRAN.
- Please note that this alkalinising agent does not eradicate bacteriuria (the presence of bacteria in the urine) although it may temporarily relieve lower urinary tract symptoms.

## **Other medicines and CITROGRAN**

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

Please consult your doctor, pharmacist or other healthcare professional for advice.

If you are taking any of the following medicines, please discuss the use of CITROGRAN with your doctor, as you may require special precautions:

- *Urinary tract antiseptics*, such as methenamine mandelate and methenamine hippurate (an antibiotic that eliminates bacteria that causes urinary tract infections) (see "**Do not take CITROGRAN**").
- *Antacids*:  
Any other antacid, including aluminium-containing antacids, since it may cause abnormally high alkalinity of the blood and body fluids, may promote the development of kidney stones and may cause elevated sodium levels in the blood. It may cause absorption of dangerously high amounts of aluminium.
- *Quinolone antibiotics*, e.g. *ciprofloxacin, norfloxacin, ofloxacin*.
- *Salicylates*, e.g. *aspirin used for pain, inflammation and fever and methyl salicylate/wintergreen oil, for treatment of skin conditions and joint pain*.
- *Tetracyclines*, *doxycycline used as antibiotics*.

You should not take CITROGRAN within 1 to 2 hours of these antibiotics.

- *Ketoconazole*:

You should take CITROGRAN at least 2 hours after ketoconazole (medication used to treat infections caused by fungus or yeast).

### **CITROGRAN with food, drink and alcohol**

CITROGRAN must be taken on an empty stomach and followed with additional water.

### **Pregnancy, breastfeeding and fertility**

The safe use of CITROGRAN in pregnant or breastfeeding mothers has not been established.

If you are breastfeeding your baby, CITROGRAN should be taken with care.

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking CITROGRAN.

### **Driving and using machinery**

The effects of CITROGRAN is not known and it has no sedative effects.

It is not always possible to predict to what extent CITROGRAN 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 CITROGRAN affects them.

### **CITROGRAN contains liquid glucose**

Patients with rare glucose-galactose malabsorption should not take this medicine.

CITROGRAN contains sodium and sugar. If you are on a sodium restricted diet or suffer from diabetes mellitus, do not take CITROGRAN.

### **3. How to take CITROGRAN**

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

Always take CITROGRAN exactly as described in this leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

#### **Adults:**

Add one to two 5 mL medicines measures (4 to 8 g) in half a glass of water, 3 to 4 times daily, taken on an empty stomach and followed with additional water. Drink the solution only after effervescence is complete.

Long-term therapy: One 5 mL (4 g) medicine measure daily.

**Children (6 to 12 years):**

Add one 5 mL medicine measure (4 g) in half a glass of water, 2 or 3 times daily, taken on an empty stomach and followed with additional water. Allow the child to drink the solution only after effervescence is complete.

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

**If you take more CITROGRAN than you should**

In the event of an overdose, or if someone has taken your medicine by mistake, you, or this person, may experience side-effects such as those listed below.

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

**If you forget to take CITROGRAN**

Always take CITROGRAN as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next day, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for the forgotten individual doses. Continue with your normal dose on the regular schedule as prescribed by your doctor or as directed above.

**4. Possible Side Effects**

CITROGRAN can have side effects.

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

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

- Shortness of breath, convulsions and coma, especially if you suffer from impaired kidney function. These are symptoms of metabolic alkalosis.
- Seizures, swelling of feet or lower legs, weakness, oedema and possible effect on the cerebral, pulmonary or peripheral circulations (excessive doses may lead to sodium overloading and hyperosmolality).

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:

- Increased thirst, dizziness, fast heartbeat, high blood pressure, irritability, muscle twitching, restlessness.
- Stomach cramps, diarrhoea or loose bowel movement.

Side effects with unknown frequency:

- Muscle weakness and mental disturbances such as restlessness, especially if you suffer from impaired kidney function. These are symptoms of metabolic alkalosis.
- Muscle hypertonicity (spasms), twitching and tetany, especially if you have low blood calcium levels.
- Abdominal distention, flatulence, belching and nausea may occur if CITROGRAN effervescent granules are taken before effervescence is complete (see "HOW TO TAKE CITROGRAN").

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. 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> or by e-mail: [drugsafetysa@cipla.com](mailto:drugsafetysa@cipla.com) or telephone: 080 222 6662 (toll free) . By reporting side effects, you can help provide more information on the safety of CITROGRAN.

## 5. How to store CITROGRAN

- Store in a cool dry place, at or below 25 °C.
- Keep the bottle tightly closed.
- Do not refrigerate or freeze.
- Keep the bottle in the outer carton.
- Do not use the medication after the expiry date stated on the container.
- Store all medicines out of reach of children.
- 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 CITROGRAN contains

The active substance are sodium citrate, sodium bicarbonate, citric acid anhydrous and tartaric acid. Each 4 g of CITROGRAN contains sodium citrate 0,613 g, sodium bicarbonate 1,716 g, citric acid anhydrous 0,702 g and tartaric acid 0,858 g.

The other ingredients are Flav Lemon Permaseal 60301-71 and liquid glucose.

### **What CITROGRAN looks like and contents of the pack**

**CITROGRAN:** White to straw coloured granules with a lemon odour and a sweet/ sour slightly lemon taste. After reconstitution with water a clear to straw coloured solution with a slight lemon odour is obtained.

**CITROGRAN** is presented in a in clear round glass bottles with a white screw cap and a dosage measure, packed in an outer carton.

Each bottle contains 60 g or 120 g effervescent granules.

### **Holder of Certificate of Registration**

**CIPLA MEDPRO (PTY) LTD.**

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### **Registration number(s)**

45/18.3/0182

### **Access to the corresponding Professional Information**

To access corresponding Professional Information, scan the QR Code below.

PLACE HOLDER:  
The QR Code to  
be generated and  
included after  
approval.