

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

CitraFleet

Powder for oral solution

Active ingredients

Each sachet contains the following active ingredients:

sodium picosulfate 10 mg

light magnesium oxide 3.5 g

citric acid anhydrous 10.97 g

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1) What is this medicine intended for?

This medicine is intended to empty/clean your bowels prior to a diagnostic procedure such as an x-ray, surgery or colonoscopy (a procedure for viewing the inside of your bowel cavity by inserting an instrument through your anus).

The emptying of the bowel is possible thanks to two types of laxatives mixed in each sachet.

Therapeutic group: Laxative.

CitraFleet contains two laxatives in each sachet which, when dissolved in water and drunk, flush and clean the bowels. It is very important to empty and clean the bowels so that your doctor/surgeon can see them clearly.

CitraFleet is intended for adults aged 18 years and older.

2) Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredients or to any of the other ingredients in this medicine (see section 6).
- You have **congestive heart failure** (a condition in which your heart is unable to properly pump blood round the body).
- **Your stomach does not empty properly** (gastric retention).
- You have stomach or duodenal **ulcers**.
- You have **blockage of the gut or failure of normal bowel movements** (ileus).
- Your doctor has told you that there is **damage to the wall of your colon** (toxic colitis).
- You have **swelling of the colon** (toxic megacolon).
- You have **recently suffered from nausea and/or vomiting**.
- You are very thirsty or think you may be **severely dehydrated**.
- Your doctor has told you that your abdomen is swollen because of fluid collection (**ascites**).
- You **have recently had abdominal surgery** (such as an appendectomy).
- You have a **gastro-intestinal obstruction or perforation**.
- Your doctor has told you that you have **active inflammatory bowel disease** (e.g., Crohn's disease or colitis).
- You have been told by your doctor that you have muscle damage resulting in leakage of muscle cell contents into the blood (**rhabdomyolysis**).
- You have a **severe kidney function disorder** or your doctor has told you that you have **too much magnesium in your blood (hypermagnesaemia)**.

Special warnings about using this medicine

Before treatment with CitraFleet, tell your doctor if:

- You **recently underwent gastrointestinal surgery**.
- You have **impaired heart or kidney** function.
- You have or have previously **water and/or electrolyte imbalance** (sodium or potassium) in your body or are taking medicines that may affect the body's water and/or electrolyte balance, such as diuretics, corticosteroids, or lithium.
- You have **epilepsy or have previously had seizures**.
- You have **low blood pressure** (hypotension).
- You are thirsty or think you may be mildly to moderately dehydrated.
- You are **elderly** or are **physically weak**.
- You have ever had low levels of blood potassium or sodium (hyponatremia or hypokalemia).

You should expect frequent, runny bowel movements after taking CitraFleet. You must drink a large quantity of clear fluids (see section 3) to compensate for fluid and electrolyte losses. Otherwise, you might suffer from dehydration and low blood pressure, which could cause you to fall or faint.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking the following:

- **Birth control pills**, because their efficacy may be lowered.
- **Medicines to treat diabetes or anti-epileptic medicines** because their efficacy may be lowered.
- **Antibiotics**, because their efficacy may be lowered.
- Other **laxatives** including bran.
- **Diuretics** such as furosemide, which are used to control fluid retention in the body.
- **Corticosteroids** such as prednisone, which are used to treat inflammation in diseases such as arthritis, asthma, hay fever, dermatitis, and inflammatory bowel disease.
- **Digoxin**, for the treatment of congestive heart failure.
- **Medications from the NSAID (non-steroidal anti-inflammatory drugs) class**, such as aspirin and ibuprofen that are used to treat pain and inflammation.
- **Tricyclic antidepressants**, such as imipramine **and amitriptyline and selective serotonin reuptake inhibitors (SSRIs)** such as fluoxetine, paroxetine, and citalopram for the treatment of depression and anxiety.
- **Antipsychotic drugs** such as haloperidol, risperidone, clozapine for the treatment of schizophrenia.
- **Lithium** used to treat bipolar disorder (manic depression).
- **Carbamazepine** used to treat epilepsy.
- **Penicillamine** used to treat rheumatoid arthritis and other diseases.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.

Driving and using machines

Do not drive or use tools or machines if you feel dizzy or tired after taking CitraFleet.

Important information about some of this medicine's ingredients

Each sachet of CitraFleet contains 195 mg (5 mmol) of potassium. This information is important if you have a kidney function disorder or if you are on a low-potassium diet.

This medicine contains less than 23 mg sodium (1 mmol) per sachet, so it is essentially considered to be 'sodium free'.

3) How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. If your bowels are not completely cleansed, the procedure may need to be repeated in the hospital. Only your doctor will determine your dose and how you should take this medicine.

You should expect bowel movements to be frequent and runny (like diarrhoea) after taking a dose of CitraFleet. This is a normal effect, indicating that the medicine is working. Make sure you have access to the toilet until the effect of the medicine subsides.

It is important you follow a special (low solids) diet on the day before your procedure is planned. When you start taking the sachets of this medicine, do not consume any solid food until after your procedure is finished. **You should always follow the dietary instructions given by your doctor.** If you have any questions, contact your doctor or pharmacist.

Unless otherwise instructed by your doctor, do not exceed the recommended dose in a 24-hour period.

Treatment plan

You should receive two sachets of CitraFleet. Each sachet contains one adult dose.

The treatment can be administered in one of the following ways:

- One sachet on the evening prior to the procedure and the second sachet in the morning of the day of the procedure.
- One sachet in the afternoon and the second sachet in the evening prior to the procedure. This schedule is suitable when the procedure is planned for early in the morning.

The time elapsed between the two sachets should be at least 5 hours.

Each sachet should be dissolved in a cup of water. Do not further dilute the medicine by drinking liquid immediately after taking each sachet.

Wait about ten minutes after taking each sachet, and then drink approximately 1.5-2 litres of a variety of clear fluids, at a rate of approximately 250 ml (a small glass) to 400 ml (a large glass) every hour. Clear soups and/or balanced electrolyte solutions are recommended to avoid dehydration. It is advisable not to drink water alone.

After taking the second sachet and drinking the 1.5-2 litres of fluid, do not eat or drink anything for at least 2 hours prior to the procedure or as instructed by your doctor.

Directions for use:

Adults 18 years and older (including the elderly):

- Step 1 - **mix the content of 1 sachet in a cup of cold tap water (approx. 150 ml).**
- Step 2 - **stir for 2-3 minutes. If the solution warms up when you stir it, wait until it cools down before drinking the whole solution. Once the solution is ready, drink it immediately. The solution will appear cloudy.**

If you have accidentally taken a higher dose, consult your doctor or pharmacist immediately.

If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Use the medicine as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4) Side effects

Like with all medicines, using CitraFleet may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Go to the hospital immediately if you are feeling:

- Difficulty breathing, you start to look flushed or have another symptom that you think may indicate that you have a severe allergic reaction (anaphylaxis). The frequency of this side effect is unknown.

Additional side effects

Very common side effects (effects that appear in more than one in ten users):

- Abdominal pain

Common side effects (effects that appear in one in ten users):

- Abdominal discomfort (abdominal distention)
- Feeling thirsty
- Anal discomfort and proctalgia (pain in the anus or buttocks)
- Fatigue, exhaustion
- Difficulty sleeping
- Headache
- Dry mouth
- Nausea

Uncommon side effects (effects that appear in one in one hundred users):

- Dizziness
- Vomiting
- inability to control your bowel movements (faecal incontinence)

Additional side effects of unknown frequency (the frequency of these effects has not been established yet):

- Hyponatraemia (low levels of blood sodium), hypokalaemia (low levels of blood potassium), epilepsy, convulsions (seizures), orthostatic hypotension (a drop in blood pressure in transition from sitting to standing, which may manifest in dizziness or instability), confusion, rash including urticaria, itching, and purpura (bleeding underneath the skin).
- Flatulence and pain

This medicine is supposed to cause very frequent bowel activity, similar to diarrhoea. However, after taking the medicine, if you have problems passing stool or are worried about it, you should consult your doctor.

If any of the side effects gets worse or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5) How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the pack/sachet. The expiry date refers to the last day of that month.

Storage conditions

- Store below 25°C.

6) Additional information

In addition to the active ingredients, this medicine also contains:

Potassium hydrogen carbonate, saccharin sodium, lemon flavour.

What the medicine looks like and contents of the pack:

In each package of CitraFleet there are two sachets that contain a white lemon flavoured and scented powder. Each sachet weighs 15.08 grams.

Registration holder's name and address: Dor Pharmaceutical Services, 6 Hashfela St., Kochave Yair.

Manufacturer's name and address:

Casen Recordati S.L.,

Autovia de Logrono Km 13,300, 50180 UTEBO, Zaragoza, Spain.

Revised in August 2021 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 151-44-33901-00