

Package leaflet: Information for the patient

CitraFleet, Powder for oral solution in sachet

Sodium picosulfate, light magnesium oxide, citric acid.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. However, you still need to take CitraFleet carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What CitraFleet is and what it is used for

You are taking CitraFleet to clean your bowels (also known as intestines and colon) before having any diagnostic procedure that requires a clean bowel, for example a colonoscopy (procedure that looks inside your bowel using a long, flexible instrument that the doctor inserts through your anus) or x-ray examination. CitraFleet is a powder that smells and tastes of lemons. It contains two types of laxatives mixed in each sachet which, when dissolved in water and drunk, wash-out and clean the bowels. It is important to have an empty, clean bowel so that your doctor or surgeon can see it clearly. CitraFleet is indicated in adults (including the elderly) aged 18 years and over.

2. What you need to know before you take CitraFleet

Do not take CitraFleet if you:

- are **allergic** to sodium picosulfate, magnesium oxide, citric acid or any of the other ingredients of this medicine (listed in section 6).
- have **congestive heart failure** (your heart is unable to properly pump blood round the body).
- have a condition called **gastric retention** (your stomach does not empty properly).
- have a **stomach ulcer** (sometimes called gastric or duodenal ulcers).
- have **blockage of the gut or failure of normal bowel movements** (sometimes called ileus).
- have been told by a doctor that you have a **damaged gut wall** (also called toxic colitis).
- have a **swollen large bowel** (also known as toxic megacolon).
- have **recently been sick or feel sick** (nausea or vomiting).
- are very thirsty or think you may be **severely dehydrated**.
- have been told by your doctor that you have a swollen abdomen due to the collection of fluid (**called ascites**).
- have **recently had surgery on your abdomen** e.g. for appendicitis.
- may have a **pierced/damaged or blocked gut** (perforated or obstructed bowel).
- have been told by your doctor that you suffer from **active inflammatory bowel disease** (such as Crohn's disease or ulcerative colitis).
- have been told by your doctor that you have damaged muscles that are leaking their contents into your blood (**rhabdomyolysis**).

- have **severe kidney problems** or have been told by your doctor that you have too much magnesium in your blood (**hypermagnesaemia**).

Warnings and precautions

Talk to your doctor or pharmacist before taking CitraFleet if you:

- have had **recent surgery on your gut**.
- have **kidney or heart trouble**.
- have **water and/or electrolyte** (sodium or potassium) **imbalance** or are **taking medicines that might affect water and/or electrolyte** (sodium or potassium) **balance** in the body, such as diuretics, corticosteroids or lithium.
- have **epilepsy or a history of fits**.
- have **low blood pressure** (hypotension).
- are thirsty or think you may be **mildly to moderately dehydrated**.
- are **elderly or physically weak**.
- have **ever suffered from low sodium or potassium in the blood** (also known as hyponatraemia or hypokalaemia).

You should keep in mind that after taking CitraFleet you will have frequent fluid stools. You should drink plenty of clear liquids (see Section 3) to replenish the loss of fluids and salts. Otherwise, you may suffer from dehydration and low blood pressure, which might cause you to faint.

Other medicines and CitraFleet

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

CitraFleet may affect or be affected by other medicines if you take them concomitantly. If you are taking any of the types of medicines listed below, your doctor might decide that you should be given a different medicine or that the dose should be adjusted. So, if you have not already spoken with your doctor about these **go back to your doctor and ask what to do**:

- **Oral contraceptives**, as their effects may be reduced.
- **Diabetic** medicines or medicines used to treat **epilepsy** (fits), as their effects may be reduced.
- **Antibiotic medicines**, as their effects may be reduced.
- Other **laxatives**, including bran.
- **Diuretics**, such as furosemide used to control fluid retention in the body.
- **Corticosteroids** such as prednisone, used to treat inflammation in diseases such as arthritis, asthma, hay fever, dermatitis and inflammatory bowel disease.
- **Digoxin**, used to treat heart failure.
- **Non-steroidal anti-inflammatory drugs (NSAIDs)** such as aspirin and ibuprofen used to treat pain and inflammation.
- **Tricyclic antidepressants** such as imipramine, and amtryptiline **and selective serotonin reuptake inhibitors (SSRIs)** such as fluoxetine, paroxetine and citalopram used to treat depression and anxiety.
- **Antipsychotic drugs** such as haloperidol, clozapine and risperidone used to treat schizophrenia.
- **Lithium** used to treat manic depression (bipolar disorder).
- **Carbamazepine** used to treat epilepsy.
- **Pencillamine** used to treat rheumatoid arthritis and other conditions.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

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

CitraFleet contains potassium and sodium

This medicine contains 5 mmol (or 195 mg) potassium per sachet. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet..

This medicine contains less than 1 mmol sodium (23 mg) per sachet, that is to say essentially 'sodium-free'.

3. How to take CitraFleet

Always take this medicine exactly as your doctor or pharmacist has told you, as the hospital procedure may have to be repeated if you do not wash-out your bowels completely. Check with your doctor or pharmacist if you are not sure.

Be prepared to expect frequent, loose bowel movements at any time after taking a dose of CitraFleet. This is normal and shows that the medicine is working. It would be sensible to make sure that you have access to a toilet until the effects have worn off.

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, you should not have 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 directed by your doctor, you should not take more than the recommended dose in any 24 hour period.

Treatment plan

You should have been given 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 recommended when the procedure is planned for early in the morning, or
- Both sachets in the morning of the day of the procedure. This regimen is only suitable when the procedure is planned in the afternoon/evening.

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

Each sachet should be reconstituted in a cup of water. Do not further dilute the product by drinking liquid immediately after the intake of 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 tumbler sized glass) to 400 ml (a large tumbler sized glass) every hour. Clear soups and/or balanced electrolyte solutions are recommended to avoid dehydration. It is advisable not to drink water alone.

After you have taken the second sachet and drunk 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 (including the elderly) aged 18 years and over.**

- **Step 1** - Mix the contents of 1 sachet in a cup of cold tap water (approximately 150 ml).
- **Step 2** - Stir for 2 - 3 minutes. If it becomes hot when you stir it, wait until it has cooled down before drinking the whole solution. Once the solution is ready, drink it immediately. The solution will appear cloudy.

If you take more CitraFleet than you should, talk to your doctor or pharmacist immediately.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The known side effects of CitraFleet are described below and are listed according to the frequency with which they occur:

Very common (may affect more than 1 in 10 people):

Abdominal pain.

Common (may affect up to 1 in 10 people):

Abdominal distension (swollen abdomen), feeling thirsty, anal discomfort and proctalgia (anal or bottom pain), fatigue (tiredness), sleep disorders, headache, dry mouth, nausea (feeling sick).

Uncommon (may affect up to 1 in 100 people):

Dizziness, vomiting (being sick), inability to control your bowel movements (faecal incontinence).

Other side effects for which the frequency of occurrence is not known (cannot be estimated from the available data):

Anaphylaxis or hypersensitivity which are serious allergic reactions. You should go straight to hospital if you have difficulty in breathing, start to look flushed, or have any other symptom that you think might mean you are having a serious allergic reaction.

Hyponatraemia (low levels of sodium in the blood), hypokalaemia (low levels of potassium in the blood), epilepsy, convulsions (fits), orthostatic hypotension (low blood pressure upon standing up which may make you feel dizzy or unsteady), feeling of confusion, rashes including urticaria (hives), pruritis (itching) and purpura (bleeding under the skin).

Flatulence (wind) and pain.

This medicine is intended to give you very regular, loose bowel movements, similar to diarrhoea. However, if after taking this medicine your bowel movements become troublesome or give you concern, you should talk to your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Departament Monitorowania Niepożądanych Działań Produktów Leczniczych Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, Al. Jerozolimskie 181C, 02-222 Warszawa, Tel.: + 48 22 49 21 301, Faks: + 48 22 49 21 309, e-mail: ndl@urpl.gov.pl. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store CitraFleet

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the sachet after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What CitraFleet contains

- The active substances are sodium picosulfate 10.0 mg, light magnesium oxide 3.5 g, citric acid 10.97 g per sachet.
- The other ingredients are potassium hydrogen carbonate, saccharin sodium, lemon flavour (lemon flavour, maltodextrin, tocopherol E307). See section 2.

What CitraFleet looks like and contents of the pack

CitraFleet is a powder for oral solution in sachet supplied in packs of 2, 50, 50 (25x2), 100, 100 (50x2), 200, 200 (100x2), 500, 500 (250x2), 1000 sachets or 50 and 50 (25x2) sachets (hospital pack). The sachets contain white powder crystals with single dose of 15.08g. Each sachet contains one adult dose. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Casen Recordati, S.L.
Autovía de Logroño Km 13,300
50180 Utebo - Zaragoza
Spain

You can get more information on CitraFleet by contacting the following e-mail address:

info@casenrecordati.com

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of the Member State	Name of the Medicinal Product
Denmark	Citrafleet
Finland	CitraFleet, Jauhe oraaliliuosta varten, annospussi
France	CitraFleet, Poudre pour solution buvable en sachet-dose
Germany	CitraFleet Pulver zur Herstellung einer Lösung zum Einnehmen in einem Beutel
UK/Ireland/Malta	CitraFleet, Powder for oral solution in sachet
Italy	CitraFleet Polvere per soluzione orale in bustina
Norway	Citrafleet, pulver til mikstur, oppløsning i dosepose
Portugal	CitraFleet, Pó para solução oral em saqueta
Spain	CitraFleet, Polvo para solución oral
Sweden	CitraFleet, Pulver till oral lösning i dospåse
Austria	CitraFleet Pulver zur Herstellung einer Lösung zum Einnehmen
Belgium	CitraFleet, poeder voor drank
Netherlands	CitraFleet, poeder voor drank
Hungary	CitraFleet, Por belsőleges oldathoz
Iceland	CitraFleet, mixtúruduft, lausn í skammtapoka
Luxembourg	CitraFleet, poudre pour solution buvable
Poland	CitraFleet, (0,01 g + 3,50 g + 10,97 g)/saszetkę, proszek do sporządzania roztworu doustnego
Czech Republic	Citrafleet prášek pro perorální roztok
Romania	CitraFleet pulbere pentru soluție orală
Slovakia	CitraFleet, prášok na perorálny roztok vo vrecku
Greece/Cyprus	CitraFleet, Κόνις για πόσιμο διάλυμα σε φακελίσκο

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