

## Package leaflet: Information for the patient

### CitraFleet oral solution

#### 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.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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 oral solution is and what it is used for
2. What you need to know before you take CitraFleet oral solution
3. How to take CitraFleet oral solution
4. Possible side effects
5. How to store CitraFleet oral solution
6. Contents of the pack and other information

#### **1. What CitraFleet oral solution is and what it is used for**

You are taking CitraFleet oral solution 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 an oral solution that smells and tastes of grenadine. It contains two types of laxatives mixed in each bottle which, when 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 oral solution is indicated in adults (including the elderly) aged 18 years and over.

#### **2. What you need to know before you take CitraFleet oral solution**

##### **Do not take CitraFleet oral solution 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 oral solution 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 oral solution 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 oral solution

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

CitraFleet oral solution 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 acetylsalicylic acid 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.
- **Penicillamine** 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 oral solution.

**CitraFleet oral solution contains sodium, sodium metabisulfite (E 223), sodium methyl p-hydroxybenzoate (E 219), ethanol and sodium propyl p-hydroxybenzoate (E 217)**

This medicine contains sodium metabisulfite (E 223). It may rarely cause severe hypersensitivity reactions and bronchospasm.

This medicine contains sodium methyl p-hydroxybenzoate (E 219) and sodium propyl p-hydroxybenzoate (E 217). It may cause allergic reactions (possibly delayed).

This medicine contains 66 mg of alcohol (ethanol) in each bottle. The amount in 160ml of this medicine is equivalent to less than 2 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains 3.4 g sodium in each bottle. This is equivalent to 173.6% of the recommended maximum daily dietary intake of sodium for an adult.

### **3. How to take CitraFleet oral solution**

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 oral solution.** 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 fibre food diet on the day before your procedure is planned. When you start taking 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 bottles of CitraFleet oral solution. Each bottle contains one adult dose.

CitraFleet oral solution is ready for you to drink right from the bottle. It does not need to be mixed or diluted.

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

- One bottle on the evening prior to the procedure and the second bottle in the morning of the day of the procedure,
- One bottle in the afternoon and the second bottle in the evening prior to the procedure. This schedule is recommended when the procedure is planned for early in the morning, or
- Both bottles 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 bottles should be at least 5 hours.

Do not further dilute the product by drinking liquid immediately after the intake of each bottle.

Wait about ten minutes after taking each bottle, 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 bottle 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.

**If you take more CitraFleet oral solution 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 oral solution 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 HPRAs Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects, you can help provide more information on the safety of this medicine.

#### **5. How to store CitraFleet oral solution**

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the bottle label 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 oral solution contains**

- The active substances are sodium picosulfate 10.0 mg, light magnesium oxide 3.5 g, citric acid 10.97 g per each bottle (160 ml).
- The other ingredients are malic acid, sodium metabisulfite (E 223), sodium methyl p-hydroxybenzoate (E 219), sodium propyl p-hydroxybenzoate (E 217), sucralose, masking flavour (modulator sweet), grenadine flavour (contains ethanol and propylene glycol (E 1520)), sodium hydroxide (for pH-adjustment) and purified water. See section 2.

### **What CitraFleet oral solution looks like and contents of the pack**

CitraFleet is a transparent oral solution, colourless or slightly yellowish with grenadine flavour supplied in:

- packs containing 2, 20, 40 or 80 bottles, or
- multipacks containing 20 (10x2), 40 (20x2) or 80 (40x2) bottles.

The bottles contain a single dose of 160ml. Each bottle 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

Marketing Authorisation Number:  
PA2028/002/002

**You can get more information on CitraFleet oral solution by contacting the following e-mail address: [info@casenrecordati.com](mailto:info@casenrecordati.com)**

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

CitraFleet: France, Finland, Germany, Greece, Ireland, Italy, Norway, Poland, Portugal, Spain, Sweden.

**This leaflet was last revised in**