Package leaflet: Information for the user
Sucralfate 1 g/5 ml Oral Suspension
sucralfate

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

1. WHAT SUCRALFATE SUSPENSION IS AND WHAT IT IS USED FOR

The name of your medicine is Sucralfate 1 g/5 ml Oral Suspension (called Sucralfate Suspension in this leaflet). Sucralfate Suspension contains a medicine called sucralfate. This belongs to a group of medicines called "Ulcer-healing" medicines. It works by forming a protective barrier over a stomach ulcer and helps stop further irritation caused by stomach acid.

Sucralfate Suspension is used to treat:

- Stomach ulcers (gastric ulcers)
- Ulcers in your bowel (duodenal ulcers)
- Inflammation of your stomach lining as a transient or permanent manifestation (acute gastritis and symptomatic chronic gastritis)
- Stomach problems due to the use of anti-inflammatory drugs belonging to the category of NSAIDs (non-steroidal anti-inflammatory drugs) (NSAID gastropathies)
- Inflammation of the oesophagus due to the reflux of liquids and/or acidic foods (reflux oesophagitis)

Sucralfate Suspension can also be used to prevent bleeding ulcers in seriously ill patients in hospital.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SUCRALFATE SUSPENSION

Do not take Sucralfate Suspension:

- If you are allergic (hypersensitive) to sucralfate or any of the other ingredients of Sucralfate Suspension (listed in Section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- If you are on dialysis for kidney problems

Do not take this medicine if any of the above apply to you. If you are not sure talk to your doctor or pharmacist before taking Sucralfate Suspension.

You must not be given this medicine by injection into a vein.

Warnings and precautions

Talk to your doctor or pharmacist before taking Sucralfate Suspension if:

- You are pregnant, trying to become pregnant or breast-feeding (see 'Pregnancy and breast-feeding' below)
- You have kidney problems

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Sucralfate Suspension.

Other medicines and Sucralfate Suspension

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

This includes medicines obtained without a prescription, including herbal medicines. This is because Sucralfate Suspension can affect the way some other medicines work. Also some other medicines can affect the way Sucralfate Suspension works.

In particular, before taking Sucralfate Suspension, tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines containing citrates
- Medicines containing aluminium
- Medicines for stomach ulcers such as cimetidine or ranitidine
- Medicines for infection (antibiotics) such as tetracycline, ciprofloxacin or norfloxacin
- Sulpiride-used for mental health problems (psychotic episodes)
- Digoxin-used for heart problems
- Phenytoin-used for fits (epilepsy)
- Warfarin-used for blood clots
- Theophylline-used for asthma or other breathing problems
- Levothyroxine-used for thyroid problems
- Quinidine-used for heart problems
- Ketaconazole-used for fungal infections

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Sucralfate Suspension.

If you are taking any other medicine, leave a two hour gap between taking Sucralfate Suspension and the other medicine. For "antacid" medicines, the gap needs to be at least half an hour.

Sucralfate Suspension with food and drink

If you are being fed by a tube into your stomach, Sucralfate Suspension should be given at least one hour before or after a feed.

Pregnancy and breast-feeding

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

Sucralfate Suspension may make you feel dizzy or drowsy. If you feel dizzy or drowsy, do not drive or use tools or machines while taking this medicine.

Sucralfate Suspension contains sodium methyl parahydroxybenzoate and sodium.

This medicinal product contains 5 mg sodium methyl parahydroxybenzoate in each 5 ml of oral suspension which may cause allergic reactions (possibly delayed).

This medicinal product contains less than 1 mmol sodium (23 mg) per 20 ml of oral suspension, that is to say essentially 'sodium-free'.

3. HOW TO TAKE SUCRALFATE SUSPENSION

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is either:

- Two 5 ml spoonfuls after waking up in the morning and two 5 ml spoonfuls at bedtime

or

- One 5 ml spoonful four times a day. Doses should be taken before meals and at bedtime

In seriously ill patients in hospital, the dose may be increased to 5 ml six times a day.

Taking this medicine

- Take this medicine by mouth
- Shake the bottle well before use
- This medicine is usually taken for 4 to 6 weeks, but may be taken for up to 12 weeks if necessary
- The maximum dose in a day is eight 5 ml spoonfuls

Use in children

Sucralfate Suspension is not suitable for children under 14 years old.

If you take more Sucralfate Suspension than you should

If you take more Sucralfate Suspension than you should, talk to a doctor or go to hospital straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

If you forget to take Sucralfate Suspension

- If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose
- Do not take a double dose to make up for a forgotten dose

If you stop taking Sucralfate Suspension

Do not stop taking Sucralfate Suspension without talking to your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Sucralfate Suspension and tell your doctor straight away if:

- You have an allergic reaction. The signs include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Tell a doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:

- Constipation or diarrhoea
- Indigestion, stomach ache or wind
- Being sick (vomiting) or feeling sick (nausea)
- Feeling dizzy, drowsy or being unsteady on your feet
- Back pain
- Dry mouth
- Headache
- Itching

Sucralfate Suspension may cause a blockage in the digestive tract of seriously ill patients in hospital. This is a rare side effect.

Sucralfate Suspension may cause aluminium to build up in your body. This can cause changes in your bones such as thinning or softening, impairment of your brain or problems with your blood.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SUCRALFATE SUSPENSION

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton and on the bottle label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

After first opening use within 1 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 Sucralfate Suspension contains

- The active substance is sucralfate. Each 5 ml of suspension contains 1 g sucralfate.
- The other ingredients are glycerol (E422), sodium dihydrogen phosphate dihydrate (E339), sodium methyl parahydroxybenzoate (E219), xanthan gum (E415), saccharin sodium (E954i), aniseed flavour (including propylene glycol, E1520), caramel flavour (including propylene glycol, E1520) and purified water.

What Sucralfate Suspension looks like and contents of the pack

Sucralfate Suspension is a white to off-white suspension with an odour of aniseed/caramel. It comes in a 200 ml amber glass bottle with a child resistant, tamper evident screw cap and 5 ml measuring spoon with intermediate graduation at 2.5 ml.

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