

Antepsin® 1g/5ml Oral Suspension

(sucralfate)

This product is available as the above name but will be referred to as Antepsin Suspension throughout this leaflet.

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 effect not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Antepsin Suspension is and what it is used for

Antepsin 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.

Antepsin Suspension is used to treat:

- Stomach ulcers
- Ulcers in your bowel
- Inflammation of your stomach lining

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

2. What you need to know before you take Antepsin Suspension

Do not take Antepsin Suspension:

- If you are allergic (hypersensitive) to sucralfate or any of the other ingredients of Antepsin 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 Antepsin Suspension.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Antepsin 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 Antepsin Suspension.

Other medicines and Antepsin 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 Antepsin Suspension can affect the way some other medicines work. Also some other medicines can affect the way Antepsin Suspension works.

In particular, before taking Antepsin 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
- Ketoconazole-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 Antepsin Suspension.

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

Antepsin Suspension with food and drink

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

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before taking this medicine if:

- You are pregnant, might become pregnant or think you might be pregnant
- You are breast-feeding or planning to breast-feed

Ask your doctor or pharmacist for advice before taking any medicine if you might be pregnant.

Driving and using machines

Antepsin 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.

Antepsin Suspension contains Hydroxybenzoates

- This medicine contains sodium propyl hydroxybenzoate and sodium methyl hydroxybenzoate. These may cause allergic reactions and sometimes this allergic reaction may not happen straight away.

3. How to take Antepsin 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
- 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

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

If you take more Antepsin Suspension than you should

If you take more Antepsin 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 Antepsin 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 Antepsin Suspension

Do not stop taking Antepsin 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, Antepsin Suspension can cause side effects, although not everybody gets them.

Stop taking Antepsin 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

Antepsin Suspension may cause a blockage in the digestive tract of seriously ill patients in hospital.

This is a rare side effect.

Antepsin 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 or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

UK - Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

5. How to store Antepsin 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. The expiry date refers to the last day of that month.

Do not store above 25°C.

Once opened the medicine should be used within 28 days.

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

If your medicine becomes discoloured or shows any other signs of deterioration consult your pharmacist who will tell you what to do.

6. Contents of the pack and other information

What Antepsin Suspension contains

- Antepsin Suspension contains the active substance sucralfate. Each 5ml dose contains 1g sucralfate.
- The other ingredients contained in the Antepsin Suspension are sodium methyl hydroxybenzoate, sodium propyl hydroxybenzoate, sodium dihydrogen phosphate dihydrate, xanthan gum, aniseed flavour, caramel flavour, sodium saccharin dihydrate, glycerol 85% and deionized water.

What Antepsin Suspension looks like and contents of the pack

Antepsin Suspension is a white to off-white suspension with an odour of aniseed/caramel. It comes in 200 ml amber glass bottle with a tamper evident screw cap and 5 ml measuring spoon.

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Manufactured by Laboratori Baldacci S.p.A., Via S. Michele degli Scalzi, 73 – Pisa, Italy.
Procured from within the EU and repackaged by the Product Licence holder: O.P.D. Laboratories Ltd., Unit 6 Colonial Way, Watford, Herts WD24 4PR.

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To request a copy of this leaflet in Braille, large print or audio please call 01923 332 796.

Sucralfate 1g/5ml Oral Suspension

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