

Package leaflet: Information for the user
Acidex Oral Suspension

sodium alginate 500 mg, sodium bicarbonate 267 mg ,calcium carbonate 160 mg/10 ml

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.

- Keep this leaflet. You may need to read it again.
- Ask your doctor or 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.
- **You must talk to a doctor if you do not feel better or if you feel worse after 7 days.**

What is in this leaflet:

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

1. What Acidex is and what it is used for

Acidex belongs to a group of medicines called ‘reflux suppressants’.

This product forms a protective layer that floats on top of the stomach contents. This layer prevents reflux and keeps the stomach contents away from the lining of the food pipe to relieve the symptoms of heartburn and indigestion.

Acidex is used for the treatment of symptoms of gastro-oesophageal reflux such as acid regurgitation, heartburn and indigestion (related to reflux), for example, following meals, or during pregnancy or in patients with symptoms related to reflux oesophagitis.

2. What you need to know before you take Acidex

Do not take Acidex:

- If you are allergic to sodium alginate, sodium bicarbonate or calcium carbonate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Take special care with Acidex if you:

- are on a sodium restricted diet

Consult your doctor if you are over 40 years and have never suffered with heartburn and acid indigestion before.

If symptoms persist after 7 days consult your doctor.

Other medicines and Acidex

Do not take this medicine within two hours of taking other medicines by mouth as it can interfere with the action of some other medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription. A time interval of 2 hours

should be considered between Acidex intake and administration of other medicinal products, especially tetracyclines, fluoroquinolones, iron salts, thyroid hormones, chloroquine, bisphosphonates and estramustine.

Acidex with food and drink

Acidex should be taken after meals as well as at bedtime.

Pregnancy and breast-feeding

You can take this product if you are pregnant or breast-feeding.

As with all medicines, the treatment duration should be limited as much as possible.

Driving and using machines

Acidex has no influence on the ability to drive and use machines.

Acidex contains sodium and parahydroxybenzoates

- This medicine contains 286.5 mg (12.45 mmol) sodium (main component of cooking/table salt) in each 20 ml dose. This is equivalent to 14.3 % of the recommended maximum daily dietary intake of sodium for an adult. The maximum daily dose of this product is equivalent to 57.2 % of the WHO recommended maximum daily intake for sodium. Talk to your doctor or pharmacist if you need this product on a daily basis for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.
- Ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216) and butyl parahydroxybenzoate may cause allergic reactions (possibly delayed).

3. How to take Acidex

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

For oral administration. Shake well before use.

Acidex should not be taken within 2 hours of taking other medicines by mouth.

The recommended dose is:

Adults and children 12 years and over: Take 10 – 20 ml (Two to four 5 ml spoonfuls) after meals and at bedtime. The maximum daily dose is 80 ml.

Children 6 to 12 years: Take 5 – 10 ml (One to two 5 ml spoonfuls) after meals and at bedtime. The maximum daily dose is 40 ml.

Children under 12 years: Should only be taken on medical advice.

Not for use in children of 6 years or under.

If you take more Acidex than you should

If you take too much of this product you may feel bloated and experience some abdominal discomfort. Consult your doctor or pharmacist if this doesn't go away.

If you forget to take Acidex

If you forget a dose it is not necessary to double the dose next time, just carry on taking as before.

4. Possible side effects

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

Very rarely (less than 1 in 10,000 patients) there is a chance of an allergic reaction to the ingredients. Symptoms of this may include skin rash, itching, difficulty breathing, dizziness or swelling of the face, lips, tongue or throat. If you experience these or any other side effects stop taking the product and consult your doctor immediately.

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

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

5. How to store Acidex

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 bottle after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Do not refrigerate.

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 to protect the environment.

6. Contents of the pack and other information

What Acidex contains

- The **active** ingredients in each 10 ml are sodium bicarbonate (267 mg), sodium alginate (500 mg), calcium carbonate 160 mg.
- The **other** ingredients are carbomer, sodium hydroxide (E524), saccharin sodium (E954), ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216), butyl parahydroxybenzoate, isopropyl alcohol, erythrosine colour (E127), star anise oil, purified water (*see end of Section 2 for further information about the ingredients*). This product does not contain sugar or gluten.

What Acidex looks like and contents of the pack

Acidex is a pink, aniseed-flavoured suspension, which is available in pack sizes of 100 ml, 150 ml, 200 ml, 250 ml, 300 ml and 500 ml, in amber glass bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland

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