

**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.**

- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- This medicine is available without prescription. However, you still need to use this product carefully to get the best results from it.
- 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. It has an aniseed flavour.

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACIDEX**

**Do NOT take Acidex:**

- If you are allergic (hypersensitive) to sodium alginate, sodium bicarbonate or calcium carbonate or any of the other ingredients in the product (see Section 6 and end of Section 2)

**Warnings and precautions**

**Take special care with Acidex if you:**

- are on a sodium restricted diet

This medicinal product contains about 6 mmoles sodium per 10 ml.

**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.**

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Leave a time interval of 2 hours between taking Acidex and taking any other medicine by mouth.

### **Acidex with food and drink**

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

### **Pregnancy and breast-feeding**

Acidex may be used during pregnancy and breast-feeding.

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

### **Driving and using machines**

Acidex has no effect on your ability to drive or to operate machinery.

### **Important information about some of the ingredients of Acidex**

Each 10 ml dose of Acidex contains:

- sodium (about 6 mmoles); care should be exercised if you are on a controlled sodium diet.
- ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216) and butyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

## **3. HOW TO TAKE ACIDEX**

Always take Acidex exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

To be taken by mouth only, after meals and at bedtime. Shake well before use. Acidex should not be taken within 2 hours of taking other medicines by mouth.

The usual dose is:

**Adults and children 12 years and over:** Take 10 – 20 ml (Two to four 5 ml spoonfuls) after meals and at bedtime.

**Children 6 to 12 years:** Take 5 – 10 ml (One to two 5 ml spoonfuls) after meals and at bedtime.

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

**Children under 6 years:** Do not give to children under 6 years of age.

### **If you take more Acidex than you should**

If you take too much of this product you may feel bloated. It is unlikely to cause any harm, but please 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 HPRAs Pharmacovigilance Earlsfort Terrace IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [www.hpra.ie](http://www.hpra.ie), e-mail: [medsafety@hpra.ie](mailto:medsafety@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 Acidex after the expiry date which is stated on the bottle or carton after EXP. The expiry date refers to the last day of that month.

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. 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, 500 ml and 1000 ml, in amber glass bottles.

Not all pack sizes may be marketed.

##### Marketing Authorisation Holder and Manufacturer

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

PA 281/75/1

**This leaflet was last updated in: July 2017**