

Package leaflet: Information for the user

Cymalon Granules for Oral Solution

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

This medicine is available without prescription. However, you still need to take Cymalon carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your signs of illness worsen or do not improve after 48 hours.
- If you get any side effects, talk to your doctor or pharmacist. This include any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Cymalon is and what it is used for

Cymalon are granules for oral solution which are used to increase the production of urine and make it less acidic. Cymalon is used to treat the symptoms of cystitis (inflammation of the urinary bladder) in women. It helps to relieve the need to pass urine (go to the toilet) frequently, cramp-like pain and burning sensation which are common symptoms of cystitis.

2. What you need to know before you take Cymalon

Do not take Cymalon

- If you are allergic to Citric Acid (anhydrous), Sodium Bicarbonate, Sodium Citrate dihydrate, Sodium Carbonate or any of the other ingredients of this medicine (listed in section 6).
- If you have severe symptoms or cloudy urine.
- If you are pregnant or breastfeeding.
- If you suffer from heart disease, high blood pressure, diabetes or kidney disease.
- If your diet only allows you to have a small amount of salt.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cymalon

- If you use this treatment frequently. If symptoms persist after the 48 hour treatment is completed please consult your doctor.

Other medicines and Cymalon

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

- Cymalon should be avoided while taking lithium or methenamine, as Cymalon may affect the action of these drugs.

Pregnancy and Breastfeeding

Cymalon should not be used in pregnancy or breastfeeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

There should be no effect on the ability to drive or operate machinery.

Cymalon contains sodium and sucrose

This medicinal product contains 1046 mg sodium per sachet. To be taken into account if you are on a controlled sodium diet.

This medicinal product also contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Cymalon

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

Adults

One sachet to be taken in water, three times a day over 48 hours. Drink immediately after reconstitution.

If you are still suffering from the symptoms of cystitis after 48 hours, please talk to your doctor.

Children

Cymalon is not recommended for children.

If you take more Cymalon than you should

If you accidentally take too much Cymalon you should consult a doctor or hospital as soon as possible.

If you forget to take Cymalon

Do not take a double dose to make up for a forgotten dose.

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.

Taking Cymalon may cause flatulence. If you notice this or any other effects, stop taking the product and tell your doctor or pharmacist.

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 HPRA

Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cymalon

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

Keep in the original pack.

Do not use this medicine after the expiry date which is stated on the sachet after EXP. The expiry date refers to the last day of that month.

Do not throw away 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 Cymalon contains

The active substances are Citric acid (anhydrous), Sodium Bicarbonate, Sodium Citrate dihydrate and Sodium Carbonate. Each sachet contains 1063.0 mg of Citric acid (anhydrous), 1200.0 mg of Sodium Bicarbonate, 2819.0 mg of Sodium Citrate dihydrate and 130.0 mg of Sodium Carbonate. This is a combined alkalinity equivalent to 4.4 g Sodium Citrate (sodium content 1 g/sachet). The other ingredients are: sucrose, saccharin sodium and natural lemon flavour (F309).

What Cymalon looks like and contents of the pack

Cymalon are granules for oral solution.

Each pack contains 6 sachets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Actavis Group PTC ehf., Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Iceland.

Manufacturer

FAMAR France, 1 Avenue du Champs de Mars, 45072 Orleans, Cedex-02, France.

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