

Package leaflet: Information for the user

Carbosan 2% w/w Gel

Carbenoxolone Sodium

ROWA[®]

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

Always use 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 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 2 weeks.

What is in this leaflet:

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

1. What Carbosan is and what it is used for

Carbosan Gel is used for the treatment of lip sores and mouth ulcers.

It contains a medicine called carbenoxolone sodium, which has anti-diuretic and anti-inflammatory properties. It acts by enhancing the production of protective mucous in the mouth.

2. What you need to know before you use Carbosan

Do not use Carbosan if you:

- are allergic to carbenoxolone sodium or any of the other ingredients of this medicine (listed in section 6)
- suffer from any severe heart, liver or kidney complaints
- suffer from high blood pressure
- are under 3 years or elderly
- have a low level of albumin (protein) in your blood
- are pregnant or breastfeeding
- are on medication for a heart condition.

Warnings and precautions

Talk to your doctor or pharmacist before using Carbosan.

- If an infection is present, you may also need an antibiotic.

If symptoms persist for more than 2 weeks, consult your doctor.

Other medicines and Carbosan

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

- Do not use if you are on medication for the treatment of heart problems.

Pregnancy and breast-feeding

Carbosan should not be used during pregnancy or lactation.

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

Driving and using machines

Carbosan does not normally produce any effects on the ability to drive or use machines.

Carbosan contains parahydroxybenzoate

May cause allergic reactions (possibly delayed).

Carbosan contains fragrance with limonene

Limonene may cause allergic reactions.

Carbosan contains cetylstearyl alcohol (polyoxyethylene-30-cetylstearyl alcohol).

May cause local skin reactions (e.g. contact dermatitis).

3. How to use Carbosan

Always use 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.

Adults and Children, over 3 years of age:

Carbosan is to be used on your lips and on ulcers in your mouth only. At the first signs of symptoms you should apply Carbosan Gel thickly to the mouth lesions after meals and at bedtime.

If you use more Carbosan than you should

If you apply more than the recommended amount of Carbosan or in the event of a large ingestion, contact your doctor or nearest hospital casualty department.

If you forget to use Carbosan

Use the gel as soon as you remember then continue as before.

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

4. Possible Side Effects

There have been no side effects reported in relation to the use of Carbosan.

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 Carbosan

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 tube after 'Exp'. The expiry date refers to the last day of that month.

Replace the cap tightly after use.

Do not store above 25° C.

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 Carbosan contains

- The active substance is carbenoxolone sodium. Each gram contains 20.8 mg carbenoxolone sodium.
- The other ingredients are polyoxyethylene-30-cetylstearyl alcohol, polyol fatty acid ester, iso-octyl stearate, imidazolidinyl urea, sodium methylparahydroxybenzoic acid, sodium ethylparahydroxybenzoic acid, sodium propylparahydroxybenzoic acid, lemon oil and purified water.

What Carbosan looks like and contents of the pack

Carbosan Gel is a translucent, colourless gel with a lemon odour.

Carbosan is available in a 5 g tube.

Marketing Authorisation Holder and Manufacturer:

Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland

This leaflet was last revised in November 2020