Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Carbosan 2% w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 g of Carbosan Gel contains 100 mg carbenoxolone sodium.

Excipient(s) with known effect:

0.60 % w/w parahydroxybenzoic acid esters, sodium salt
0.10 % w/w lemon oil containing limonene in a range of 0.056 % w/w - 0.078 % w/w
16.50 % w/w polyoxyethylene 30 cetylstearyl alcohol
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Gel
A translucent, colourless gel with a lemon odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Carbosan Gel is indicated in the symptomatic relief and treatment of lip sores, mouth ulcers or aphthous changes in the oral mucous membranes.

4.2 Posology and method of administration

Route of Administration: For cutaneous use

Recommended Dosage Schedule:

Adults and children over 3 years only:
Apply thickly to lesions after meals and at bedtime.

4.3 Contraindications

Carbosan Gel is contra-indicated in patients suffering from severe cardiac, renal and hepatic impairment, patients with hypertension or those who are receiving cardiac glycosides.

Carbosan Gel is contra-indicated in elderly patients and in those patients who have low serum albumin.

Carbosan Gel is also contra-indicated during pregnancy and lactation.

4.4 Special warnings and precautions for use

If bacterial infection is superimposed, appropriate therapy should be instituted. If symptoms persist for more than 2 weeks consult your doctor.

Carbosan contains parahydroxybenzoate.

May cause allergic reactions (possibly delayed).

Carbosan contains cetylstearyl alcohol:
May cause local skin reactions (e.g. contact dermatitis).

Carbosan contains fragrance:
This medicine contains lemon oil fragrance with allergens, where limonene is one of the fragrance allergens listed.

Allergens may cause allergic reactions.

In addition to allergic reactions in sensitised patients, nonsensitised patients may become sensitised

4.5 Interaction with other medicinal products and other forms of interactions

Carbosan Gel should not be used by patients who are receiving cardiac glycosides.

4.6 Fertility, pregnancy and lactation

Carbosan Gel should not be used during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

The use of Carbosan Gel is unlikely to result in any impairment of the ability of patients to drive or operate machinery.

4.8 Undesirable effects

Side effects to the use of Carbosan Gel have not been reported.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance. Website: www.hpra.ie.

4.9 Overdose

No specific data is available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Carbenoxolone Sodium is a derivative of enoxolone with anti-inflammatory and anti-diuretic properties.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyoxyethylene-30-cetylstearyl alcohol
Polyol fatty acid ester

Iso-Octyl stearate
Imidazolidinyl urea
Sodium methylparahydroxybenzoic acid
Sodium ethylparahydroxybenzoic acid
Sodium propylparahydroxybenzoic acid
Lemon oil
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Replace cap tightly after use.
Do not store above 25°C.

6.5 Nature and contents of container

The immediate container for Carbosan Gel is an aluminium tube that has an external white lacquer and a gold coloured internal lacquer coating. The tube has a white screw-on cap. Pack size: 5g.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7 MARKETING AUTHORISATION HOLDER

Rowa Pharmaceuticals Limited
Newtown
Bantry
Co. Cork
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0074/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 March 1987

Date of last renewal: 13 March 2007

10 DATE OF REVISION OF THE TEXT

November 2020