

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Bocasan 68.635% w/w + 29.415% w/w Gargle, Powder for Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Perborate, monohydrate 68.635 % w/w

Sodium Bitartrate, anhydrous 29.415 % w/w

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gargle, powder for solution.

White, free-flowing powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

The treatment of acute or chronic gingivitis; and for cleansing the gingival tissue of the oral cavity.

4.2 Posology and method of administration

For use, dissolve in 30 ml water (about a tablespoon) of at about the temperature of a hot drink. The powder will dissolve to a clear solution. Use as a mouthwash: swish the solution around the mouth then spit it out. Do not rinse with or drink any other solution or eat for half an hour after use. Repeat three times daily after meals.

If you accidentally miss a dose just continue at the first opportunity but keep to the maximum of 3 sachets in any one day.

Not to be used for longer than 7 days, or exceptionally up to 14 days on dental or medical advice.

Consult your dentist or doctor if the original symptoms of gum inflammation do not go away after 7 days of treatment.

4.3 Contraindications

Contra-indicated in the case of patients with severe renal disease (blood urea nitrogen above double normal values). Mouth washes with high frequency might provoke toxic boron levels in the serum as renal excretion of boron is impaired. Toxic reactions are not foreseen in normal use but, if large quantities of Bocasan were ingested, then it would be necessary to consider the possibility of poisoning resulting from the boron present.

4.4 Special warnings and precautions for use

Pharmaceutical precautions: There are no special requirements for the storage of Bocasan.

Precautions and drug interactions: Do not swallow the mouthwash solution.

Warnings and adverse effects:

Care must be taken not to swallow the BOCASAN solution. If you do swallow a small amount then no great harm will follow, but if you accidentally take a large amount then tell your doctor immediately or go to your nearest Casualty Department.

BOCASAN should not be used if you have kidney disease or any illness which restricts your ability to pass urine.

BOCASAN is suitable for use by adults and children over 12 years of age, although precautions should be taken to prevent children from swallowing the solution. Not for use by children under 12 years of age.

4.5 Interaction with other medicinal products and other forms of interaction

None in normal use.

4.6 Pregnancy and lactation

No restriction in use.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Occasional transient burning sensation.

4.9 Overdose

Symptoms, emergency procedures, antidotes.

Symptoms of boron poisoning include an erythematous rash, vomiting, diarrhoea, depression of the circulation, marked weakness, sub normal temperature, profound shock and coma; in some cases there may be signs of meningeal irritation or convulsions.

Antidote after ingestion: Empty stomach by stomach tube or emetic. Give purgative dose of magnesium sulphate and transfusions of plasma and Ringer's solution. Keep the patient warm and treat for shock. Give oxygen inhalation if necessary.

Sensitivity: certain patients may experience a burning sensation, sensitisation, or irritation when using Bocasan, and these patients should be instructed to use the solution at half strength. In the unlikely case of the symptoms persisting the use of rinse should be discontinued.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not determined

5.2 Pharmacokinetic properties

Not determined

5.3 Preclinical safety data

Not determined

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin sodium
Peppermint oil
Vanillin
Ginger
Menthol

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Cardboard carton containing 20 sachets, each being of paper/aluminium foil/polythene and containing 1.7 gram Bocasan.

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

Gillette Group UK Ltd
Gillette Corner
Great West Road
Isleworth
Middlesex TW7 5NP
United Kingdom

Trading style:
Gillette and/or Oral B

8 MARKETING AUTHORISATION NUMBER

PA1261/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06 April 2001
Date of last renewal: 06 April 2006

10 DATE OF REVISION OF THE TEXT

May 2007