

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Chlorhexidine Gluconate Mouthspray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Gluconate 0.20 (% w/v)

Excipient(s) with known effect

Sorbitol 12.93 %

Absolute Ethanol 5.00%

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oromucosal Spray

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Chlorhexidine Gluconate Mouthspray is an antimicrobial solution which inhibits the formation of dental plaque. It is indicated as an aid to the treatment and prevention of gingivitis and in the maintenance of oral hygiene, particularly in situations where tooth brushing cannot be adequately employed (e.g. following oral surgery or in physically handicapped patients).

4.2 Posology and method of administration

Posology

Children, adults and the elderly

Chlorhexidine Gluconate Mouthspray should be applied as required to the tooth and gingival surfaces, using up to 12 actuations of the spray (approximately 0.14ml of solution per actuation) twice daily (once in the morning and once in the evening).

Method of administration

The spray should be directed inside the mouth onto the dental and gingival surfaces. For the treatment of gingivitis, a course of about one-month is advisable, although some variation in response is to be expected.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

For oral use only. Do not swallow. Expel from the mouth after each use. Keep away from the eyes and ears. If the spray comes into contact with the eyes, wash out well with water. Keep out of reach and sight of children.

This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per spray.

This medicine contains 0.02 mg of sorbitol in each spray.

The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account.

The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

4.5 Interaction with other medicinal products and other forms of interaction

Chlorhexidine Gluconate 0.2% is incompatible with anionic agents which are usually present in conventional dentifrices. These should therefore be used before Chlorhexidine Gluconate Mouthspray (rinsing the mouth between applications) or at a different time of the day.

4.6 Fertility, pregnancy and lactation

Chlorhexidine has been in widespread use for many years and no harmful effects in human pregnancy have been reported. However, as with all drugs, caution should be exercised. Chlorhexidine Gluconate Mouthspray should only be used when the benefit to the mother has been assessed by a clinician.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Irritative skin reactions to chlorhexidine can occur occasionally. Generalised allergic reactions to chlorhexidine have also been reported but are extremely rare.

A superficial discoloration of the dorsum of the tongue may occur. This disappears after treatment is discontinued. Discoloration of the teeth and silicate or composite restorations may also occur. This stain is not permanent and can largely be prevented by brushing with a conventional toothpaste daily before using this spray.

However, in certain cases, a professional prophylaxis (scaling and polishing) may be required to remove this stain completely. Stained anterior tooth-coloured restorations with poor margins or rough surfaces which are not adequately cleaned by professional prophylaxis may require replacement.

Similarly where normal tooth brushing is not possible, as for example with intermaxillary fixation, or with extensive orthodontic appliances, scaling and polishing may also be required once the underlying conditions have been resolved.

Transient disturbances of taste sensation and a burning sensation of the tongue may occur on initial use of the spray. These effects usually diminish with continued use. Oral paraesthesia /hypoesthesia may also occur with chlorhexidine use.

In cases where oral desquamation occurs it may be necessary to discontinue treatment. Very occasionally, swelling of the parotid glands during use of oral chlorhexidine has been reported. In all cases spontaneous resolution has occurred on discontinuing treatment.

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 the Yellow Card Scheme Website at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Chlorhexidine is poorly absorbed by the oral route, therefore systemic effects are unlikely even if large volumes are swallowed. However, gastric lavage followed by supportive measures may be used as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiinfectives and antiseptics for local oral treatment.
ATC code: A01AB03

Chlorhexidine gluconate is a bisguanide antiseptic and disinfectant which is bacteriocidal or bacteriostatic against a wide range of gram negative and gram positive vegetative bacteria, yeasts, dermatophyte fungi and lipophylic viruses. The antimicrobial activity covers most of the important species occurring in the oral microflora.

5.2 Pharmacokinetic properties

Because of its cationic nature, chlorhexidine (gluconate) binds strongly to skin, mucosa and other tissues and is thus very poorly absorbed. No detectable blood levels have been found following oral use.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol,
Sorbitol,
Cremophor RH60,
Peppermint Flavour,
Purified Water

6.2 Incompatibilities

Chlorhexidine Gluconate Mouthspray is incompatible with anionic agents which are often present in toothpastes. Therefore these should be used before the mouthspray, rinsing the mouth between applications, or at a different time of the day.

Hypochlorite bleaches may cause brown stains to develop in fabrics previously in contact with chlorhexidine.

6.3 Shelf life

Two Years

6.4 Special precautions for storage

Store below 25°C

6.5 Nature and contents of container

Plastic coated type III bottle with pump valve, polypropylene nozzle actuator and polypropylene overcap, enclosed in a carton, containing chlorhexidine gluconate 0.2% w/v solution (65ml).

6.6 Special precautions for disposal and other handling

Direct the spray inside the mouth onto the surface of the teeth and gums. Use twice a day (morning and evening), using up to 12 shots of the spray each time (each shot delivers about 0.14ml of solution).

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 48259/0021

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

9 May 2003

10 DATE OF REVISION OF THE TEXT

06/11/2023