SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

DENTREX (Chlorhexidine Mouthwash BP)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

Chlorhexidine Gluconate Solution BP	
Diluted to Chlorhexidine Gluconate	0.2% w/v
In a pleasantly flavoured aqueous base	q.s
Colour: Carmoisine &Tartrazine	

3 PHARMACEUTICAL FORM

Oromucosal solution
A red coloured clear Liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For inhibition of the formation of dental plaque.

As an aid in the treatment and prevention of gingivitis and in the maintenance of oral hygiene, particularly in situations where toothbrushing cannot be adequately employed (eg following oral surgery, in mentally or physically handicapped patients).

Also for use in a post-periodontal surgery or treatment* regimen to promote gingivalhealing.

*NB: Use as part of a post-periodontal treatment regimen has only been adequately studied over the short term and following standard root surface instrumentation.

It is useful in the management of aphthous ulceration and oral candidal infections (egdenture stomatitis and thrush).

4.2 Posology and method of administration

Adults:

Thoroughly rinse the mouth for about one minute with 10ml twice daily. Spit out after use. In the dental surgery the patient should be instructed to rinse the mouth for one minute prior to treatment.

For the treatment of gingivitis a course of about one month is advisable although some variation in response is to be expected. In the case of aphthous ulceration and oral candidal infections treatment should be continued for 48 hours after clinical resolution. For the treatment of dental stomatitis the dentures should be cleansed and soaked in Chlorhexidine Mouthwash for fifteen minutes twice daily.

Do not exceed the stated dose.

Children and the Elderly:

The normal adult dose is appropriate for elderly patients and children of 12 years and over unless otherwise recommended by the dentist or the physician.

Children under 12 years of age should not use the product unless recommended by a healthcare professional.

Method of administration

External (oral) use. [This product is not intended to be swallowed].

4.3 Contraindications

Chlorhexidine is contraindicated for patients who have previously shown a hypersensitivity reaction to Chlorhexidine or to any of the excipients in the formulation. However, such reactions are extremely rare.

4.4 Special warnings and precautions for use

For oral (external) use only. Do not swallow. Keep out of the eyes and ears.

If the mouthwash comes into contact with the eyes, wash out promptly and thoroughly with water.

In case of soreness, swelling or irritation of the mouth, stop using the product and consult a healthcare professional.

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

In case of swelling or difficulty breathing, stop using the product and seek immediate medical help. Transient disturbances of taste sensation and a numbness, tingling or burning sensation of the tongue may occur on initial use of the mouthwash. These effects usually diminish with continued use. If the condition persists, consult a healthcare professional.

Discolouration of the teeth and tongue may occur. The stain is not permanent and canlargely be prevented by reducing the consumption of dietary chromagens such as tea, coffee or red wine. In the case of dentures this can be prevented by cleaning with a conventional denture cleaner. In certain cases professional treatment (scaling and polishing) may be required to remove the 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 toothbrushing is not possible, for example with intermaxillary fixation, or with extensive orthodontic appliances, scaling and polishing may also be required once the underlying condition has been resolved.

This medicine contains Macrogolglycerol hydroxystearate which may cause skinreactions.

4.5 Interaction with other medicinal products and other forms of interaction

Chlorhexidine is incompatible with anionic agents.

4.6 Fertility, Pregnancy and lactation

There is no evidence of any adverse effects on the foetus arising from the use of Chlorhexidine during pregnancy or on infants during lactation. Therefore no special precautions are recommended.

4.7 Effects on ability to drive and use machines

None have been reported or are known.

4.8 Undesirable effects

Adverse events are listed below by system organ class and frequency. Frequencies are defined as: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); and very rare (<1/10,000). The data from clinical trials are estimates. Post-marketing data refer to reporting rate rather than true frequency.

Clinical Trial Data

Gastrointestinal Disorders
Very common: Tongue coated

Common: Dry mouth

Nervous System Disorders
Common: Aguesia / dysguesia
Glossodynia
Oral paraesthesia / hypoaesthesia

Post Marketing Data

Gastrointestinal Disorders
Isolated reports:
Discoloration of the teeth and tongue (see section 4.4)Irritation of the mouth (see section 4.4)
Desquamation / swelling of oral mucosa (see section
4.4)
Parotid gland swelling

Immune System disorders
Isolated reports:
Hypersensitivity and anaphylaxis (section 4.3and 4.4)
Undesirable effects are generally minor and local in nature.

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

4.9 Overdose

This has not been reported.

Due to the alcohol content (7.0% v/v), ingestion of large amounts by children requires attention, seek medical advice for appropriate action.

Accidental ingestion: Chlorhexidine taken orally is poorly absorbed. Systemic effects are unlikely even if large volumes are ingested. However, gastric lavage may be advisable using milk, raw egg, gelatin or mild soap. Employ supportive measures as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-infectives and antiseptics for local oral treatment

ATC code: A01A B03

Chlorhexidine Mouthwash contains 0.2% w/v chlorhexidine digluconate which is an antimicrobial preparation for external use. It is effective against a wide range of Gram negative and Gram positive vegetative bacteria, yeasts, dermatophyte fungi and lipophilic viruses. It is active against a wide range of important oral pathogens and is therefore effective in the treatment of many common dental conditions.

5.2 Pharmacokinetic properties

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

5.3 Preclinical safety data

No information further to that contained in other sections of the SPC is included.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sr. No.	Raw Material	Pharmacopoeia
1	Sorbitol 70%	BP
2	Propylene glycol	BP
3	Methyl Hydroxybenzoate	BP
4	Propyl Hydroxybenzoate	BP
5	Polyoxyl 40 Hydrogenated Castor Oil	USP
6	Levomenthol	BP
7	Colour Tartrazine	IHS
8	Colour Carmoisine Supra	IHS
9	Essence Peppermint ESS	IHS
10	Purified Water	BP

6.2 Incompatibilities

Hypochlorite bleaches may cause brown stains to develop in fabrics that havepreviously been in contact with preparations containing chlorhexidine.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30ºC in dry and dark place.

6.5 Nature and contents of container

150 ml filled in a PET bottle packed in a carton

6.6 Special precautions for disposal

None

7 Marketing Authorisation Holder

Kilitch Drugs (India) Limited
37, Ujagar Industrial Estate,
W.T Patil Marg, Deonar,
Mumbai 400 088,Maharashtra, India.
Website- www.kilitch.com

8 Marketing Authorisation Number(S) issued by Ethiopian FDA and date of MA authorization

07198/07578/VAR/2021

9 Date of First Authorisation/Renewal Of TheAuthorisation

10-03-2022

10 Date of Revision of the Text

07/07/2023