SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
Chlorhexidine gluconate 0.2% m/v mouthwash (Peppermint)
Orachlor® Peppermint Mouthwash

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Chlorhexidine gluconate 0.2% w/v
Also contains alcohol 5.4% v/v. For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Oromucosal solution
A clear colourless solution with a characteristic peppermint flavour.

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 (e.g. following oral surgery, in mentally or physically handicapped patients).

Also for use in a post-periodontal surgery or treatment* regimen to promote gingival healing.
*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 (e.g. denture stomatitis and thrush).

4.2 Posology and method of administration
Adults:
Thoroughly rinse the mouth for about one minute with 10 ml 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 gluconate 0.2% m/v 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.

Route of administration
Oromucosal use. [This product is not intended to be swallowed].

4.3 Contraindications
Chlorhexidine gluconate 0.2% m/v mouthwash is contraindicated for patients who have previously shown a hypersensitivity reaction to Chlorhexidine or to any of the excipients in the formulation.

4.4 Special warnings and precautions for use
For oromucosal 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 gluconate 0.2% m/v mouthwash is incompatible with anionic agents which are usually present in conventional dentifrices. These should therefore be used before Chlorhexidine gluconate 0.2% m/v mouthwash (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.

Discoloration of the teeth and tongue may occur. The stain is not permanent and can largely 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.

Polyoxyl 40 hydrogenated castor oil may cause skin reactions.

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 digluconate 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 (≥1/1000 to <1/100); rare (≥1/10,000 to <1/1000); 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: Ageusia / dysgeusia Glossodynia
Oral paraesthesia / hypoesthesia

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 (see section 4.3 and 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 e-PV desktop applications (https://drive.google.com/file/d/16hwTz0587ZWtSWadbBAMwQPOD_KSExZP/view) or search for e-PV Mobile applications on the Google Play or Apple App Store.

4.9 Overdose
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
Pharmacological Classification: 20.3.4 Antiseptic mouthwashes, gargles, sprays, paints etc.

Chlorhexidine gluconate 0.2% m/v 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 found following 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
Ethanol (96 percent) BP
Polyoxyl 40 Hydrogenated castor oil
Sorbitol solution 70% BP
Peppermint oil
Purified water.

6.2 Incompatibilities
Hypochlorite bleaches may cause brown stains to develop in fabrics that have previously been in contact with preparations containing chlorhexidine.

6.3 Shelf life
24 months.
Shelf-life after opening: 3 months.

6.4 Special precautions for storage
Store below 30°C.

6.5 Nature and contents of container
Amber round glass bottle with polypropylene screw cap.
Each bottle contains 200 ml.

6.6 Special precautions for disposal and other handling
None

7. APPLICANT
Varichem Pharmaceuticals (Pvt.) Ltd.
194 Gleneagles Road, Willowvale
Harare, Zimbabwe

8. MANUFACTURER
Varichem Pharmaceuticals (Pvt.) Ltd.
194 Gleneagles Road, Willowvale
Harare, Zimbabwe

9. REGISTRATION DETAILS

Zimbabwe Reg. No.: 2023/20.3.4/6371
Zimbabwe category for distribution: Household Remedies (H.R.)

10. DATE OF REVISION OF THE TEXT

December 2023