**Professional Information**

**SCHEDULING STATUS**

S0

## 1. NAME OF THE MEDICINE

Meridol Periodontal Antiseptic Mouthwash

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 2 mg chlorhexidine digluconate.

One dose of 10 ml contains 20 mg chlorhexidine digluconate.

Excipient: Macrogolglycerol hydroxystearate 2,5 mg/ml.

**Contains sweetener: Sorbitol.**

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

A.32.10 Dental Preparations.

Clear blue solution, antiseptic mouthwash.

## 4. CLINICAL PARTICULARS

### 4.1. Therapeutic indications

Meridol Periodontal is indicated in adults and children above the age of 7:

- for the short-term adjuvant treatment of inflammation of the gingival and the oral mucosa.
- for peri- and post-procedural use in periodontal therapies to prevent infections of oral surgical wounds.

## 4.2. Posology and method of administration

For adults and children above the age of 7:

The oral cavity should be rinsed thoroughly with 10 ml Meridol Periodontal twice a day for one minute and spit out afterwards. The solution should be applied after teeth have been brushed and the oral cavity rinsed thoroughly with water.

The solution is ready for use and should hence be used undiluted.

Meridol Periodontal would normally not to be used for more than 7 days at a time. It may be used over a longer period of time if advised by the dentist or the physician.

Children above the age of 7 and the elderly:

There are no special dosage recommendations for either elderly patients or children above the age of 7. The normal adult dose is appropriate unless otherwise recommended by the dentist or the physician.

## 4.3. Contraindications

Hypersensitivity to the active substance or to any of the excipients.

The use of a mouth rinse is contraindicated in conditions where it is presumed that the mouthwash may be swallowed.

## 4.4. Special warnings and precautions for use

For oromucosal use only – should be kept out of the eyes and ears or other tissues except the oral mucosa. If the mouthwash comes into contact with the eyes, it should be washed out promptly and thoroughly with plenty of water.

In the case of ulcerations and erosive-desquamate exfoliation of the oral mucosa, the medicinal product should not be used.

Continuous use of Meridol Periodontal as an oral rinsing solution without technically cleaning the teeth may enhance gingival bleeding.

Continuous use could modify the oral microbial flora, this being associated with the risk of bacterial and fungal spreading (candidiasis). If symptoms persist after 7 days and/or are associated with fever, therapeutic options should be reconsidered.

Chlorhexidine digluconate may cause acute allergic reactions including anaphylaxis.

Sugar-containing food or drinks should not be consumed within an hour of using Meridol Periodontal.

Macrogolglycerol hydroxystearate may cause skin reactions.

Propylene glycol may cause skin irritation.

Children require adult supervision when using Meridol Periodontal.

### 4.5. Interaction with other medicines and other forms of interaction

The efficacy of chlorhexidine is influenced by anionic substances (e.g. sodium dodecyl sulphate, synonym: sodium lauryl sulphate), which may be components of toothpastes. Therefore, these should not be used simultaneously with Meridol Periodontal but before the oral cavity is rinsed with chlorhexidine.

This restriction does not apply to toothpastes containing amphoteric tensides.

Meridol Periodontal can cause stains when spilt on clothing.

### 4.6. Fertility, pregnancy and lactation

**Pregnancy**

Meridol Periodontal should be used with caution in pregnancy, since there is not enough clinical experience with chlorhexidine in pregnant women.

**Lactation**

It is not documented whether or not chlorhexidine is excreted in human milk, therefore caution should be exercised when administering the medicinal product to nursing women.

### 4.7. Effects on ability to drive and use machines

No studies on the effects of the ability to drive and use machines have been performed. No effect is expected.

**4.8. Undesirable effects**

Very common (≥ 1/10)

Common (≥ 1/100 < 1/10)

Uncommon (≥ 1/1,000 < 1/100)

Rare (≥ 1/10,000 < 1/1,000)

Very rare (< 1/10,000) not known (cannot be estimated from the available data)

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Eye disorders

Very rare: Corneal lesion following accidental application to the eye.

Gastrointestinal disorders

Very common: Tongue discolouration and teeth staining. These discolorations of hard tooth substance and dental restorations can be removed by the dentist in most cases but professional prophylaxis may be required in some cases.

Taste alteration, oral paraesthesia, tongue irritation and/or oral mucosal irritation (stomatitis). These effects are reversible after finishing the application of Meridol Periodal.

Common: Dental calculus, oral mucosal exfoliation and stomatitis.

Uncommon: Oral mucosal disorder, hypoaesthesia, tingling / numbness of the mouth.

Very rare: Reversible parotid gland swelling.

Skin and subcutaneous tissue disorders

Rare: Rash.

Immune system disorders

Rare: Anaphylactic reactions with symptoms such as bronchospasm, dyspnea, peri-orbital oedema, hypotension, and shock, allergic reactions after local application of chlorhexidine, hypersensitivity reactions.

*Reporting of suspected adverse reactions*

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

### 4.9. Overdose

Signs of intoxication are not known. Chlorhexidine swallowed accidentally is poorly absorbed by the digestive system.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1. Pharmacodynamic properties

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

ATC-Code: A01AB03

Chlorhexidine is a cationic agent that is rapidly adsorbed by bacterial cells, e.g. Escherichia coli and Staphylococcus aureus. The higher the concentration of chlorhexidine is in the suspension of bacteria, the higher the adsorption of Chlorhexidine by bacteria. This interaction of chlorhexidine and the bacterial cell membrane results in leakage and ultimately in bacterial death detected by a decrease in mean single survivor time of bacteria. Antibacterial activity of chlorhexidine is based on its interaction with bacterial membranes resulting in leakage. Plaque inhibition is likely to occur at the tooth surface itself by tooth-bound chlorhexidine, i.e. plaque is prevented from forming because bacteria attaching to the tooth surface cannot multiply.

Chlorhexidine is a base and therefore most stable in the form of a salt.

The free base, the diacetate and the dihydrochloride are only poorly soluble in water whereas the digluconate (Synonym: bis (D-gluconate)) (> 50 g/100 ml) is very soluble in water. Hence, the digluconate is used.

Chlorhexidine and its salts show a broad antimicrobial effect against gram-positive and gram-negative bacteria.

The effect against some gram-negative bacteria (Pseudomonas- and Proteus-types) and against certain yeasts, dermatophytes and mycobacteria is poor. It is ineffective against bacteria spores and fungus spores, viruses and putrefactive fungi. In the presence of soaps, blood and pus (fractions of cells) the efficacy of chlorhexidine is reduced. Rinsing the mouth with 10 ml of a 0,2 % chlorhexidine-

solution leads to a strong reduction of the quantity of bacteria in saliva.

This correlates with a reduced rate of formation of dental plaque. When using the mouthwash over several months the efficacy decreases by the reversible shift in the bacteria spectrum of oral flora and tooth plaque.

The antibacterial properties of chlorhexidine are on the one hand directed against acid producing, cariogenic microorganisms of the dental plaque and on the other hand also against anaerobic and facultative anaerobic microorganisms which lead to inflammations of the gingiva. Thus, chlorhexidine prevents inflammation of the gingiva caused by bacteria.

### 5.2. Pharmacokinetic properties

After repeated application of chlorhexidine on healthy skin no absorption of the substance could be seen in adults. In contrast, small amounts of the substance (up to 1,0 µg/ml) were found in the blood of preterm and newborn infants ($28^{th}$ to $39^{th}$ week of pregnancy) after bathing them in 4 % chlorhexidine digluconate-detergent solution (no clinical symptoms).

Due to its cationic character chlorhexidine fixes strongly to the skin, mucosae and other tissues and is thus poorly absorbed.

After rinsing the mouth, chlorhexidine adsorbs to the dental enamel, dentine, cement, dental pellicles, mucosae and dental restorations.

Due to slow desorption, chlorhexidine is detectable in the saliva up to eight hours (depot effect). The absorption of chlorhexidine via intact oral mucosa is not known.

In different test species, chlorhexidine is excreted via the faeces (90 %) and only approximately 1 % via the urine. In humans, the elimination half-life was 4 days.

### 5.3. Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction.

When applied topically in higher concentrations (2,0 %) to the oral mucosa of hamsters, chlorhexidine caused leukoplasia and hyperplasia. A 0,2 % solution did not induce such changes. Chlorhexidine may delay wound healing, in particular when bone is involved. The topical application of chlorhexidine (≤ 0,01 %) caused corneal damage in rabbits and cats.

Higher concentrations were tolerated by rabbits in another study. Chlorhexidine was ototoxic in guinea pigs and cats when applied directly into the tympanic cavity in concentrations as low as 0,05 %. A sensitisation to chlorhexidine was achieved in some Guinea pig models but not in others. In mice, an immune response was only induced when chlorhexidine was complexed with a protein carrier.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1. List of excipients

Macrogolglycerol hydroxystearate 2,5 mg/ml, Sorbitol (1000 mg), Glycerol, Peppermint Oil, Citric acid monohydrate, Patent blue V (E131), Propylene glycol, Cetylpyridinium Chloride, Purified Water.

### 6.2. Incompatibilities

Chlorhexidine is incompatible with anionic substances that may be components of toothpastes.

Chlorhexidine is inactivated by sucrose.

### 6.3. Shelf life

3 years.

After first opening the Meridol Periodontal should be discarded after 4 weeks.

### 6.4. Special precautions for storage

Store at or below 25 °C.

### 6.5. Nature and contents of container

Bottle made of polyethylene terephthalate with a white screw cap and a sealing ring made of polyethylene. The measuring device of 10 ml made of polypropylene is part of the screw cap.

The bottle contains 300 ml solution.

### 6.6. Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

## 7. HOLDER OF CERTIFICATE OF REGISTRATION

MC Pharma (Pty) Ltd.

62 Constantia Avenue

Mnandi

Centurion

0149

Telephone: 012 668 3019

Email: pharmacist@mcpharma.co.za

## 8. REGISTRATION NUMBER

51/32.10/0374

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29 November 2022

## 10. DATE OF THE REVISION OF TEXT

26 March 2026