#### **SCHEDULING STATUS:**

S0

PROPRIETARY NAME (and dosage form):
CORSODYL MOUTHWASH MINT (Solution)
CORSODYL MOUTHWASH ORIGINAL (Solution)

#### **COMPOSITION:**

Active ingredient: 2 mg/ml chlorhexidine gluconate.

Inactive ingredients:

**CORSODYL MOUTHWASH MINT:** Glycerol, macrogolglycerol hydroxystearate, optamint flavour, purified water and sorbitol. Contains sugar. Sorbitol 15 % w/w

**CORSODYL MOUTHWASH ORIGINAL:** Glycerol, macrogolglycerol hydroxystearate, aniseed flavour purified water and sorbitol. Contains sugar. Sorbitol 15 % w/w

#### **CATERGORY AND CLASS:**

A 16.4 Nasopharyngeal and buccopharyngeal antiseptics

#### PHARMACOLOGICAL ACTION:

Chlorhexidine is a bactericidal cationic antiseptic. It acts by destroying the cell membrane and precipitating the cell cytoplasm. It has been shown that chlorhexidine binds to the hydroxyapatite of tooth enamel, to the pellicle of the tooth surface and to salivary mucins. It slowly desorbs from these sites to exert a prolonged bactericidal effect for several hours.

#### **INDICATIONS:**

CORSODYL MOUTHWASH is an antibacterial solution which inhibits the formation of dental plaque. It is indicated 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 periodontal and other oral surgery or in mentally or physically handicapped patients). It reduces the duration and severity of both aphthous ulceration and oral ulcers caused by mechanical or chemical injuries e.g. orthodontic appliances. It aids in management of recurrent oral candidal infections.

#### **CONTRAINDICATIONS:**

**CORSODYL MOUTHWASH** is contraindicated in those patients who have known hypersensitivity to chlorhexidine gluconate or any of the ingredients in the product.

## **WARNINGS AND SPECIAL PRECAUTIONS:**

For oral use only. Do not swallow.

Keep out of the eyes and ears. In case of accidental contact with the eyes, wash out promptly and thoroughly with water.

**DISCOLOURATION:** A superficial yellow-brown discolouration of the dorsum of the tongue, of teeth and on silicate or composite restorations may occur. The former disappears after treatment is discontinued; the latter can largely be prevented by brushing with conventional toothpaste, or in the case of dentures, cleaning with a proprietary denture cleanser. Where this is not possible as for example with intermaxillary fixation, or with extensive orthodontic appliances, a dental prophylaxis may be required once the underlying condition has resolved.

**TASTE:** Disturbances of taste sensation and numbness, tingling or burning sensation of the tongue may occur on initial use of **CORSODYL MOUTHWASH.** These effects usually diminish with continued use. If the condition persists a doctor should be consulted.

**ORAL DESQUAMATION:** Oral desquamation may occur on using CORSODYL MOUTHWASH. This may require dilution of the mouthwash (5 ml mouthwash with 5 ml tap water freshly mixed) and less vigorous rinsing, or discontinuation of the mouthwash.

**PAROTID GLAND SWELLING:** Swelling of the parotid glands during use of CORSODYL MOUTHWASH has been reported. In all cases spontaneous resolution has occurred on discontinuing treatment.

CORSODYL MOUTHWASH is incompatible with the detergents in most toothpaste. If toothbrushing with conventional toothpaste is carried out in addition to CORSODYL MOUTHWASH, this should either be done before the use of CORSODYL MOUTHWASH, rinsing the mouth thoroughly between applications, or at a different time of the day (See INTERACTIONS).

Effects on ability to drive and use machines:

**CORSODYL MOUTHWASH** has no or negligible influence on the ability to drive or the use of machinery.

#### **INTERACTIONS:**

Clinically significant interactions with other medicines are not known.

CORSODYL is incompatible with anionic agents e.g. sodium lauryl sulphate (see WARNINGS AND SPECIAL PRECAUTONS).

#### **HUMAN REPRODUCTION:**

Safety in pregnancy and lactation has not been established.

## **DOSAGE AND DIRECTIONS FOR USE:**

The measuring cap on the bottle holds 10 ml when filled to the line. Thoroughly rinse the mouth for about one minute with 10 ml twice daily. For the treatment of gingivitis, a course of about a month is advisable although some variation in response is to be expected. In the case of oral candidal infections, treatment should be continued 48 hours after clinical resolution. For the

treatment of denture stomatitis, the dentures should be cleansed and soaked in the solution for 15 minutes twice daily.

## Children and elderly:

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

Children under 12 years of age should not use this product.

#### SIDE EFFECTS:

Side effects are generally minor and local in nature. The frequency of the following adverse events are unknown.

**Immune system disorders:** Hypersensitivity and anaphylaxis (see CONTRAINDICATIONS). **Nervous system disorders:** Transient taste disturbance, transient numbness, tingling or burning sensation of the tongue may occur on initial use (see WARNINGS AND SPECIAL PRECAUTIONS).

**Gastrointestinal disorders:** Discolouration of the teeth and tongue, soreness/irritation of the mouth, desquamation/soreness/swelling of oral mucosa, parotid gland swelling (WARNINGS AND SPECIAL PRECAUTIONS).

In case of soreness, swelling or irritation of the mouth, use of the product should be stopped and a dentist or doctor should be consulted.

#### KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

In the event of excessive systemic ingestion of CORSODYL MOUTHWASH, gastric lavage

is indicated. Employ supportive measures as appropriate.

#### **IDENTIFICATION:**

**CORSODYL MOUTHWASH MINT:** A clear or slightly opalescent transparent solution with an odour of peppermint.

**CORSODYL MOUTHWASH ORIGINAL:** A clear or slightly opalescent transparent solution with an odour of aniseed.

#### PRESENTATION:

#### **CORSODYL MOUTHWASH MINT:**

300 ml PET Bottle: 300 ml amber colour PET bottle with polypropylene plastic closure. 600 ml PET Bottle: 600 ml amber colour PET bottle with polypropylene plastic closure.

#### **CORSODYL MOUTHWASH ORIGINAL:**

300 ml PET bottle: 300 ml Amber color PET bottle with polypropylene plastic closure.

#### STORAGE INSTRUCTIONS:

Store at or below 25 °C.

Keep out of reach of children.

## **REGISTRATION NUMBER:**

CORSODYL MOUTHWASH MINT: Z/16.4/352
CORSODYL MOUTHWASH ORIGINAL: S/16.4/182

# NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER OF THE CERTIFICATE OF REGISTRATION:

Haleon South Africa (Pty) Ltd, 11 Hawkins Avenue, Epping Industria 1, Cape Town, 7450

#### DATE OF PUBLICATION OF THIS PROFESSIONAL INFORMATION:

The date of registration of the medicine (CORSODYL MOUTHWASH MINT): 25 August 1986 The date of registration of the medicine (CORSODYL MOUTHWASH ORIGINAL): 30 September 1992

The date of the most recent amendment to the professional information: 16 April 2015.