SCHEDULING STATUS:

S0

PROPRIETARY NAME AND DOSAGE FORM:

CORSODYL MOUTHWASH ORIGINAL (Solution)

Read all of this leaflet carefully because it contains important information for you.

CORSODYL MOUTHWASH ORIGINAL is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use CORSODYL MOUTHWASH ORIGINAL carefully to get the best results from it.

• Keep this leaflet. You may need to read it again.

• Do not share CORSODYL MOUTHWASH ORIGINAL with any other person.

• Ask your pharmacist if you need more information or advice.

• You must see a doctor if your symptoms worsen or do not improve within 7 days.

1. WHAT CORSODYL MOUTHWASH ORIGINAL CONTAINS:

The active substance is 2 mg/ml chlorhexidine gluconate.

The inactive ingredients include glycerol, macrogolglycerol hydroxystearate, aniseed, purified water and sorbitol.

Contains sugar. Sorbitol 15 % w/w.

2. WHAT CORSODYL MOUTHWASH ORIGINAL IS USED FOR:

Chlorhexidine, the active ingredient, is an antibacterial which inhibits bacteria that grows in the plaque that forms on your teeth between brushings. It is used as an aid in the treatment and prevention of gingivitis, and in the maintenance of the oral hygiene, particularly in situations where tooth brushing cannot be adequately employed (e.g. following periodontal and other oral surgery or in mentally or physically handicapped patients). CORSODYL MOUTHWASH ORIGINAL also helps in reducing the duration and severity of the oral ulcers caused by mechanical or chemical injuries e.g. orthodontic appliances and as an aid in the management of recurrent thrush infections.

3. BEFORE YOU USE CORSODYL MOUTHWASH ORIGINAL:

Do not use CORSODYL MOUTHWASH ORIGINAL:

• if you have ever had an allergic reaction to any product containing chlorhexidine or any of the inactive ingredients in CORSODYL MOUTHWASH ORIGINAL.

Take special care with CORSODYL MOUTHWASH ORIGINAL:

• if CORSODYL MOUTHWASH ORIGINAL comes into accidental contact with eyes and ears. Wash out immediately and thoroughly with water.

• if you experience soreness, swelling or irritation of the mouth. Please stop using CORSODYL MOUTHWASH ORIGINAL and consult your doctor or dentist.

• if you experience disturbance of taste sensation and numbness, tingling or burning sensation of the tongue on initial use of CORSODYL MOUTHWASH ORIGINAL. These effects usually lessen with continued use. If the condition persists, please consult your doctor.

• if you experience oral desquamation (peeling of the skin inside the mouth). This may require dilution of the mouthwash (5 ml mouthwash with 5 ml tap water freshly mixed) and less vigorous rinsing or you may need to stop using CORSODYL MOUTHWASH ORIGINAL.

• if you experience swelling of the parotid (salivary) glands. This generally resolves by itself once treatment with CORSODYL MOUTHWASH ORIGINAL is stopped.

• if you experience a yellow-brown discolouration of the tongue, teeth, tooth fillings or dentures. Discolouration of the tongue usually disappears after treatment is discontinued. Discolouration of the teeth can be prevented by brushing with toothpaste and in the case of dentures cleaning with an appropriate denture cleanser.

• when brushing teeth with conventional toothpaste. CORSODYL MOUTHWASH ORIGINAL is incompatible with the cleaning agents in most toothpastes. Brushing of teeth should therefore be done before the use of CORSODYL MOUTHWASH ORIGINAL, rinsing the mouth thoroughly between applications or at a different time of the day.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking CORSODYL MOUTHWASH ORIGINAL.

Using other medicines with CORSODYL MOUTHWASH ORIGINAL:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

CORSODYL MOUTHWASH ORIGINAL is incompatible with the cleaning agents in most toothpastes. Brushing of teeth should therefore be done before the use of CORSODYL MOUTHWASH ORIGINAL, rinsing the mouth thoroughly between applications or at a different time of the day.

4. HOW TO USE CORSODYL MOUTHWASH ORIGINAL:

Follow your doctor’s instructions if this medicine was prescribed. Do not share medicines prescribed for you with any other person.

If you are treating yourself then follow the instructions on the label. Do not exceed the stated dose.

CORSODYL MOUTHWASH ORIGINAL should be used after you have brushed your teeth. Rinse the toothpaste completely from your mouth with water before using CORSODYL MOUTHWASH ORIGINAL.

The measuring cap on the bottle holds 10 ml when filled to the line.

For normal use, swish 10 ml of CORSODYL MOUTHWASH ORIGINAL, around the mouth for about one minute and then spit out. DO NOT SWALLOW THE MEDICINE. This should be done twice a day.

Replace cap after use.

For the treatment of gingivitis, continue treatment for about one month.

For the treatment of oral candidal (thrush) infections, continue treatment for 2 days after your symptoms have disappeared.

For the treatment of denture stomatitis (inflammation in the mouth), the dentures should be cleaned first.

Once they have been cleaned, then soak your dentures in CORSODYL MOUTHWASH ORIGINAL solution for 15 minutes twice a day.

CORSODYL MOUTHWASH ORIGINAL is not recommended in children less than 12 years of age.

If you use more CORSODYL MOUTHWASH ORIGINAL than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

5. POSSIBLE SIDE EFFECTS:

CORSODYL MOUTHWASH ORIGINAL can have side effects.

Not all side effects reported for CORSODYL MOUTHWASH ORIGINAL are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using CORSODYL

MOUTHWASH ORIGINAL, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happen, stop taking CORSODYL MOUTHWASH ORIGINAL and tell your doctor immediately or go to the casualty department at your nearest hospital:

• rash, swelling of the lips, tongue, throat or face or have difficulty in breathing.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CORSODYL MOUTHWASH ORIGINAL. You may need urgent medical attention or hospitalization.

Tell your doctor or dentist if you notice any of the following:

• a change in taste

• tingling or burning sensation when you first use CORSODYL MOUTHWASH ORIGINAL. This usually goes away with continued use

• staining of the teeth, mouth, tooth fillings and dentures or other mouth appliances

• mouth irritation

• swollen glands on side of face or neck

• tongue tip irritation

If you notice any of the side effects which are not mentioned above, please check with your dentist, doctor or pharmacist.

6. STORING AND DISPOSING OF CORSODYL MOUTHWASH ORIGINAL:

Keep out of reach and sight of children. Store at or below 25 °C.

Do not use if the expiry date stated on the label and carton has passed. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF CORSODYL MOUTHWASH ORIGINAL:

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

8. IDENTIFICATION OF CORSODYL MOUTHWASH ORIGINAL:

A clear to slightly opalescent, transparent solution with an odour of aniseed.

9. REGISTRATION NUMBER:

S/16.4/182

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Haleon South Africa (Pty) Ltd,

11 Hawkins Avenue, Epping Industria 1, Cape Town, 7450

0800 007 018

11. DATE OF PUBLICATION:

The date of registration of the medicine: 30 September 1992.

Date of the most recent amendment to the professional information as approved by the Authority: 16 April 2015.

The corresponding professional information may be obtained from:

https://www.haleonhealthpartner.com/en-za/oral-health/brands/corsodyl/products/short-term-treatment/