Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

The medicine is dispensed without a physician's prescription

Corsodyl[™] Mouthwash

Active Ingredient: chlorhexidine digluconate 0.2% w/v

List of the additional ingredients detailed in section 6.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the physician or the pharmacist.

The medicine is intended for use in patient above the age of 12 years. Under this age refer to the physician before use.

The product should be used in a proper manner. For more information consult with a pharmacist.

1. What is the medicine intended for?

- For inhibition of formation of dental plaque.
- As an aid in the treatment and prevention of gingivitis.
- As an aid in the maintenance of oral hygiene.
- For use following dental surgery or treatments, to promote healing of the gums.
- For use in mouth ulcers, inflammations due to dentures and oral thrush.

Therapeutic group: Antiseptic.

2. Before using the medicine

Do not use if you had an allergic reaction to chlorhexidine digluconate or to any of the ingredients of the medicine.

Special warnings regarding the use of the medicine

- **Do not use in children under 12 years** unless recommended by a physician.
- Do not use anywhere other than in your mouth. Wash thoroughly if you get any in your eyes or ears.
- **Do not use immediately after brushing your teeth.** See: 'How should you use the medicine' for more information.
- **Do not bleach fabrics** that have been in contact with the mouthwash.

If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the physician or the pharmacist.

Pregnancy and breast-feeding

Do not use the product without consulting a physician before starting the treatment.

Important information about some ingredients of the product

macrogolglycerol hydroxystearate may cause skin reactions.

3. How should you use the medicine?

You should check with the physician or the pharmacist if you are unsure.

Use only if seal on cap is present and intact before opening.

Toothpastes can stop the mouthwash working. Rinse your mouth thoroughly with water and wait 5 minutes after brushing your teeth before using Corsodyl Mouthwash. You can also use the mouthwash at a different time of day.

The usual dosage is:

Use twice a day. Fill the cap to 10 ml line. Rinse mouth thoroughly for 1 minute then spit out.

Gingivitis: A one month course is recommended.

Mouth ulcers and oral thrush: Continue to use for 2 days after healing has occurred.

Mouth inflammations due to use of dentures: Clean and soak your dentures in the mouthwash for 15 minutes twice a day.

Following dental operations: Rinse as directed by your dentist.

Do not exceed the recommended dose. Do not swallow.

If your symptoms persist, see your physician.

The mouthwash contains alcohol if a child has accidentally swallowed a large amount, seek medical help immediately and bring the package of the medicine with you.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

4. Side effects

As with any medicine, use of Corsodyl Mouthwash may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Stop using the mouthwash and **seek immediate medical help** if you get **a rash, swelling of the mouth or face** or **have difficulty breathing.** These effects may be symptoms of severe allergic reaction which is very rare. **Stop using** the mouthwash and **tell your physician** if you get **irritation of the mouth, soreness** or **swelling of the inside of the cheeks.** These effects should go away when treatment is stopped.

Other side effects that may occur:

Temporary staining of the tongue. This disappears when treatment is stopped.

Temporary staining of the teeth. This can normally be removed by brushing. You can avoid staining by not drinking tea, coffee or red wine – especially one hour after use, and by brushing daily with toothpaste (see 'How should you use the medicine'). If staining continues it can be removed with a scale and polish from your dentist or hygienist. You can clean your dentures with denture cleaner.

You may notice **a change of taste, burning sensation, tingling, or stinging of the tongue** when you first use the mouthwash. This usually goes away with continued use. If symptoms persist, **see a physician**.

Swelling of salivary glands.

If **peeling of the skin** inside the mouth occurs, dilute the mouthwash with an equal amount of water.

If a side effect has appeared, if any of the side effects get worse or when you suffer from a side effect that has not been mentioned in the leaflet, you should consult the physician, dentist or pharmacist.

5. <u>How to store the medicine?</u>

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Store below 25°C. Use within 3 months of opening.

6. Additional information

In addition to the active ingredient the medicine also contains -

Sorbitol, ethanol 96%, macrogolglycerol hydroxystearate, peppermint oil and purified water.

What does the medicine look like and what is the content of the package – Bottle of 300 ml with screw cap.

License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.

Manufacturer: Purna Pharmaceuticals, Puurs, Belgium.

This leaflet was checked and approved by the Ministry of Health in: June 2014.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 029-96-21599