PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed without a doctor's prescription

CORSODYL DENTAL GEL 1% w/w

Active ingredient and its concentration: Chlorhexidine Digluconate 1% w/w

The inactive ingredients are listed in section 6 and section 2 under the title "Important information about some of the ingredients of the medicine".

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 doctor or the pharmacist.

Use the preparation according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you need more information.

1. What is the medicine intended for?

- For inhibition of plaque formation.
- As an aid in the treatment and prevention of gum inflammation (gingivitis).
- As an aid in the maintenance of oral hygiene.
- For use after dental surgeries or treatments, to promote healing of the gums.
- For use in ulcers, inflammations due to dentures and oral thrush.
- As an aid in the prevention of dental caries for those at high risk, as an adjunct to fluoride.

The active ingredient chlorhexidine digluconate is an antibacterial agent that reduces plaque formation.

2. Before using the medicine

Do not use this medicine if:

• You are sensitive (allergic) to chlorhexidine digluconate or to any one of the other ingredients this medicine contains (detailed in section 6).

Special warnings regarding the use of the medicine:

- Do not use this medicine in children under 12 years of age, unless recommended by a dentist.
- **Do not use this medicine anywhere else except in your mouth.** Rinse thoroughly if the preparation comes in contact with your eyes or ears.
- Do not use this medicine immediately after brushing your teeth. The toothpaste can impair the activity of the preparation. After brushing the teeth, rinse the mouth thoroughly with water and wait 5 minutes before using Corsodyl Dental Gel. Alternatively you can use Corsodyl Dental Gel at a different time during the day.
- Stop using Corsodyl Dental Gel and seek urgent medical help if you experience a severe allergic reaction. For more information refer to the section "Side effects".
- Temporary staining of the teeth and tongue may occur. For more information refer to the section "Side effects".
- You may notice a **change in the sense of taste or a burning sensation.** For more information refer to the section "Side effects".
- **Do not bleach fabrics** that have been in contact with the gel.

Drug interactions:

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

Pregnancy, breastfeeding and fertility:

There is no evidence of harm to the fetus when using Corsodyl Dental Gel. You can use Corsodyl Dental Gel if you are **pregnant** or **breastfeeding**.

Important information about some of the ingredients of the medicine:

Corsodyl Dental Gel contains the ingredient Macrogolglycerol hydroxystearate, which may cause skin irritation.

3. How should you use the medicine?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The accepted dosage is:

- **Gingivitis:** Brush your teeth for at least one minute, once or twice a day using 2 cm of gel. Continue treatment for about one month.
- Mouth ulcers and oral thrush: Apply gel directly on the sore areas using your fingertip
 or a cotton swab, once or twice a day for at least one minute. Continue to use for 2 days
 after healing.
- **Oral inflammations due to dentures:** Before inserting the dentures, gently apply Corsodyl Dental Gel on the dentures, in the areas that come in contact with the gums.
- As an aid in the prevention of dental caries or after dental surgeries: Use as directed by your dentist.

If your symptoms persist, refer to your doctor.

Do not exceed the recommended dose.

Do not swallow, for topical use in the oral cavity.

If you took an overdose or if a child swallowed this medicine by mistake, immediately go to the doctor or the emergency room of the hospital and take the package of the medicine with you.

If you have forgotten to take this medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult a doctor.

Do not take medicines in the dark! Check the label and the dose <u>every time</u> you take the medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

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

- Stop using Corsodyl Dental Gel and seek medical help immediately if you develop a rash, swelling of the lips, tongue, throat or face or if you have difficulty breathing. These effects may be symptoms of a severe and very rare allergic reaction.
- Stop using the gel and contact your dentist if you experience irritation, pain or swelling in the mouth.

Other side effects that may occur:

Side effects with unknown frequency (effects whose frequency has not yet been determined):

- **Temporary staining of the tongue.** The staining disappears when treatment is stopped.
- **Temporary staining of the teeth.** This staining can usually 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 section 3 "How should you use the medicine?"). If the staining remains, it can be removed by cleaning and polishing by the dentist or dental hygienist. You can clean your dentures using a denture cleanser.
- You may notice a change in taste or a burning sensation when you first use the gel.
 This usually goes away with continued treatment.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il/

5. How to store the medicine

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- 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 at a temperature below 25°C.
- Once opened for the first time, use within 6 months.

6. Additional information

- In addition to the active ingredient the medicine also contains:

 Purified water, Isopropyl Alcohol, Hydroxypropylcellulose, Macrogolglycerol Hydroxystearate, Sodium Acetate, Peppermint Oil, Levomenthol.
- What does the medicine look like and what are the contents of the package: A tube containing 50 grams of a clear or slightly cloudy, mint scented gel.
- Marketing authorization holder: GSK Consumer Healthcare Israel Ltd., P.O.box 3256, Petach Tikva.
- Manufacturer: Purna Pharmaceuticals, Rijksweg 17, 2870 Puurs, Belgium.
- Revised in May 2021 in accordance with the Ministry of Health guidelines.
- Registration number of the medicine in the national drug registry of the Ministry of Health: 114-62-29571

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