

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

This medicine is dispensed without a doctor's prescription

Hexidyl Dental Gel

Gel for use in the oral cavity

The active ingredient and its concentration:

Chlorhexidine digluconate 1% w/w

The inactive ingredients are listed in section 6 and in 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 section 3 of this leaflet. Consult the pharmacist if you need further 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, inflammation due to dentures and oral thrush.
- As an aid in the prevention of dental caries for those at high risk, in addition 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 the active ingredient chlorhexidine digluconate or to any of the other ingredients this medicine contains (detailed in section 6).

Special warnings regarding the use of the medicine:

- **Do not use the 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 the medicine immediately after brushing your teeth. The toothpaste can impair the activity of the preparation.** After brushing your teeth, rinse the mouth thoroughly with water and wait 5 minutes before using Hexidyl Dental Gel. Alternatively, Hexidyl Dental Gel can be used at a different time during the day.
- **Stop using Hexidyl Dental Gel and seek urgent medical help if you experience a severe allergic reaction.** See additional information in section 4.
- **Temporary staining of the teeth and tongue may occur.** See additional information in section 4.
- You may notice a **change in the sense of taste or a burning sensation.** See additional information in section 4.
- **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 Hexidyl Dental Gel. You can use Hexidyl Dental Gel if you are pregnant or breastfeeding.

Important information about some of the ingredients of the medicine:

Hexidyl Dental Gel contains the ingredient PEG 40 hydrogenated castor oil (also called: macroglycerol 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 usual 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 inflammation due to dentures:** before inserting

the dentures, gently apply Hexidyl 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, go to the doctor or to a hospital emergency room immediately and take the package of the medicine with you.

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

Do not take medicines in the dark! Check the label and the dose every time you take a 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 Hexidyl 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 Hexidyl Dental Gel and seek medical help immediately** if you develop **rash, swelling of the lips, tongue, throat or face or if you have breathing difficulties.** These effects may be symptoms of a serious and very rare allergic reaction.

- **Stop using the gel and contact your dentist** if you experience **irritation, pain or swelling of 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). 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 the sense of 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.
- **Storage conditions:** store at a temperature below 25°C.
- **Shelf life after first opening:** 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, Hydroxypropyl Cellulose, PEG 40 Hydrogenated Castor Oil (Macroglycerol Hydroxystearate), Sodium Acetate Anhydrous, Levomenthol, Peppermint Oil.
- **What does the medicine look like and what are the contents of the package?** Metal tube with screw cap, packed in a carton box. The tube contains clear mint flavor gel with a characteristic mint odor.
- **Size of the package:** a tube containing 60 grams of gel.
- **Manufacturer and marketing authorization holder:** Ben Shimon Floris Ltd., Industrial Park Misgav, D.N. 2017400.

Registration number of the medicine in the national drug registry of the Ministry of Health: 175-39-36041-00

This leaflet was checked and approved by the Ministry of Health in 01/2024.