

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

This medicine is dispensed without a doctor's prescription

Solodent Mouthwash

Mouthwash solution



Composition:

Chlorhexidine digluconate 0.2% w/v
Inactive ingredients and allergens in the medicine – see section 2 “Important information about some of the ingredients of the medicine” and section 6 “Additional information”.

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.

The medicine is intended for use in patients above 12 years of age. Below this age, refer to a doctor before use. Use the medicine according to the instructions in section 3 – “How should you use the medicine?” in this leaflet. Consult the pharmacist if you need more information. Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve.

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 treatment of ulcers, inflammations due to denture use and oral thrush.

Therapeutic class: antiseptic

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 (see section 6 “Additional information”).

Special warnings regarding the use of the medicine:

- **Do not use in children under 12 years of age** unless recommended by a doctor.
- **Use the medicine as intended.** Do not swallow. If the solution comes into contact with the eyes or ears, wash them thoroughly with water.
- **In case of a severe allergic reaction, discontinue use and seek immediate assistance.** See section 4 “Side effects”.
- **Do not use immediately after brushing your teeth.** See section 3 “How should you use the medicine?” for additional information.
- **Do not bleach fabrics** that have been in contact with the mouthwash.
- **Temporary staining of the teeth and tongue may occur.** See section 4 “Side effects”.
- You may experience a change in the sense of taste or feel a burning sensation. See section 4 “Side effects”.

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

Pregnancy and breastfeeding:

There is no need to avoid using the medicine if you are pregnant or breastfeeding.

Important information about some of the ingredients of the medicine

- The medicine contains the ingredient PEG 40 hydrogenated castor oil (also called macrogolglycerol hydroxystearate) which may cause skin irritation.
- The medicine contains alcohol which may cause a burning sensation on damaged skin. This medicine contains 5.656 ml of alcohol in each 100 ml, a concentration equivalent to 0.05656 ml/ml.

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 medicine.

The generally accepted dosage is: twice a day.

- **Gum inflammation:** it is recommended to use for one month.
- **Mouth ulcers and oral thrush:** continue using for an additional two days after recovery.
- **Mouth inflammations due to denture use:** clean and soak the dentures in the mouthwash for 15 minutes twice a day.

- **After dental surgery:** follow your dentist's instructions.

Do not exceed the recommended dose.

Method of administration:

Do not swallow.

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

Toothpastes may impair the activity of the mouthwash. After brushing your teeth, rinse your mouth thoroughly with water and wait 5 minutes before using **Solodent Mouthwash**. Alternatively, you can also use the mouthwash at a different time of the day.

Instructions for use:

Fill the measuring cup to the 10 ml line, rinse the mouth thoroughly with the medicine for one minute and then spit out the medicine.

If the symptoms persist, **refer to the doctor.**

If you accidentally took a higher dosage

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.

Do not take medicines in the dark! Check the label and the dose every time 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, using **Solodent Mouthwash** 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 the medicine and seek immediate medical assistance if you experience one or more of the following effects:

- **Rash**
- **Swelling of the mouth or face**
- **Breathing difficulties**

These effects may be symptoms of a serious and very rare allergic reaction.

Stop using the medicine and refer to a doctor if you experience one or more of the following effects:

- **Mouth irritation**
- **Pain**
- **Swelling of the inner part of the cheeks**

Very common side effects – effects that occur in more

than 1 user out of 10:

- **Temporary staining of the tongue** which disappears when treatment is discontinued.

Common side effects – effects that occur in 1-10 users out of 100:

- Dry mouth.
- **Change in the sense of taste, a sensation of burning, numbness, or pricking in the tongue** when you use the mouthwash for the first time. This usually goes away with continued treatment.

If the effects persist – refer to the doctor.

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

- **Temporary staining of the teeth** which can usually be removed by brushing. This staining can be prevented by avoiding 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. Dentures can be cleaned using a denture cleanser.
- **Swelling of the salivary glands.**
- **Peeling of the skin** inside the mouth. In order to avoid this, dilute the mouthwash with an equal amount of water.

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 the doctor.

Reporting side effects

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.
- Keep in the original package to protect from light.
- The medicine can be used for up to 6 months after first opening the bottle, and no later than the expiry date that appears on the package.

6. Additional information:

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

Purified Water, Sorbitol Solution, Ethanol 95% (Alcohol 95%), PEG 40 Hydrogenated Castor Oil, Peppermint Oil
What does the medicine look like and what are the contents of the package?

A brown bottle that contains a clear solution. Comes with a measuring cup.

Size of the package: 300 ml.

Manufacturer and marketing authorization holder:
Ben Shimon Floris Ltd., Industrial Park Misgav, D.N. 2017400, Israel.

This leaflet was revised in 07/2024 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health:

163-01-36040-00