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

Non-prescription medicine

SOLODENT

ORAL LOCAL SOLUTION

Active ingredient:

Chlorhexidine digluconate 0.2% w/v

For the list of inactive ingredients and allergens in the preparation – see section 6.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

The medicine is indicated for patients over the age 12; below this age, consult a doctor before utilization. You should use this medicinal product according to the dosage instructions described in this leaflet. Consult a pharmacist if you need further information You should consult a doctor if your symptoms worsen or do not improve.

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 the event of mouth ulcers, inflammations due to dentures and oral thrush.

Therapeutic group: Antiseptic.

2. BEFORE USING THE MEDICNE:

Do not use this medicine if you are sensitive to the active ingredient chlorhexidine digluconate, or to any of the other ingredients included therein (as specified in section 6 "Further information").

Special warnings regarding the use of the medicine: • Do not use this medicine in children under the age of 12 without consulting a doctor.

• Use this medicine **according to its intended use.** Do not swallow. In case of contact with the eyes or ears, rinse them thoroughly with water.

• **In case of severe allergic reaction, stop using the medicine and immediately seek medical assistance. See section 4** "**Side effects**".

• **Do not use this product immediately after brushing teeth. See section 3** "How should you use the medicine" for further information.

• **Do not bleach fabrics** that were in contact with the mouthwash.

• **Temporary dental and tongue staining may occur. See section 4 "Side effects".**

• There may be a change in the sense of taste, or a burning sensation may be felt. **See section 4 "Side effects". If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist.**

Pregnancy and breastfeeding

There is no objection to using this medicine if you are pregnant or breastfeeding.

IMPORTANT INFORMATION ABOUT SOME COMPONENTS OF THE FORMULATION.

• The excipient "PEG 40 Hydrogenated Castor Oil ", may cause skin reactions.

• This formulation contains alcohol.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain about the dosage and mode of use of the medicine.

Use only if the closing system covering the cap is intact prior to opening. Be sure to close the bottle immediately after use.

Do not exceed the recommended dosage.

Do not swallow.

Toothpastes may interfere with the action of mouthwash. After brushing your teeth, rinse the mouth thoroughly with water and wait 5 minutes before using **SOLODENT.**

Alternatively, you can use the mouthwash at another time of the day.

The usual dosage of the medicine is twice daily. Fill the measuring cup up to 10 mL line, rinse your mouth thoroughly with the drug for one minute and then spit out the medicine.

• **Gingivitis:** Recommended use is for one month. • **Ulcerations and candidal infections:** Use for additional two days after the area has healed. • **Mouth inflammations caused by dentures:** Clean and soak the dentures in the mouthwash for 15 minutes twice a day.

• **Following dental surgery:**

Use according to the dentist's instructions.

If your symptoms persist, refer to your doctor. If you have taken an overdose, or if a child has accidentally swallowed the medicine, contact your doctor or refer to a hospital emergency room immediately and bring the package of the medicine with you.

Do not take medicines in the dark! Check the indication and the dose each time you take the medicine. Wear glasses if you need them. If you have further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, the use of **SOLODENT** 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.

Discontinue treatment with the mouthwash and **immediately seek medical assistance** if any of the following symptoms occur: **rash, swelling of the mouth or face, or difficulty breathing.** These effects may be symptoms of a severe allergic reaction, which is very rare.

Discontinue treatment with the mouthwash and **seek medical assistance** if you notice **irritation in the mouth, soreness or swelling of the inner part of the cheeks.**

Very common side effects – Side effects that appear in more than one user out of ten:

Temporary staining of the tongue.

This disappears when the treatment is discontinued.

Common side effects - Side effects that appear in 1 – 10 users out of 100: Dry mouth. You may notice a **change in the sense of taste, burning sensation, tingling or stanning of the tongue,** upon the first use of the mouthwash. These usually cease with continued use. If the symptoms persist, contact your doctor.

Additional side effects: **Temporary staining of the teeth.** This can usually be removed by brushing. Staining can be prevented by avoiding drinking tea, coffee or red wine - especially an hour after use, and by daily brushing your teeth with toothpaste (see Chapter 3, "**How should you use the medicine**"). If the stains remain, they can be removed by cleaning and polishing by the dentist or dental hygienist. You can clean your dentures using special denture cleaners.

Swelling of the salivary glands.

If peeling of the skin occurs in the mouth, dilute the mouthwash with an equal amount of water. If a side effect occurs, if one of the side effects worsens, or in any event that you experience any side effect not mentioned in this leaflet, consult your doctor, dentist or a pharmacist. Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment", which can be accessed at the homepage of the Ministry of Health website: www.health.gov.il

referring to the online form for reporting side effects, or by entering the link: https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

• Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the sight and reach of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instructions from your doctor.

• Do not use the medicine after the expiry date that appears on the package/ bottle/ carton/ label. The expiry date refers to the last day of the month. Must be stored at a temperature under 25°C. Keep in the original package to protect from light. **After first opening of the bottle**, to be used within 6 months.

6. FURTHER INFORMATION

In addition to the active ingredient, the drug contains also the following inactive ingredients: Purified water, Sorbitol solution, Ethanol 95% (Alcohol 95%), PEG 40 Hydrogenated Castor Oil, Peppermint oil.

HOW THE MEDICNE LOOKS LIKE AND WHAT ARE THE CONTENTS OF THE PACKAGE:

• The drug looks like a transparent solution, with a sweetish mint flavor, and has a characteristic smell of mint.

The solution is packed in a 300 mL plastic bottle with a screw cap, placed in a cardboard box. The package includes a measuring cup.

Size of package: The medicine is provided in a package, as specified – in a plastic bottle containing 300 mL solution.

Manufactured for & Distributed by:

Super-Pharm (Israel) LTD. P.O. box 2171, Herzeliyya 4672516.

Manufacturer and Registration holder:

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This leaflet has been revised in 01.21 according to MOHs guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 163-01-36040-00