

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS
(PREPARATIONS) - 1986**

This medicine is sold without a doctor's prescription

Tarodent Mouthwash

Active ingredient: Chlorhexidine gluconate 0.2% w/v

See section 6 for a list of the additional ingredients.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.

This medicine is intended for patients over 12 years old. Consult your doctor before you use it in younger children. Use this medicine according to the instructions in the section about dosage in this package insert. Consult a pharmacist if you need further information.

1. What is this medicine intended for?

- for inhibition of plaque formation
- as an aid in treatment and prevention of gingivitis
- as an aid in maintaining oral hygiene
- to be used after dental surgeries or treatments, to facilitate healing of gums
- for use in treatment of ulcers in the mouth, inflammations due to dental prostheses, and fungal infections of the mouth

Therapeutic group: Antiseptic

2. Before using this medicine

X Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient chlorhexidine gluconate or to any of the other ingredients that this medicine contains (see section 6 'Further Information').

Special warnings regarding use of the medicine:

- **Do not use in children under 12 years old** unless recommended by your doctor.
- **Do not use anywhere other than in your mouth.** Do not swallow. Wash thoroughly with water if any gets into your eyes or ears.
- **In case of a severe allergic reaction, stop using this medicine and get help immediately.** See 'Side effects'.
- **Do not use immediately after brushing your teeth.** See 'How to use this medicine?' for more information.
- **Do not bleach fabrics** that have come into contact with this mouthwash.
- **Temporary staining may appear on your teeth and tongue.** See 'Side effects'.
- You may experience a change in your sense of taste or you may feel stinging. See 'Side effects'.

¶ If you are taking, or have recently taken, any other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist.

¶ Pregnancy and breastfeeding

You can use this medicine if you are pregnant or breastfeeding.

3. How to use this medicine?

Check with your doctor or pharmacist if you are not sure.

Do not exceed the recommended dose.

Do not swallow.

Toothpastes may interfere with mouthwash activity. After brushing your teeth, rinse your mouth well with water and wait 5 minutes before using Tarodent Mouthwash; or use the mouthwash at a different time of day.

The recommended dose is:

Use twice a day. Fill the measuring cup up to the 10 ml line. Rinse your mouth thoroughly for one minute and then spit out.

Gingivitis: A one month course is recommended.

Mouth ulcers and fungal infections of the mouth: Continue to use for 2 days after healing.

Inflammations due to dental prostheses: Clean and soak your dental prostheses in the mouthwash for 15 minutes twice a day.

After dental surgeries: Rinse as directed by your dentist.

If your symptoms persist, **see your doctor.**

Be sure to measure the dose in the special measuring cup.

If an adult or a child has accidentally swallowed some of the medicine, go immediately to a doctor or a hospital emergency room and bring the medicine package with you.

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

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Tarodent 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 mouthwash and **seek immediate medical help** if you get a **rash, swelling of your mouth or face**, or if **you have difficulty breathing**. These effects may be symptoms of a severe allergic reaction which is very rare.

Stop using the mouthwash and **see your doctor** if you get **irritation of the mouth, soreness or swelling of the inside of the cheeks**.

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 to use this medicine'). If staining remains 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 in your sense of taste, a burning, numbing or pricking sensation in your tongue** when you first use the mouthwash. This usually goes away with continued use. If the effects persist, consult your doctor.
- If **peeling of the skin** inside the mouth occurs, dilute the mouthwash with an equal amount of water.

If you experience any side-effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor, dentist, or pharmacist.

You can report side effects to the Ministry of Health by clicking on the link: "Reporting side effects due to medical treatment" that is found on the homepage of the Ministry of Health website (www.health.gov.il) which refers to the online form for reporting side effects. You can also use this link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of sight and reach of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Store in a cool and dark place.
- Store in the original package.
- 300 ml package: Use within 9 months of opening. 50 ml package: Use within 1 month of opening.

6. Further information

In addition to the active ingredient, this medicine also contains:
purified water, sorbitol sol., ethanol, polysorbate 80, peppermint oil

What the medicine looks like and the contents of the package: colorless, clear to slightly cloudy mint scented solution. The medicine is packaged in a plastic bottle with a child-resistant cap and a measuring cup. The bottle contains 300 ml or 50 ml of solution. Not all pack sizes may be marketed.

Manufacturer and registration holder

Taro Pharmaceutical Industries Ltd., 14 Hakitor St., Haifa Bay 2624761.

This leaflet was reviewed and approved by the Ministry of Health in June 2013 and revised in accordance with Ministry of Health guidelines in August 2018.

Registration number of the medicine in the Ministry of Health National Drug Registry: 60.32.27698