

Patient Information Leaflet

SCHEDULING STATUS:

S0

Meridol Periodontal Antiseptic Mouthwash

Chlorhexidine digluconate

Contains sweetener: Sorbitol.

Read all of this leaflet carefully because it contains important information for you

Meridol Periodontal Antiseptic Mouthwash is available without a doctor's prescription. Nevertheless, you still need to use Meridol Periodontal Antiseptic Mouthwash carefully to get the best results from it.

- Keep this leaflet. You may need to read it again. Do not share Meridol Periodontal Antiseptic Mouthwash with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- If you experience any side effects, talk to your doctor, dentist or pharmacist. This includes any possible side effects not listed in this leaflet.
- You must see a doctor if your symptoms worsen or do not improve 7 days.

What is in this leaflet

1. What Meridol Periodontal Antiseptic Mouthwash is and what it is used for
2. What you need to know before you use Meridol Periodontal Antiseptic Mouthwash
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1. What Meridol Periodontal Antiseptic Mouthwash is and what it is used for

Meridol Periodontal is an antiseptic which temporarily reduces the number of bacteria in the mouth (thereby inhibiting the formation of dental plaque).

Meridol Periodontal is used for adults and children over the age of 7:

- for the short-term supportive treatment of inflammation of gums and mucous membrane in the mouth.
- before, during or after courses of treatment for gums and supporting structures of the teeth and to prevent infections of surgical wounds.

2. What you need to know before you use Meridol Periodontal Antiseptic Mouthwash

Do not use Meridol Periodontal Antiseptic Mouthwash:

- if you are hypersensitive (allergic) to chlorhexidine digluconate or any of the other ingredients of Meridol Periodontal Antiseptic Mouthwash (listed in section 6).
- in children under 7 years

people that are unable to control their swallowing effectively must not use the mouthwash. Children require adult supervision when using Meridol Periodontal

Warnings and precautions

Take special care with Meridol Periodontal Antiseptic Mouthwash:

For rinsing the mouth only – keep out of the eyes and ears or other cavities/orifices except the inside of your mouth. In case of contact with eyes, rinse immediately with water and contact your doctor immediately.

Meridol Periodontal should not be used, if you have ulcers or peeling in the oral cavity. Continuous rinsing of your mouth with Meridol Periodontal instead of brushing your teeth may exacerbate bleeding of the gums.

Do not use Meridol Periodontal for longer than 7 days at a time unless your doctor or dentist advises a longer treatment.

Continuous usage could increase the risk of bacterial or fungal infections.

Chlorhexidine digluconate, the active substance in Meridol Periodontal may in rare cases cause severe allergic reactions, leading to a drop in blood pressure and even to unconsciousness.

Early symptoms of a severe allergic reaction may be skin rash or asthma.

If you notice these symptoms, stop using Meridol Periodontal and contact your doctor as soon as possible (See Possible Side Effects).

Meridol Periodontal can cause staining if spilt on clothing.

Other medicines and Meridol Periodontal Antiseptic Mouthwash

Always tell your doctor, dentist or pharmacist if you are taking any other medicine, including medicines obtained without a prescription. (This includes all complementary or traditional medicines.)

The effectiveness of Meridol Periodontal may be affected by some toothpaste ingredients. Therefore, ideally use Meridol Periodontal at a separate time to tooth brushing. If you use Meridol Periodontal just after brushing, rinse your mouth thoroughly with water before rinsing with Meridol.

Meridol Periodontal Antiseptic Mouthwash with food and drinks.

Do not consume sugar-containing food or drinks within an hour of using Meridol Periodontal.

Pregnancy and breastfeeding

There is limited experience with the use of Meridol in pregnant women. Also, it is not known whether chlorhexidine is present in breast milk.

Therefore, you should use Meridol Periodontal with caution. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, dentist or pharmacist for advice before taking this medicine.

Driving and using machines

It is not expected that using Meridol Periodontal will affect your ability to drive and operate machinery.

Meridol Periodontal Antiseptic Mouthwash contains macrogol glycerol hydroxystearate.

This substance may cause skin reactions.

3. How to use Meridol Periodontal Antiseptic Mouthwash

For rinsing the mouth only. Do not swallow.

Always use Meridol Periodontal exactly as described in this leaflet or as your doctor or dentist has advised you.

You should check with your doctor, dentist, or pharmacist if you are not sure about the correct use of Meridol Periodontal.

Meridol Periodontal is safe for the use in adults and children over the age of 7 only.

Use Meridol Periodontal twice a day, ideally at a different time to brushing your teeth.

Rinse your mouth with 10 ml (1 cap) of Meridol Periodontal for one minute and spit out.

If you use Meridol Periodontal just after brushing, rinse your mouth thoroughly with water before rinsing with Meridol Periodontal.

Meridol Periodontal is ready for use and therefore should not be diluted. The screwcap on the bottle contains a measuring device to measure a 10 ml dose.

Duration of course of treatment:

Meridol Periodontal would normally not be used for longer than 7 days at a time.

It may only be used over a longer period if advised by your doctor or dentist.

Children over the age of 7 and elderly:

There are no special dosage recommendations for either elderly patients or children over the age of 7.

The normal adult dose is appropriate unless otherwise recommended by your doctor or dentist.

If you use more Meridol Periodontal Antiseptic Mouthwash than you should

Cases of overdosing when using Meridol Periodontal have not been reported.

Accidentally swallowed solution is only poorly absorbed by the gut. If you swallowed larger amounts of Meridol Periodontal tell your doctor or dentist.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use Meridol Periodontal Antiseptic Mouthwash:

Do not take / receive a double dose to make up for forgotten individual doses. Continue treatment as usual according to the instructions.

If you have any further questions on the use of this product, ask your doctor, dentist or pharmacist.

4. Possible side effects

Meridol Periodontal Antiseptic Mouthwash can have side effects.

Below is a list of known side effects which patients have experienced while using chlorhexidine digluconate:

Rare side effects: (seen in at least 1 in 10,000 patients, but in less than 1 in 1,000 patients):

- anaphylactic (allergic) reactions with symptoms such as:
- constriction of the airways (making it difficult to breath)
- general breathing problems
- swelling around the eyes
- low blood pressure
- shock
- allergic reactions after localised use of chlorhexidine
- hypersensitivity reactions
- rash
- tingling / numbness of the mouth

Very rare side effects (seen in less than 1 in 10, 000 patients) or side effects, for which it is not known how common they are (because it cannot be estimated from the data available):

- permanent damage to the cornea when the solution gets into the eye.
- swelling of the salivary gland near the ear (which reduces when the treatment has stopped)

Should you suffer from anaphylactic or allergic reactions please contact your doctor immediately.

In case of contact with eyes, rinse immediately with water and contact your doctor immediately.

Other side effects in order of frequency:

Very common side effects (seen in at least 1 in 10 patients):

- discolouration of the tongue and staining of teeth (hard tooth substance, tooth coloured dental restorations)

In most cases the staining will be temporary only for the duration of use of Meridol Periodontal. In some cases if the teeth remain stained, you may need a professional polish of your teeth by your dentist or hygienist.

Other very common side effects:

- change of taste in the mouth
- a prickling sensation of the mucosa of the mouth
- irritation of the tongue
- irritation of the mucosa in the mouth

These side effects will disappear once you stop using Meridol Periodontal.

Common side effects (seen in at least 1 in 100 patients, but in less than 1 in 10 patients):

- formation of hard deposits on the teeth above the gum line.
- peeling of the mucous membrane in the mouth.

- inflammation of the mouth.

Uncommon side effects (seen in at least 1 in 10, 000 patients, but less than 1 in 100 patients):

- disorder of mucous membrane in the mouth.

Not all side effects reported for Meridol Periodontal Antiseptic Mouthwash are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Meridol Periodontal Antiseptic Mouthwash, please consult your health care provider for advice.

Reporting of side effects

If you get side effects, talk to your doctor, dentist or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Meridol Periodontal Antiseptic Mouthwash.

5. How to store Meridol Periodontal Antiseptic Mouthwash

Store all medicines out of reach of children.

Do not use Meridol Periodontal after the expiry date which is stated on the carton and the bottle after “EXP”. The expiry date refers to the last day of that month.

Store in a cool dry place. Store at or below 25 °C

Meridol Periodontal should be discarded 4 weeks after first opening.

Do not throw away any medicines via waste water or household waste.

Ask your pharmacist about how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Meridol Periodontal Antiseptic Mouthwash contains

- The active substance is chlorhexidine digluconate. 1 ml contains 2 mg chlorhexidine digluconate. One dose of 10 ml contains 20 mg chlorhexidine digluconate.
- The other ingredients are sorbitol, liquid (non-crystallising), glycerol, macrogol glycerol hydroxystearate, citric acid monohydrate (for pH-adjustment), peppermint oil, Patent blue V (E 131), purified water, cetylpyridinium chloride and propylene glycol.

What Meridol Periodontal Antiseptic Mouthwash looks like and contents of the pack

Meridol Periodontal is a clear blue solution.

Package size: Bottle containing 300 ml.

White bottle made of polyethylene terephthalate with a white screw cap and a sealing ring made of polyethylene. The measuring device of 10 ml made of polypropylene is part of the screw cap.

The bottle contains 300 ml of the solution.

Holder of Certificate of Registration

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