



Colgate®

PRO GUM HEALTH

0.2 %

ANTISEPTIC MOUTHWASH

CHLORHEXIDINE DIGLUCONATE

Note: The name of this medicinal product is Colgate Pro Gum Health 0.2% Antiseptic Mouthwash but will be referred to as Colgate Pro Gum Health mouthwash throughout this leaflet.

Read all of this leaflet carefully before you start using this medicine, because it contains important information for you. This medicine is available without prescription. However, you still need to use Colgate Pro Gum Health mouthwash carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist or dentist if you need more information or advice.
- If you get any side effects, talk to your doctor, dentist, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor, dentist, or pharmacist if you do not feel better or if you feel worse after 7 days.

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1. WHAT COLGATE PRO GUM HEALTH MOUTHWASH IS AND WHAT IT IS USED FOR

Colgate Pro Gum Health mouthwash is an antiseptic which temporarily reduces the number of germs in the mouth (thereby inhibiting the formation of dental plaque). Colgate Pro Gum Health mouthwash is used for adults and children over the age of 6

- 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 COLGATE PRO GUM HEALTH MOUTHWASH

Do not use Colgate Pro Gum Health mouthwash

If you are allergic (hypersensitive) to chlorhexidine digluconate or any of the other ingredients of Colgate Pro Gum Health mouthwash (listed in section 6). People that are unable to control their swallowing effectively must not use a mouth rinse.

Take special care with Colgate Pro Gum Health mouthwash

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

Colgate Pro Gum Health mouthwash should not be used, if you have ulcers or peeling in the oral cavity.

Continuous rinsing of your mouth with Colgate Pro Gum Health mouthwash instead of brushing your teeth may exacerbate bleeding of the gums.

Do not use Colgate Pro Gum Health mouthwash for longer than 7 days at a time unless your doctor or dentist advises a longer treatment. A continuous usage could increase the risk of bacterial or fungal infections.

Chlorhexidine digluconate, the active substance in Colgate Pro Gum Health mouthwash, 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 Colgate Pro Gum Health mouthwash and contact your doctor as soon as possible (see under section 4: "Possible side effects").

Colgate Pro Gum Health mouthwash can cause staining, if spilt on clothing.

Other medicines and Colgate Pro Gum Health mouthwash

Tell your doctor, dentist, or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription. The effectiveness of Colgate Pro Gum Health mouthwash may be affected by some toothpaste ingredients. Therefore, ideally use Colgate Pro Gum Health mouthwash at a separate time to toothbrushing. If you use Colgate Pro Gum Health mouthwash just after brushing rinse thoroughly your mouth with water before rinsing with Colgate Pro Gum Health mouthwash.

Colgate Pro Gum Health mouthwash with food and drink

Do not consume sugar-containing food or drinks within an hour of using Colgate Pro Gum Health mouthwash.

Pregnancy and breast-feeding

There is limited experience with the use of Colgate Pro Gum Health mouthwash in pregnant women. Also, it is not known, whether chlorhexidine is present in breast milk. Therefore, you should use Colgate Pro Gum Health mouthwash with caution. If you are pregnant or breast-feeding, ask your doctor, dentist, or pharmacist for advice before using Colgate Pro Gum Health mouthwash as for any medicine.

Driving and using machines

It is not expected that using Colgate Pro Gum Health mouthwash will affect your ability to drive and operate machinery.

Important information about some of the ingredients of Colgate Pro Gum Health mouthwash

Colgate Pro Gum Health mouthwash contains macrogol glycerol hydroxystearate. This substance may cause skin reactions. Propylene glycol may cause skin irritation.

3. HOW TO USE COLGATE PRO GUM HEALTH MOUTHWASH

For rinsing the mouth only. Do not swallow. Always use Colgate Pro Gum Health mouthwash 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 Colgate Pro Gum Health mouthwash. Colgate Pro Gum Health mouthwash is for the use of adults and children over the age of 6 only.

Use Colgate Pro Gum Health mouthwash twice a day, ideally at a different time to brushing your teeth:

- Rinse your mouth with 10 ml (1 cap) of Colgate Pro Gum Health mouthwash for one minute and spit out.

If you use Colgate Pro Gum Health mouthwash just after brushing, rinse your mouth thoroughly with water before rinsing with Colgate Pro Gum Health mouthwash. Colgate Pro Gum Health mouthwash is ready for use and should not be diluted. The screw-cap on the bottle contains a measuring device to measure a 10 ml dose.

Duration of course of treatment

Colgate Pro Gum Health mouthwash 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 6 and the elderly

There are no special dosage recommendations for either elderly patients or children over the age of 6. The normal adult dose is appropriate unless otherwise recommended by your doctor or dentist.

If you use more Colgate Pro Gum Health mouthwash than you should

Cases of overdosing when using Colgate Pro Gum Health mouthwash have not been reported. Accidentally swallowed solution is only poorly absorbed by the gut. If you swallowed larger amounts of Colgate Pro Gum Health mouthwash, tell your doctor or dentist.

If you forget to use Colgate Pro Gum Health mouthwash

Do not use a double dose to make up for a forgotten dose. 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

Like all medicines, Colgate Pro Gum Health mouthwash can cause side effects, although not everybody gets them. 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 breathe)
 - general breathing problems
 - swelling around the eyes
 - low blood pressure
 - shock
 - allergic reactions after localised use of chlorhexidine
 - hypersensitivity reactions
 - rash

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

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 during usage of Colgate Pro Gum Health mouthwash. In some cases if staining of the teeth persists, you may need a professional polish of your teeth by your dentist or hygienist.

Other very common side effects:

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

These effects will disappear once you stop using Colgate Pro Gum Health mouthwash.

- 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 1,000 patients, but in less than 1 in 100 patients):
- disorder of mucous membrane in 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 currently available):

- swelling of the salivary gland near the ear (which reduces when the treatment has stopped)

Reporting of side effects

If you get any side effects, talk to your doctor, dentist or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE COLGATE PRO GUM HEALTH MOUTHWASH

Keep Colgate Pro Gum Health mouthwash out of sight and reach of children. Do not use Colgate Pro Gum Health mouthwash 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. This medicinal product does not require any special storage conditions. The product should be discarded 4 weeks after first opening. Do not throw away any medicines via wastewater 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 Colgate Pro Gum Health 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.
- Other ingredients are Sorbitol, liquid (non-crystallising), Glycerol, Propylene glycol, Macrogol glycerol hydroxystearate, Cetylpyridinium Chloride, Citric acid monohydrate (for pH-adjustment), Peppermint oil, Patent blue V (E 131), Purified water.

What Colgate Pro Gum Health mouthwash looks like and contents of the pack

Colgate Pro Gum Health mouthwash is a clear blue solution. Package size: Bottle containing 300 ml.

Marketing Authorisation Holder

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On request, this leaflet is available in formats suitable for the blind and partially-sighted.

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