

PACKAGE LEAFLET: INFORMATION

FOR THE USER

Corsodyl Aniseed 0.2% w/v Mouthwash

Chlorhexidine digluconate

WHAT YOU SHOULD KNOW ABOUT CORSODYL ANISEED MOUTHWASH

Please read this leaflet carefully before you start to use Corsodyl Aniseed Mouthwash, especially the section headed "Before you start using Corsodyl Aniseed Mouthwash". This leaflet provides some of the information available on your medicine. If you have any questions or are not sure about anything, ask your dentist, doctor, or pharmacist.

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1. What is Corsodyl Aniseed Mouthwash and what is it used for

The active ingredient chlorhexidine digluconate is known as an antimicrobial. This means that it kills off a wide range of bacteria, yeasts, some fungi, and some viruses that cause infection and inflammation in your mouth. Corsodyl Aniseed Mouthwash is a clear to slightly opalescent transparent solution with an odour of aniseed and is used to stop plaque forming on your teeth and gums. It helps in the treatment and prevention of gingivitis, which causes reddening, swelling and sometimes bleeding of gums. Other uses include keeping your mouth clean in situations where you are unable to brush your teeth effectively (e.g. following dental surgery or treatment or if you have disabilities), helping healing in the mouth, and helping treat mouth ulcers, denture stomatitis (infection/inflammation in your mouth caused by your dentures) and oral thrush. These diseases are caused by a fungus called *Candida albicans* which leads to white furry patches in your mouth or redness under your denture(s).

2. Before you start using Corsodyl Aniseed Mouthwash

For external use in the mouth only. This means that you should only use the mouthwash in the mouth, and you should try not to swallow any. Keep out of the eyes and ears. If you accidentally get some in your eyes, wash out quickly and thoroughly with water.

Do not use Corsodyl Aniseed Mouthwash if you have ever had an allergic reaction to chlorhexidine digluconate or to any of the ingredients listed in Section 6. Macrogolglycerol hydroxystearate may cause skin reactions. Do not use in children under 12, unless recommended by a healthcare professional. Stop using the mouthwash and seek immediate medical help if you get a rash, swelling of the lips, tongue, throat or face, soreness or irritation of the mouth or have difficulty breathing. See Section 4 for more information. You may notice a change of taste, tingling or burning sensation when

you first use Corsodyl. See Section 4 for more information. Temporary staining of the teeth and tongue may occur. See Section 4 for more information. If you are cleaning your teeth as normal, you should use your regular toothpaste before the mouthwash (rinsing your mouth well with water and wait for 5 minutes before using the mouthwash) as some toothpastes can stop Corsodyl working. Also, you can use Corsodyl at a different time of the day.

If you are pregnant or breastfeeding: You may use Corsodyl Aniseed Mouthwash if you are pregnant or breastfeeding. However, you should be careful about using any medicinal product while you are pregnant, and you should discuss this with your dentist, doctor, or pharmacist.

3. How to use Corsodyl Aniseed Mouthwash

Twice daily, rinse the mouth well for about one minute with 10ml (up to the line in the cap) of the mouthwash.

Do not exceed the stated dose. If you are having dental surgery, you should rinse before treatment, as instructed by your dentist. You should use the mouthwash for as long as your dentist or doctor tells you to, or as stated below. For the treatment of red, swollen or bleeding gums (gingivitis), you should use the mouthwash for about one month. You will probably use about two bottles during this time. For mouth ulcers, denture stomatitis, and thrush, continue using the mouthwash for two days after the symptoms have disappeared, up to

a maximum of one month. For the treatment of denture stomatitis, you should also thoroughly clean your dentures and then soak them in the mouthwash for fifteen minutes twice daily.

If your symptoms persist after you have used the mouthwash for the recommended time, stop using it and consult your dentist or doctor.

What you should do if you swallow some Corsodyl Aniseed Mouthwash

If you swallow any by accident, you are unlikely to get any bad effects. However, you should contact your dentist, doctor, or pharmacist if you swallow more than the suggested dose of 10ml.

If swallowed by a child, seek medical attention.

4. Possible side effects

When using the mouthwash, you may find that your tongue gets discoloured. This goes away once you stop using the mouthwash. You may also get discolouration of the teeth, crowns, and dentures. This stain is not permanent and is caused when the chlorhexidine reacts with natural colour substances in some food and drink. It can largely be prevented by proper brushing with regular toothpaste daily and rinsing well with water before using the mouthwash and by reducing your consumption of tea, coffee, and red wine. In the case of dentures, you will need to use a conventional denture cleaner in addition to the soak in the mouthwash. Occasionally this cleaning of teeth and dentures will not be enough to completely remove the stain and you will have to ask your dentist for help.

If you have visible white fillings, you are recommended to obtain your dentist's or doctor's advice before using the product. Occasionally dentists are not able to properly clean such fillings, particularly if they have rough surfaces or edges, or after prolonged use of the mouthwash. Replacement of the fillings might then be necessary. If you are unable to brush your teeth properly, for example if you have a bridge or wear a brace, you may have to ask your dentist to clean them after finishing treatment with the mouthwash. When you start using the mouthwash, you may find

that your food tastes a bit unusual, or you get a tingling or burning feeling on the tongue. These effects usually go away as you continue to use the mouthwash. However, if it continues then speak to a healthcare professional. Occasionally you may get some shedding of the lining of the mouth when you use the mouthwash. If this happens you should dilute the recommended amount of mouthwash with an equal amount of tap water and mix well just before use. This should allow you to continue using the mouthwash without any further problems.

If you get soreness or irritation of the mouth, stop using the mouthwash and tell your dentist, doctor, or pharmacist. Very occasionally you may get some swelling of the salivary glands in your cheek, when using the mouthwash. This should disappear once you discontinue use. Very rarely severe allergic reactions may occur (anaphylaxis). If you get a rash, swelling of the lips, tongue, throat, face or have difficulty breathing, you should see a doctor immediately. If you are concerned about any of these symptoms, or you experience any other unusual effects, stop using the product and tell your dentist, doctor, or pharmacist at once.

Reporting of side effects: If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Corsodyl Aniseed Mouthwash

Do not use the mouthwash after the expiry date (EXP) shown on the pack. The expiry date refers to the last day of the month.

Do not store above 25°C. Use within

6 months of opening. Store in the original container in order to protect from light.

Keep out of the sight and reach of children.

6. Further information

Active ingredient is Chlorhexidine Digluconate 0.2% w/v equivalent to Chlorhexidine Digluconate Solution

Ph. Eur. 1.0% v/v.

Other ingredients are Glycerol, Macrogolglycerol Hydroxystearate, Sorbitol Liquid 70% (Non-Crystallising), Aniseed Flavour and purified water. This pack contains Corsodyl Aniseed Mouthwash in a 300ml bottle.

The product authorisation holder is: Haleon Ireland Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland, and all enquiries should be sent to this address.

The manufacturer is:

Omega Pharma Manufacturing GmbH & Co. KG, Benzstraße 25, 71083, Herrenberg, Germany or Purna Pharmaceuticals NV, Rijksweg 17, 2870 Puurs, Belgium.

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