

Dentomycin^{*}

2%w/w Periodontal Gel

Minocycline (as hydrochloride dihydrate)

Patient Information

Please read all of this leaflet carefully before you receive the medicine.

This leaflet tells you about DENTOMYCIN 2%w/w Periodontal Gel (DENTOMYCIN).

Keep the leaflet as you may want to read it again.

If you have any further questions please ask your dentist.

If you experience any troublesome side effects or any effects not listed in this leaflet tell your dentist or doctor.

In this leaflet:

1. What DENTOMYCIN is and what it is used for
2. Before you receive DENTOMYCIN
3. How DENTOMYCIN is used
4. Possible side effects
5. How to store DENTOMYCIN
6. Further information

1. WHAT DENTOMYCIN IS AND WHAT IT IS USED FOR

DENTOMYCIN contains the active ingredient minocycline. Minocycline is one of a group of antibiotics called tetracyclines.

DENTOMYCIN can be used to treat moderate to severe chronic periodontitis in adults. Periodontitis is a disease of the gums and tissues which support and attach the teeth to the gums and jaw bone.

Periodontitis causes spaces to develop between the gums and the teeth (periodontal pockets); some of the fibres which attach the tooth to the jaw and some of the bone may be lost. Periodontitis is the most common reason that teeth are lost in older people.

2. BEFORE YOU RECEIVE DENTOMYCIN

You should not receive DENTOMYCIN if:

- you are allergic to any tetracycline antibiotic (e.g. oxytetracycline, tetracycline, chlortetracycline, demeclocycline, doxycycline or minocycline) or any of the ingredients in the gel (see section 6 for more details)
- you have kidney failure
- the patient is under 12 years of age.

This medicine is not suitable for everybody. Speak to your dentist before you receive this medicine if:

- you have liver or kidney disease.

Taking other medicines

Before you receive DENTOMYCIN please tell your dentist if you are taking medicines to thin the blood (e.g. warfarin), including any other medicines you might have bought without a prescription.

Pregnancy and breast-feeding

Talk to your dentist or doctor before treatment with DENTOMYCIN.

Driving and operating machinery

There are no known effects of DENTOMYCIN on your ability to drive or use machinery.

3. HOW DENTOMYCIN IS USED

DENTOMYCIN will be applied by your dentist. Your dentist will use the applicator supplied with DENTOMYCIN to fill each 'periodontal pocket' until it overflows. The dentist will wipe the applicator with an antiseptic before using it to treat another tooth but the same applicator can be used for treating several teeth. Your dentist must allow the applicator to reach room temperature 15 minutes before use and must not remove it from the aluminium pouch until immediately before use.

Your dentist will apply DENTOMYCIN every 14 days on three or four occasions. After you have received 3-4 treatments you will not receive the gel again for at least 6 months.
You should not brush or floss your teeth, use mouthwash, eat or drink for at least 2 hours after the gel has been applied.

4. POSSIBLE SIDE-EFFECTS

As with all medicines DENTOMYCIN can cause side-effects in some people, although not everybody will get them. Tell your dentist immediately or go to hospital if you experience any of the following symptoms of an allergic reaction:

- swelling of the eyes, mouth and possibly hands, feet and throat
- breathing difficulties
- rash
- hives (raised, often itchy, red patches on the skin)
- itching.

These side effects are very rare but may be serious. If they occur you may need urgent medical attention. The side effects which can occur when people are using DENTOMYCIN are listed below according to how commonly they occur.

Common (likely to affect more than 1 in 100 people):

- Irritation at the site of application.

Uncommon (likely to affect up to 1 in every 100 people):

- Upset stomach and diarrhoea
- A feeling of uneasiness
- Swelling at the site of application.

In clinical trials some patients who received DENTOMYCIN after subgingival scaling and root planing, and some who did not, developed dental abscesses and bruising; these side effects were thought to be due to scaling and root planing rather than treatment with DENTOMYCIN.

Reporting of side effects

If you get any side effects, talk to your doctor or dentist. This includes any possible side effects not listed in this leaflet.

In the UK you can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

In Ireland you can report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5. HOW TO STORE DENTOMYCIN

Remember to keep all medicines in a safe place. Keep medicines out of the sight and reach of children. Your dentist will keep and dispose of DENTOMYCIN for you. It should be stored in a refrigerator between 2-8°C (or up to 30°C for a maximum of 10 days) in the original packaging and not frozen. It should not be used after the expiry date (end of the month) which is printed on the applicator, pouch and carton.

6. FURTHER INFORMATION

What DENTOMYCIN contains

The active ingredient in DENTOMYCIN is minocycline hydrochloride dihydrate equivalent to minocycline 2% w/w. Other ingredients which are used to make DENTOMYCIN include hyetellose, magnesium chloride hexahydrate, ammonio methacrylate copolymer (type B), triacetin (E1518), glycerol (E422).

What DENTOMYCIN looks like

DENTOMYCIN is a light yellow-coloured gel. It is supplied in cartons containing 5 polypropylene applicators, each encased in a laminated aluminum pouch. Each applicator contains 0.5g of the gel.

Marketing authorization holder and manufacturer

Henry Schein UK Holdings Ltd.

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* Trade Mark