

SUMMARY OF PRODUCT CHARACTERISTICS

Product Summary

1. NAME OF THE MEDICINAL PRODUCT

Dentomycin 2%w/w Periodontal Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Minocycline hydrochloride dihydrate equivalent to minocycline 2% w/w

3. PHARMACEUTICAL FORM

A light yellow-coloured gel.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

DENTOMYCIN is indicated for the treatment of moderate to severe chronic adult periodontitis. It should be used as an adjunct to conventional scaling and root planning, in pockets of 5mm or greater.

4.2. Posology and method of administration

Route of administration:

DENTOMYCIN is intended to be applied directly into the periodontal pocket by means of the specially designed applicator.

Posology:

Adults

DENTOMYCIN should be administered following scaling and root planing, to periodontal pockets with a probing depth of at least 5 mm. The tip of the applicator should be inserted to the point of resistance in each pocket to be treated before the medication is administered. The amount of gel administered should be sufficient to fill each pocket to the point of overflow.

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The applicator should be wiped with 70% ethanol between applications to each individual tooth to avoid transfer of bacteria between periodontal pockets. Each disposable applicator should be used for a single patient to treat a number of periodontal pockets. However a new applicator must be used at each visit.

Treatment should be initiated with applications every 14 days for a total of three to four applications (e.g. 0, 2, 4 and 6 weeks). Treatment with the gel should not normally be repeated within 6 months of initial therapy.

Tooth brushing, flossing, mouth washing, drinking or eating should be avoided for at least two hours immediately following administration of the medication.

Elderly

As adults, although caution should be exercised in patients with hepatic dysfunction or severe renal impairment.

Children

The use of tetracyclines during tooth development in children under the age of 12 years may cause permanent discolouration. Enamel hypoplasia has also been reported. DENTOMYCIN is therefore contra-indicated in children of this age group.

There is no data to support the use of DENTOMYCIN in children over 12 years of age and therefore its use cannot be recommended.

4.3. Contraindications

Known hypersensitivity to tetracyclines; complete renal failure; children under the age of 12 years.

4.4. Special warnings and precautions for use

Because of the potential for the development of sensitisation following subgingival administration, the treatment area should be closely observed. If signs and/or symptoms of sensitisation (itching, swelling, papules, rubefaction, etc) develop, further therapy should be discontinued.

Warnings and precautions associated with systemically administered minocycline should be considered before periodontal use, especially in patients with hepatic dysfunction, severe renal impairment, and in patients taking other potentially hepatotoxic drugs. (No data is available on the use of DENTOMYCIN in these groups of patients).

Type 1A_{IN} (C1.Z) variation to update
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However as the dose of minocycline associated with subgingival administration of DENTOMYCIN is significantly lower than the dose with systemic administration, the resulting serum levels are correspondingly much lower.

Although not seen in clinical trials with DENTOMYCIN, systemic use of antibiotic preparations may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs or if an infection caused by minocycline-resistant bacteria or non-sensitive bacteria develops locally, the medication should be discontinued and appropriate therapy instituted.

4.5. Interactions with other medicinal products and other forms of interaction

Tetracyclines depress plasma prothrombin activity. Reduced doses of concomitant anticoagulants may therefore be necessary. The relevance of this statement to DENTOMYCIN has not been established.

Cross-resistance between tetracyclines may develop in micro-organisms, as may cross-sensitisation in patients.

4.6. Pregnancy and lactation

Use in pregnancy:

There are no specific data available on the use of DENTOMYCIN in pregnancy.

Results of animal studies indicate that tetracyclines cross the placenta, are found in foetal tissues and can have toxic effects on the developing foetus (often related to retardation of skeletal development). Evidence of embryotoxicity has also been noted in animals treated early in pregnancy.

The use of drugs of the tetracycline class during tooth development (last half of pregnancy) may cause permanent discoloration of the teeth (yellow-grey-brown). This adverse reaction is more common during long term use of the drug but has been observed following repeated short term courses. Enamel hypoplasia has also been reported. DENTOMYCIN should therefore not be used in pregnancy unless considered essential.

Use in lactation:

There are no specific data available on the use of DENTOMYCIN during lactation.

Tetracyclines have been found in the milk of lactating women who are taking a drug in this class. Permanent tooth discoloration may occur in the developing infant and enamel hypoplasia has also been reported.

DENTOMYCIN should therefore not be used during lactation unless considered essential.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

Local irritation has been reported following subgingival administration of DENTOMYCIN in clinical trials (representing a total incidence of 1.4%). A single case of gingival oedema was reported (0.2%).

Dental abscesses were reported in a clinical trial in both DENTOMYCIN and vehicle control group following subgingival scaling and root planing, as was a single case of ecchymosis. The latter two side effects are both thought to result from the process of treatment rather than the drug therapy.

Reports of systemic side effects in clinical trials with DENTOMYCIN were rare but included diarrhoea (at an overall incidence of 0.5%) and a single case each of upset stomach (0.2%) and mild dysphoria (0.2%).

Adverse reactions associated with the systemic administration of minocycline are thought to be much less likely to occur with the subgingival application of DENTOMYCIN, due to the relatively low serum levels involved. However, there have been very rare reports of hypersensitivity reactions, including angioedema, bronchospasm/dyspnoea, rash, urticaria and pruritus and the possibility of systemic reactions occurring should be borne in mind.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

4.9. Overdose

Overdose with DENTOMYCIN is thought to be highly unlikely due to the small quantities per syringe. If however it were to occur, the treatment for minocycline overdose is gastric lavage plus appropriate supportive treatment. There is no specific antidote.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Minocycline hydrochloride has in vitro antibacterial activity against a wide range of gram-negative and gram-positive organisms thought to be related to periodontal disease, including *Porphyromonas gingivalis* (formerly *Bacteroides gingivalis*), *Prevotella intermedia* (formerly *Bacteroides intermedius*) and *Actinobacillus actinomycetemcomitans*, as well as *Wolinella recta*, *Peptostreptococcus* spp, *Fusobacterium nucleatum* and *Eikenella corrodens* and *Spirochaetes*.

5.2. Pharmacokinetic properties

In a pharmacokinetic study, concentrations of minocycline in gingival crevicular fluid remained at clinical-effective levels for a minimum of three days following the administration of 0.05 g gel (1 mg minocycline) into periodontal pockets.

Serum levels after subgingival administration and even after direct oral administration of 0.5 g gel (10 mg minocycline) were only in the range of 0.1-0.2 µg/ml. These levels are much lower than the serum levels which would be associated with the normal oral dose of 100-200 mg/day minocycline used in systemic therapy. To demonstrate this, DENTOMYCIN following the fourth application has a $C_{\max}^{(a)}$ (mean) of 0.10 µg/ml, whereas MINOCIN 50 mg Tablets administered 12 hourly result in steady state levels C_{\max} (mean) of 2.08 µg/ml and $C_{\min}^{(b)}$ (mean) of 1.09 µg/ml.

(a) C_{\max} = maximum serum concentration.

(b) C_{\min} = minimum serum concentration.

5.3. Preclinical safety data

Nothing of further relevance to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Hyetellose
Magnesium Chloride Hexahydrate (E511)
Ammonio Methacrylate Copolymer (type B)
Triacetin (E15 18)
Glycerol(E422)

6.2. Incompatibilities

None known.

6.3. Shelf life

36 months.

6.4 Special precautions for storage

DENTOMYCIN should be stored in a refrigerator (2-8°C) in the original packaging.
Do not freeze.

Product may be stored at temperatures up to 30°C for a maximum period of 10 days.

6.5. Nature and contents of container

0.5 g of gel contained in a polypropylene applicator encased in a laminated aluminium bag.

Each carton contains 5 applicators.

6.6. Instruction for use/handling, and disposal

It is recommended that applicators are allowed to equilibrate to room temperature for approximately 15 minutes prior to use.

See Section 4.2.

Administrative Data

7. MARKETING AUTHORISATION HOLDER

Henry Schein UK Holdings Ltd
Medcare House
Centurion Close
Gillingham Business Park
Kent
ME8 0SB
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 27880/0001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/01/07

10. DATE OF REVISION OF THE TEXT

5th December 2014

PL 27880/0001

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