Summary Of Product Characteristics

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.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Periodontal Gel.
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 planing, 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.

Adults:

DENTOMYCIN should be administered following scaling and root planing, to peridontal 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.

The applicator should wiped with 70% ethanol between applications to each individual tooth to avoid transfer of bacteria between periodontal pockets.
Posology:

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.

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Tooth brushing, flossing, mouth-washing, drinking or eating should be avoided for at least 2 hours immediately following administration of 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 contraindicated in children of this age group.

There are 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 special 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).

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 nonsensitive bacteria develops locally, the medication should be discontinued and appropriate therapy instituted.

4.5 Interaction with other medicinal products and other forms of interactions

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 Fertility, 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 discolouration 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 discolouration 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

The most commonly reported adverse event is local irritation, occurring in less than 2% of patients. 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 the possibility of systemic reactions occurring should be considered.

Adverse reactions are listed by frequency: very common (≥1/10), common (≥1/100, <1/10); uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1,000); very rare (≤1/10,000), not known (cannot be estimated from available data).

The following undesirable effects have been observed:

Infections and infestations
Frequency not known: Application site abscess.
Dental abscesses were reported in a clinical trial in both DENTOMYCIN and vehicle control group following subgingival scaling and root planing. These are thought to result from the process of treatment rather than the drug therapy.

Immune system disorders
Frequency not known: Hypersensitivity reactions, including angioedema, bronchospasm/dyspnoea, rash, urticaria and pruritus, have been reported in the post-marketing period.

Psychiatric disorders
Uncommon: Mild dysphoria.

Gastrointestinal
Uncommon: Gingival oedema, diarrhoea, stomach discomfort

General and administration site disorders
Common: Application site irritation (e.g. pain, inflammation, erythema, rash)
Frequency not known: Application site ecchymosis.
A single case of ecchymosis was reported in a clinical trial in both DENTOMYCIN and vehicle control group following subgingival scaling and root planing. This was thought to result from the process of treatment rather than the drug therapy.

Reporting of suspected adverse reactions

Healthcare professionals are asked to report any suspected adverse reactions preferably through the online reporting option accessible from the HPRA homepage. A downloadable report form is also accessible from the HPRA website, which may be completed manually and submitted to the HPRA via 'freepost', in addition to the traditional post-paid 'yellow card' option. FREEPOST HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie.

4.9 Overdosage

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 clinically-effective levels for a minimum of three days following the administration of 0.05g gel (lmg minocycline) into periodontal pockets.

Serum levels after subgingival administration and even after direct oral administration of 0.5g gel (10mg minocycline) were only in the range of 0.1-0.2µg/ml. These levels are much lower than the serum levels which would be associated with the normal oral dose of 100-200mg/day minocycline used in systemic therapy. To demonstrate this, DENTOMYCIN following the fourth application has a C_{max}[(a)] (mean) of 0.10µg/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} = minium 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

Not applicable.

6.3 Shelf life

At 2-8°C: 3 years
Up to 30°C: 10 days
See section 6.4.
For in-use information, see section 4.2.

6.4 Special precautions for storage

Store 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.
See Section 6.6.

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Product should not be removed from the aluminium pouch until immediately before use.

6.5 Nature and contents of container

0.5g of gel contained in an applicator consisting of a polypropylene syringe barrel, polypropylene plunger rod and elastomer cap and gasket (plunger stopper) encased in a laminate aluminium pouch.

Each carton contains 5 applicators.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

It is recommended that applicators are allowed to equilibrate to room temperature for approximately 15 minutes prior to use.
See section 4.2. (posology and method of administration)
Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Henry Schein UK Holdings Limited
Medcare House
Centurion Close
Gillingham Business Park
Gillingham
Kent
ME8 OSB
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PA 1321/001/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of first authorisation: l0th December 1998
Date of Last renewal 10th December 2008

10. DATE OF REVISION OF THE TEXT

5th December 2014

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