Summary of Product Characteristics (SmPC)

1. Name of the medicinal product
METROGYL DENTA GEL
(Metronidazole Gel)

2. Qualitative and quantitative composition
Each Gram of Gel Contains:
Metronidazole Benzoate BP
Equivalent to Metronidazole…….10 mg
Chlorhexidine Gluconate Solution BP…0.25 % w/w
(As Preservative)
Water Soluble Gel Base……..q.s.

For the full list of excipients, see section 6.1

3. Pharmaceutical form
Gel (for dental use only).

4. Clinical particulars
4.1 Therapeutic indications
– Inhibition of formation of dental plaque.
– As an aid in the treatment and prevention of gingivitis.
– As an aid to maintaining oral hygiene.
– For use in a post-peridontal surgery or treatment regimen to promote gingival healing.
– It is useful in the management of recurrent aphthous ulceration.
– It is useful in the management of recurrent oral candidal infections.
– As an aid in the prevention of dental caries in high-caries-risk patients (for example xerostomia sufferers), when used in a regimen as an adjunct to fluoride.

4.2 Posology and method of administration
The dental gel is designed for application to periodontal area.
Metrogyl Denta is applied to the periodontal area twice daily. Dosage is individual, dependent upon the number of teeth to be treated.
Apply and rub Metrogyl Denta Gel, twice daily to entire affected area after washing for 30 seconds or as directed by Physician.

4.3 Contraindications
– Known hypersensitivity to metronidazole and components.
– Pregnancy and lactation.

4.4 Special warnings and precautions for use
For oral use only. Do not swallow. Keep out of the eyes and ears. If the gel comes into contact with the eyes, wash out promptly and thoroughly with water. In case of soreness, swelling or irritation of the mouth, stop using the product and consult a healthcare professional. Metronidazole Denta is incompatible with anionic agents which are usually present in conventional dentifrices. These should therefore be used before Metronidazole Denta (rinsing the mouth and toothbrush between applications) or at a different time of day.
In some patients, metronidazole may have an effect similar to that of disulfiram on the metabolism of alcohol, with symptoms of intolerance as result. This effect may persist for up to 48 hours after discontinuation of treatment.
Patients should be told not to drink alcohol or alcoholic beverages.

When treating mouth ulcers or oral thrush infections, treatment should be continued for two days after the symptoms have cleared up. When treating inflammation caused by denture rubbing, the dentures should be cleaned and soaked for 15 minutes twice a day in chlorhexidine mouthwash.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant ingestion of disulfiram can produce acute conditions of confusion. Metronidazole may potentiate the anticoagulant effect of warfarin.
Chlorhexidine is incompatible with anionic agents.

4.6 Fertility, pregnancy and breastfeeding

Pregnancy

There has been no experience to date with the use of Metronidazole gel in pregnant patients. In case of oral administration, Metronidazole crosses the placental barrier and enters foetal circulation rapidly. No foetotoxicity was observed after oral Metronidazole in either rats or mice. However because animal reproduction studies are not always predictive of human response and since oral Metronidazole has been shown to be a carcinogen in some rodents this drug should not be given during pregnancy.

Lactation

After oral administration Metronidazole is secreted in breast milk in concentration similar to those found in plasma. Even though blood levels are significantly lower with cutaneous application of Metronidazole gel than those achieved after oral Metronidazole in nursing mothers, this drug should not be given during lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Because of the low plasma concentration after local application of the Metrogyl Denta Gel, the risk of systemic side effects is low.

The following adverse experiences have been reported with the topical use of Metronidazole-

Chlorhexidine combination: burning, irritation, dryness, transient redness, metallic state, staining of teeth, tingling or numbness of extremities and nausea.

Adverse effects, caused by Metronidazole

The most common are local and are related to the application, namely a bitter taste and temporary local tenderness. Headache has been reported.

Adverse effects, caused by Chlorhexidine

Irritative skin reactions: irritative skin reactions to Chlorhexidine preparations can occasionally occur.

Generalised reactions

Allergic reactions, hypersensitivity and anaphylaxis to Chlorhexidine have also been reported but are extremely rare. Surfaces which are not adequately cleaned by professional prophylaxis may require replacement.

4.9 Overdose

Accidental ingestion: chlorhexidine and metronidazole taken orally are poorly absorbed. Systemic effects are unlikely even if large amounts are ingested. However, gastric lavage may be advisable using milk, raw egg, gelatin or mild soap. Employ supportive measures as appropriate.

5. Pharmaceutical properties

5.1 Pharmacodynamic properties

The combined antimicrobic preparation for treatment and prophylaxes of infectious diseases-inflammatory of an oral cavity. Action of a preparation is caused by properties of the components entering into its composition.

Metronidazole is an antibiotic active against those organisms that are predominant in the subgingival flora in adult periodontitis. Metronidazole has a bactericidal effect against *Bacteroides spp., Fusobacterium, Selemonas, Wolinella, Spirochetes*, and other anaerobic organisms, but does not affect aerobic bacteria.

Chlorhexidine is effective against a wide range of Gram negative and Gram positive vegetative bacteria, yeasts, dermatophyte fungi and lipophilic viruses. It is active against a wide range of important oral pathogens and is therefore effective in the treatment of many common dental conditions.

5.2 Pharmacokinetic properties

When applied topically there is little if any systemic absorption of metronidazole.

Because of its cationic nature, chlorhexidine bonds strongly to skin, mucosa and other tissues and is thus very poorly absorbed. No detectable blood levels have been found following oral use.

5.3 Preclinical safety data

No remarks

6. Pharmaceutical particulars

6.1 List of excipients

Propylene Glycol BP
Carbomer Homopolymer TYPE C NF
Disodium Edetate BP
Saccharine BP
Levomenthol BP
Sodium Hydroxide Pellets BP
Purified Water BP

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store at temperature not exceeding 30°C. Do not freeze.

6.5 Nature and content of container

10g & 20 g Aluminium tube packed in a carton along with leaflet.
10g & 20 g Laminated tube packed in a carton along with leaflet.

6.6 Special precautions for disposal and other handling
Not Applicable

7. Marketing authorization holder

UNIQUE PHARMACEUTICAL LABORATORIES
(A Div. of J. B. Chemicals and Pharmaceuticals Ltd.)
Neelam Centre, B wing, 4th Floor, Hind Cycle Road,
Worli Mumbai - 400 030

8. Marketing Authorization Number
04958/07159/NMR/2019

9. Date of First Authorization/Renewal of the Authorization
04/02/2020

10. Date of revision of the text
27/07/2023