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metrogyl*Gel

metronidazole gel USP

Composition :

Each gram of gel contains :

Metronidazole USP 10 mg

Preservatives:

Methyl Paraben BP 0.032% w/w

Propyl Paraben BP 0.04% w/w

Water soluble gel base q.s.

Description :

Colourless to pale yellow smooth gel.

Pharmacodynamic properties :

Metronidazole is an effective,broud-spectrum antiprotozoal and antibacterial drug from the group of nitroimidzole. It is effective for the clinical treatment of patients with pyo-inflammatory diseases.

Pharmacokinetic properties :

Bioavailability studies on the topical administration of 1 gram of Metronidazole of gel to face of 10 rosacea patients showed a maximum serum concentration of 66 nanograms per milliter in one patient. This concentration is approximately 100 times less than concentration afforded by a single 250mg oral tablet. The serum metronidazole concentrations were below the detectable limits of the assay at the majority of time points in all patients.Three of the patients detectable serum concentration of metronidzole at any time point.The mean dose of gel applied during clinical studies was 600mg which represents 4.5mg of metronidazole per application. Therefore,under normal usage levels, the formulation affords minimal serum concentration of metronidazole.

Indications :

Metrogyl Gel is indicated for topical application in the treatment of inflammatory papules, pustules and erythema of rosacea.

Contraindications :

Metrogyl Gel is contraindicated in individuals with a history of hypersensitivity to metronidazole.

Precautions :

Because of the minimum absorption of metronidazole and consequently its insignificant plasma concentration after topical administration, the adverse experiences reported with the oral form of

the drug have not been reported with metrogyl gel.

Information for the Patients:

This medication is to be used as directed by the Physician. It is for external use only. Avoid contact with the eyes.

Drug Interactions:

Drug interactions are less likely with topical administration but should be kept in mind when metrogyl gel is prescribed for patients who are receiving anticoagulant treatment. Oral metronidazole has been reported to potentiate the anticoagulant effect of coumarin and warfarin resulting in a prolongation of prothrombin time.

Pregnancy & Lactation:

The safety of topically applied metronidazole in pregnancy and lactation has not been adequately established. It should be used only if clearly needed.

Adverse Reactions:

Adverse conditions reported include watery (tearing) eyes, if the gel is applied too closely to this area, transient redness, and mild dryness, burning and skin irritation. None of the side effect exceeded an incidence of 2% of patients.

Overdosage:

Not reported.

Dosage & Administration:

Apply and rub in a thin film of metrogyl gel twice daily, morning and evening to entire affected areas after washing. Significant therapeutic results should be noticed within three weeks. Clinical studies have demonstrated continuing improvement through nine weeks of therapy.

Storage:

Store in cool place, below 30°C. Protect from light.

Presentation :

30 g tube.

Shelf Life:

48 months from the date of manufacture.

Date of Revision: November 2023

Manufactured by :
UNIQUE PHARMACEUTICAL LABORATORIES
(A Division of J. B. Chemicals & Pharmaceuticals Limited)
Plot No. 304-308, G.I.D.C. Industrial Area, Panoli: 394 116, INDIA.
* Trade Mark

Product Registration Holder/Imported by:
UNIMED SDN BHD
53, Jalan Tembaga SD 5/2B,
Bandar Sri Damansara 52200,
Kuala Lumpur, Malaysia.

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125 mm

168 mm

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