



Ivermectin Cream 1.0% w/w



COMPOSITION:

Each gram contains:

Ivermectin IP	10 mg
Cream base	q.s.
Preservatives:	
Methylparaben IP	0.18% w/w
Propylparaben IP	0.02% w/w

DESCRIPTION:

Ivrea Cream contains Ivermectin, a semi-synthetic derivative isolated from the fermentation of *Streptomyces avermitilis* that belongs to the Ivermectin family of macrocyclic lactones.

CLINICAL PHARMACOLOGY:

Mechanism of Action

The mechanism of action of ivermectin cream in treating rosacea lesions is unknown, but may be due to a combination of its anti-inflammatory effects and its antiparasitic effects on the Demodex mite, which lives on the skin and may contribute to the symptoms of rosacea.

Pharmacokinetics

Absorption

The absorption of ivermectin from ivermectin cream was evaluated in a clinical trial in 15 adult male and female subjects with severe papulopustular rosacea applying 1 g ivermectin cream, 1% once daily. At steady state (after 2 weeks of treatment), the highest mean $\pm$ standard deviation) plasma concentrations of ivermectin peaked (T_{max}) at 10 $\pm$ 8 hours post-dose, the maximum concentration (C_{max}) was 2.10 $\pm$ 1.04 ng/mL (range: 0.69 to 4.02 ng/mL) and the area under the concentration curve (AUC_{0-24hr}) was 36.14 $\pm$ 15.56 ng.hr/mL (range: 13.69 to 75.16 ng.hr/mL). In addition, systemic exposure assessment in longer treatment duration (Phase 3 studies) showed that there was no plasma accumulation of ivermectin over the 52-week treatment period.

Distribution

An in vitro study demonstrated that ivermectin is greater than 99% bound to plasma proteins and is bound primarily to human serum albumin. No significant binding of ivermectin to erythrocytes was observed.

Metabolism

In vitro studies using human hepatic microsomes and recombinant CYP450 enzymes have shown that ivermectin is primarily metabolized by CYP3A4. In vitro studies show that ivermectin at therapeutic concentrations does not inhibit the CYP450 isoenzymes 1A2, 2A6, 2B6, 2C8, 2C9, 2C19, 2D6, 2E1, 3A4 or 4A11, or induce 1A2, 2B6, 2C9 or 3A4.

Excretion

The apparent terminal half-life averaged 6.5 days (mean $\pm$ standard deviation: 155 $\pm$ 40 hours, range 92 to 238 hours) in patients receiving a once daily cutaneous application of ivermectin cream for 28 days.

INDICATIONS AND USAGE:

Ivrea cream, 1.0% is indicated for the treatment of inflammatory lesions of rosacea.

CONTRAINDICATIONS:

None.

WARNINGS & PRECAUTIONS:

Ivrea cream is for use on the face only. Do not use Ivrea cream in your eyes, mouth or vagina.

Keep Ivrea cream out of the reach of children.

ADVERSE REACTIONS:

Adverse reactions, reported in $\leq$ 1% of subjects treated with ivermectin cream for at least 3 months in vehicle-controlled clinical trials, included skin burning sensation and skin irritation.

PREGNANCY & LACTATION:

Pregnancy

The available data on the use of ivermectin, including ivermectin cream, in pregnant women are insufficient to establish a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.

Lactation

The presence of ivermectin in human milk following topical administration of ivermectin has not been evaluated. There are no data available regarding the effects of ivermectin on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ivermectin cream and any potential adverse effects on the breastfed infant from ivermectin cream or from the underlying maternal conditions.

DOSAGE AND ADMINISTRATION:

Apply to the affected areas of the face once daily. Use a pea-size amount for each area of the face (forehead, chin, nose, each cheek) that is affected. Spread as a thin layer, avoiding the eyes and lips.

STORAGE: Store below 25°C. Do not freeze.

PRESENTATION:

Available in 30g Lami Tube

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