

Isotromin ®



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Each capsule contains Composition

Isotretinoin20 mg

Indications

Systemic treatment of nodulo-cystic and conglobate acne, severe acne, acne which has not responded to adequate course of systemic antibacterial or acne associated with psychological problems.

Description

Isotretinoin is an oral drug used for the treatment and prevention of severe acne. Acne is caused by inflammation of the skin. It primarily affects teenagers, but it also affects adults. Severe acne causes permanent scarring of the skin. The inflammation is caused in part by an increased secretion of sebum (oily substance) from glands in the skin (sebaceous glands). The sebum provokes inflammation, and the inflammation resolves (heals) with the formation of a scar (keratinization). The exact mechanism of action of isotretinoin is not known; however, it may reduce acne by reducing the secretion of sebum. If less sebum is secreted it is likely that there will be less inflammation and keratinization.

Adverse effects

Most adverse effects resemble vitamin A toxicity. Adverse drug reactions associated with isotretinoin therapy include:

Common: mild acne flare, dryness of skin, lips and mucous membranes, cheilitis, itch, skin fragility, skin peeling, rash, flushing, photosensitivity, nose bleeds, dry eyes, eye irritation, conjunctivitis, reduced tolerance to contact lenses, hyperlipidaemia, raised liver enzymes, headaches, hair thinning, myalgia and/or arthralgia.

The following adverse effects have been reported to persist, even after discontinuing therapy: alopecia (hair loss), arthralgias, decreased night vision, degenerative disc disease, keloids, bone disease and depression (in some cases). High dosages of isotretinoin have been reported to cause rosacea (a disease of severe facial skin redness and irritation).

While vitamin E supplements have been advocated by some to reduce the toxicity of high-dose retinoids without reducing drug efficacy, it does not appear to be effective.

Patients receiving isotretinoin therapy are not permitted to donate blood during and for at least one month after discontinuation of isotretinoin therapy.





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Dosage

Adults: Initially 500 mcg/kg daily (in 1-2 divided doses) with food, for 4 weeks. If good response, continue for further 8-12 weeks; if little response increase to 1 mg/kg daily 8-12 weeks. If intolerant, reduce dose to 100-200 mcg/kg daily. Usually given for 16 weeks, repeat course is not normally required.

Children Not recommended.

Presentations

10 caps.

<u>Note</u>: This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.

Information for Health Care Professionals

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