

NAME AND DOSAGE FORM OF PRODUCT:
BETAXOLOL OPHTHALMIC SOLUTION U.S.P.
(IOBET EYE DROPS)

Dosage Form : Eye Drops

THERAPEUTIC CLASS:

Anti Glaucoma Agent.

DESCRIPTION:

Clear, Colourless solution

NAME (S) AND STRENGTH (S) OF ACTIVE INGREDIENT(S):

Betaxolol 0.5% w/v

(as Betaxolol hydrochloride U.S.P 0.56% w/v)

PHARMACODYNAMICS:

Betaxolol hydrochloride is topical application to the eye, reduces both elevated and Normal intraocular pressure(IOP) in patients with or without glaucoma. Betaxolol Reduces IOP without affecting papillary size or accommodation. Inpatients with Elevated IOP, topical betaxolol reduces mean IOP by about 20 -35 % from base line. Iris colour does not appear to substantially affect IOP response to the drug.

INDICATION:

Betaxolol 0.5% eye drops have been shown to be effective in lowering intraocular pressure and may be used in patients with chronic open-angle glaucoma and ocular

Hypertension. It may be used alone or in combination with other intraocular pressure

Lowering medicaments.

CONTRA INDICATIONS:

Hypersensitivity to any component of this product. Betaxolol 0.5% eye drops are contraindicated in patients with sinus bradycardia, greater than a first degree atrioventricular block, cardiogenic shock, or patients with overt cardiac failure.

DOSAGE AND ADMINISTRATION:

Betaxolol hydrochloric is applied topically to the eye as an ophthalmic solution.

For the initial treatment of open-angle glaucoma or ocular hypertension, the usual

Dosage of betaxolol is 1 or 2 dropsof the 0.5% solution in the affected eye(s) twice daily.

Because of diurnal variations, it has been suggested that IOP be measured at different

Times during the day to determine if an adequate hypotensive effect is maintained in

Patients receiving twice-daily therapy.

OVERDOSAGE:

No information is available on overdosage of humans.

The symptoms which might be expected with an overdose of a systemically administered

Beta-1-adrenergic receptor blocking agent are bradycardia, hypotension and acute cardiac Failure.

A topical overdose of betaxolol 0.5% eye drops may be flushed from the eye. Patients

Suspected of developing thyrotoxicosis should be managed carefully to avoid abrupt withdrwal of Beta-adrenergic blocking agents, which might precipitate a thyroid storm

Muscle weakness:

Beta-adrenergic blockade has been reported to potentiate muscle weakness consitent

With certain myasthenic symptoms (eg., diplopia, ptosis and generalized weaknes)

Major surgery:

Consideration should be given to the gradual withdrwal of betaadrenergic blocking agents prior to general anesthesia because of the reduced ability of the heart respond

To beta-adrenergically mediated sympathetic reflex stimuli.

Pulmonary:

Caution should be exercised in the treatment of glaucoma patients with excessive

Restriction of pulmonary function. There have been reports of asthamatic attacks

And pulmonary distress during betaxolol treatment.

WARNING:

Topically applied beta-adrenergic agents may be absorbed systemically. The same adverse reactions found with systemic administration of beta-adrenergic blocking

Agents may occur with topical administration. For exmple, severe respiratory reactions

And cardiac reactions, including death due to bronchospasm in patients with asthma,

And rarely death in association with cardiac failure, have been reported with topical

Application of beta-adrenergic blocking agents.

SIDE EFFECTS:

The most frequent event associated with the use of betaxolol 0.5% Eye drops has been

Transient ocular discomfort. The following other conditions have been reported in small

Numbers of patients; blurred vision, corneal punctuate keratitis, foreign body sensation,

Photophobia, tearing, itching, dryness of eyes, erythemia, inflammation, discharge, ocular

Pain, decreased visual acuity and crusty lashes.

DRUG INTERACTIONS:

Patients who are receiving a beta-adrenergic blocking agent orally and should be observed for a potential additive effect either on the intraocular pressure or on the known

Systemic effects of beta blockade.

Close observation of the patient is recommended when a beta blocker is administred to

Patients receiving catecholamine-depleting drugs such as reserpine, because of possible Additive effects and the production of hypotension and /or bradycardia.

Betaxolol is an adrenergic blocking agent; therefore caution should be exercised in patients using concomitant adrenergic psychotropic drugs.

STORAGE CONDITIONS:

Storage conditions: Store the vial well closed in a cool place.

SHELF LIFE:

24 Months from the date of Manufacturing

NAME AND ADDRESS OF MANUFACTURER:

FDC limited.,

B-8, M.I.D.C.,

Waluj,

Dist. Aurangabad 431 136,

India.

NAME AND ADDRES OF THE IMPORT:

UNIMED SDN BHD

53, JALAN TEMBAGA SD 5/2B,

BANDAR SRI DAMANSARA

5200, KUALA LUMPUR,

MALASIA.