BACK

1 cm
Barcode

hovid

hovid Moxifloxacin Ophthalmic Solution 0.5% w/v

Data are very limited to establish efficacy and safety of hovid Moxifloxacin Ophthalmic Solution in the treatment of conjunctivitis in neonates. Therefore use of this medicinal product to treat conjunctivitis in neonates is not recommended.

hovid Moxifloxacin Ophthalmic Solution should not be used for the prophylaxis or empiric treatment of gonococcal conjunctivitis, including gonococcal ophthalmia neonatorum, because of the prevalence of fluoroquinolone-resistant *Neisseria gonorrhoeae*. Patients with eye infections caused by *Neisseria gonorrhoeae* should receive appropriate systemic treatment.

hovid Moxifloxacin Ophthalmic Solution is not recommended for the treatment of Chlamydia trachomatis in patients less than 2 years of age as it has not been evaluated in such patients. Patients older than 2 years of age with eye infections caused by *Chlamydia trachomitis* should receive appropriate systemic treatment.

Neonates with ophthalmia neonatorum should receive appropriate treatment for their condition, e.g. systemic treatment in cases caused by *Chlamydia trachomitis* or *Neisseria gonorrhoeae*.

Patients should be advised not to wear contact lenses if they have signs and symptoms of a bacterial ocular infection.

hovid Moxifloxacin Ophthalmic Solution has no or negligible influence on the ability to drive and use machines, however, as with any eye drops, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, the patient should wait until their vision clears before driving or using machinery.

PREGNANCY AND LACTATION

Pregnancy
There are no adequate data from the use of moxifloxacin ophthalmic solution in pregnant women. However, no effects on pregnancy are anticipated since the systemic exposure to moxifloxacin is negligible. hovid Moxifloxacin Ophthalmic Solution can be used during pregnancy.

Breastfeeding
It is unknown whether moxifloxacin or its metabolites are excreted in human milk. Animal studies have shown excretion of low levels in breast milk after oral administration of moxifloxacin. However, at therapeutic doses of moxifloxacin ophthalmic solution, no effects on the suckling child are anticipated. hovid Moxifloxacin Ophthalmic Solution can be used during breast-feeding.

Fertility
Studies have not been performed to evaluate the effect of ocular administration of moxifloxacin ophthalmic solution on fertility.

DRUG INTERACTIONS

No specific interaction studies have been performed with moxifloxacin ophthalmic solution. Given the low systemic concentration of moxifloxacin following topical ocular administration, drug interactions are unlikely to occur.

MAIN SIDE/ADVERSE EFFECTS

Blood and lymphatic system disorders
Rare: haemoglobin decreased.

Immune system disorders
Not known: hypersensitivity

Nervous system disorders
Uncommon: headache
Rare: paresthesia
Not known: dizziness

Eye disorders
Common: eye pain, eye irritation
Uncommon: punctate keratitis, dry eye, conjunctival haemorrhage, ocular hyperaemia, eye pruritus, eyelid oedema, ocular discomfort
Rare: corneal epithelium defect, corneal disorder, conjunctivitis, blepharitis, eye swelling, conjunctival oedema, vision blurred, visual acuity reduced, asthenopia, erythema of eyelid.
Not known: endophthalmitis, ulcerative keratitis, corneal erosion, corneal abrasion, intraocular pressure increased, corneal opacity, corneal infiltrates, corneal deposits, eye allergy, keratitis, corneal oedema, photophobia, , eyelid oedema, lacrimation increased, eye discharge, foreign body sensation in eyes

Cardiac disorders
Not known: palpitations

Respiratory, thoracic and mediastinal disorders
Rare: nasal discomfort, pharyngolaryngeal pain, sensation of foreign body (throat)
Not known: dyspnoea

Gastrointestional disorders
Uncommon: dysgeusia
Rare: vomiting
Not known: nausea

Hepatobiliary disorders
Rare: alanine aminotransferase increased, gamma-glutamyltransferase increased

Skin and subcutaneous tissue disorders
Not known: erythema, rash, pruritus, urticarial.

OVERDOSE AND TREATMENT

The limited holding capacity of the conjunctival sac for ophthalmic products practically precludes any overdosing of the medicinal product. The total amount of moxifloxacin in a single container is too small to induce adverse effects after accidental ingestion.

DOSAGE AND ADMINISTRATION

Bacterial conjunctivitis
One drop in the affected eye(s) 3 times a day for 7 days.

Pre-operation and post-operation
One drop in the affected eye(s) 5 times a day before operation and 3 times a day after operation.

Note: The information given here is limited. For further information, consult your doctor or pharmacist.

Storage: Store below 30°C. Protect from light.

It is recommended to discard any remaining contents one month after opening.

Presentation/Packaging: Ophthalmic solution of 5ml, 1 bottle per box.

Product Registration Holder/Repacked by:
HOVID Bhd.
121, Jalan Tunku Abdul Rahman, 30010 Ipoh, Malaysia.
Manufactured by: Amanta Healthcare Ltd.
(formerly Marck Biosciences Ltd.)
Plot No. 876, NH No 8, Hariyala, Matar, Kheda, Gujarat, India.

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hovid