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GRAIN DIRECTION :

MATERIAL CODE: KLF0024E1

VERSION: 002

Attn : MS. MAYVIS
From : MAYA
I hereby verify & confirm that this draft is the final copy. Any subsequence changes of the design and content of the end product will not be borne by THUNDER PRINT SDN. BHD.
Customer Signature & Date

CUSTOMER : XEPA-SOUL
DESCRIPTION : Myopine 0.01% Eye Drops 5ml (IDB)
MEASUREMENT : 110MM (W) X 160MM (H)
MATERIAL : PDSM 050

COLOUR : BLACK
FINISHING : -

16.6.2025

160mm

80mm

110mm

1. NAME OF THE MEDICINAL PRODUCT
MYOPINE Eye Drops 0.01% w/v
2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 5ml contains Atropine Sulphate 0.01% w/v and 5ml Benzalkonium Chloride 0.01% w/v as preservative. For the full list of excipients. see section 6.1.
3. PHARMACEUTICAL FORM
Clear, colourless, sterile solution. Available in 5ml plastic dropper bottle.
4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Control progression of Myopia in children aged 6 to 12 years with documented myopic progression of >0.5 D per year.
4.2 Posology and method of administration
Posology
One drop topically in eye(s) once at night
Method of administration
For ocular use. After cap is removed, if tamper evident snap collar is loose, remove before using product.
To prevent contamination of the dropper tip and solution, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip. Keep the bottle tightly closed when not in use.
A daily dose of atropine 0.01% is an effective first-line treatment in children aged 6 to 12 years with documented myopic progression of >0.5 D in the preceding year with few side effects. Because atropine appeared more effective in the second year than the first, treatment initially should be continued for at least 2 years. If there is a good response to atropine 0.01% (e.g., almost no progression or progression <0.25 D in the second year) especially in older children aged >13 years, then atropine 0.01% could be stopped.
If an increase in myopia then occurs, then children could be restarted on atropine. If the initial response to atropine was more moderate (e.g., progression of 0.25–0.75 D in the second year), then one could consider continuing atropine 0.01% for a longer period until progression slows to <0.25 D per year, as it might do in the mid to late teens.
Use in patients with hepatic or renal impairment
The safety and efficacy of MYOPINE Eye Drops 0.01% w/v and in patients with hepatic and renal impairment have not been established.
4.3 Contraindications
Persons with glaucoma or a tendency towards glaucoma, and with hypersensitivity to belladonna alkaloids, or to any of the excipients of MYOPINE Eye Drops 0.01% w/v
4.4 Special warnings and precautions
For external use only. Excessive use may produce symptoms of systemic atropine poisoning.
Risk benefit should be considered when the following medical problems exist:
Keratoconus
Atropine may produce fixed dilated pupils.
Synechiae
Atropine may increase the risk of adherence of the iris to lens.
Use in children
Atropine sulfate monohydrate should not be used in children who have previously had severe systemic reaction to atropine. An increased susceptibility to atropine has been reported in children with Down's syndrome, spastic paralysis, or brain damage; therefore atropine should be used with great caution in these patients. No difference in myopia progression was observed in children with light and dark-coloured eyes when treated with atropine 0.01% eye drops. Limited clinical evidence is available for the long-term safety of atropine 0.01% eye drops in children and adolescents. It is recommended that regular eye health clinical reviews are conducted if long term treatment is planned, including the monitoring of anterior segment development, IOP, retinal health and myopia progression.
Careful monitoring of anterior segment development should be considered in clinical application of topical atropine for prolonged periods in very young children. MYOPINE 0.01% eye drops should not be used in children less than 6 years of age.
Photophobia
If children experience photophobia or glare associated with atropine use, they may be offered polychromatic glasses or encouraged to wear sunglasses. In a clinical study, photophobia was resolved in 72% of the children reporting this effect by using photochromic lenses or sunglasses (see Section 4.8 Undesirable effects).
Poor visual acuity
If children experience poor visual acuity associated with atropine use, they may be prescribed progressive glasses. In a clinical study, poor near vision acuity was improved in 96% of children by the use of multifocal lenses (see Section 4.8 Undesirable effects).
Rebound Myopia upon Discontinuation
Discontinuation of the atropine 0.01% eye drops may lead to a rebound in myopia. In a clinical study, the rates of myopia progression after a 12 month washout for children administered atropine 0.01% eye drops for 2 years was -0.28 ± 0.33 D (see Section 4.8 Undesirable effects).
Use in the elderly
MYOPINE 0.01% eye drops are not indicated for use in the elderly.
Effects on laboratory tests
No data available.
4.5 Interaction with other medicinal products and other forms of interaction
No drug interactions were reported in the pooled clinical studies.
The effects of atropine and other antimuscarinics may be enhanced by use with other drugs having antimuscarinic properties, such as amantadine, some antihistamines, phenothiazine antipsychotics, and tricyclic antidepressant.
4.6 Fertility, pregnancy and lactation

Pregnancy
There are no or limited amount of data from the use of MYOPINE Eye Drops 0.01% w/v in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. There are documented systemic effects stemming from ophthalmic atropine use.
MYOPINE Eye Drops 0.01% w/v is not recommended during pregnancy and in women of childbearing potential not using contraception.
Breast-feeding
It is unknown whether atropine is excreted in human milk. However, atropine and antimuscarinic agents have been shown to adversely affect lactation in preclinical and in clinical studies. A risk to the newborns or infants cannot be excluded.
MYOPINE Eye Drops 0.01% w/v should not be used during breast-feeding.
Fertility
Studies have not been performed to evaluate the effects of topical ocular administration of atropine on fertility.
4.7 Effects on ability to drive and use machines
Not Applicable
4.8 Undesirable effects
May be associated with stinging sensation on instillation. May cause allergy (itch, irritation, and redness), blurring of near vision and glare in some children.
The most frequent ocular side effects with atropine eye drops include photophobia (due to pupillary mydriasis), reduction of visual acuity (due to accommodative paralysis), and local allergic response.
4.9 Overdose
A topical overdose of MYOPINE Eye Drops 0.01% w/v may be flushed from the eye(s) with lukewarm water.
Systemic anticholinergic effects have occasionally developed after use of ophthalmic preparations for cyclopegia (which typically involve higher doses of atropine), mostly in young children. Typical symptoms observed are dry eyes, dizziness, tachycardia, constipation and skin flushing.
However, there were no cases of overdose reported in the pooled pivotal clinical studies. There is low risk of overdose with MYOPINE Eye Drops 0.01% w/v due to the low concentration of active substance (0.01% w/v), with the maximum amount delivered per 5 ml bottle equivalent to 0.5 mg atropine sulphate.
5.PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Mydriatics, Cycloplegics and anticholinergics
ATC code: S01FA01
Mechanism of action and pharmacodynamic effects
Antimuscarinic drugs such as atropine are competitive inhibitors of the actions of acetylcholine at the muscarinic receptors of autonomic effector sites innervated by parasympathetic (cholinergic postganglionic) nerves; they are also inhibitors of the action of acetylcholine on smooth muscle lacking cholinergic innervation.
In the eye, atropine is capable of blocking muscarinic receptors on the iris sphincter muscle and the ciliary muscle controlling lens curvature, resulting in pupil dilation (mydriasis) and temporary paralysis of accommodation (cycloplegia). The mechanism of topical low-dose atropine for control of progression of myopia has been postulated to involve the up- and downregulation of retinal and scleral muscarinic receptors (M1/M4) with influence on the scleral matrix.
5.2 Pharmacokinetic properties
Absorption
Atropine is readily absorbed from the gastrointestinal tract; it is also readily absorbed from mucous membranes, the eye, and to some extent through intact skin.
Following the instillation of 30 microlitres of 1% atropine sulfate ophthalmic solution (0.3 mg) into the lower cul-de-sac of one eye in young health volunteers, the average ocular bioavailability was estimated as 63.6 ± 28.6%. No cardiovascular changes were observed.
Distribution
It is rapidly cleared from the blood and is distributed throughout the body. It crosses the blood-brain barrier.
Metabolism
It is incompletely metabolised in the liver.
Excretion
It is excreted in the urine as unchanged drug and metabolism. A half-life 4 hours has been reported.
6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Benzalkonium chloride, boric acid, hypromellose, disodium edetate and purified water.
6.2 Incompatibilities
Not applicable.
6.3 Special precautions for storage
Store below 30°C. Discard 4 weeks after first opening. Keep out of the sight and reach of children.
6.4 Nature and contents of container
Clear, colourless, sterile solution. Available in 5ml plastic dropper bottle.
6.5 Special precautions for disposal
For further information, please consult your pharmacist or physician.
Revision Date: July 2025
Manufacturer
Xepa-Soul Pattinson (Malaysia) Sdn Bhd
1-5 Cheng Industrial Estate, 75250 Melaka, Malaysia.
Product Registration Holder
IDB VisionCare Sdn Bhd
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KLF0024E1 002

160mm

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