AIM

0.5ml Unit Dose

ATROPINE eye drops 0.01%

Preservative FREE × Convenience × NO Contamination

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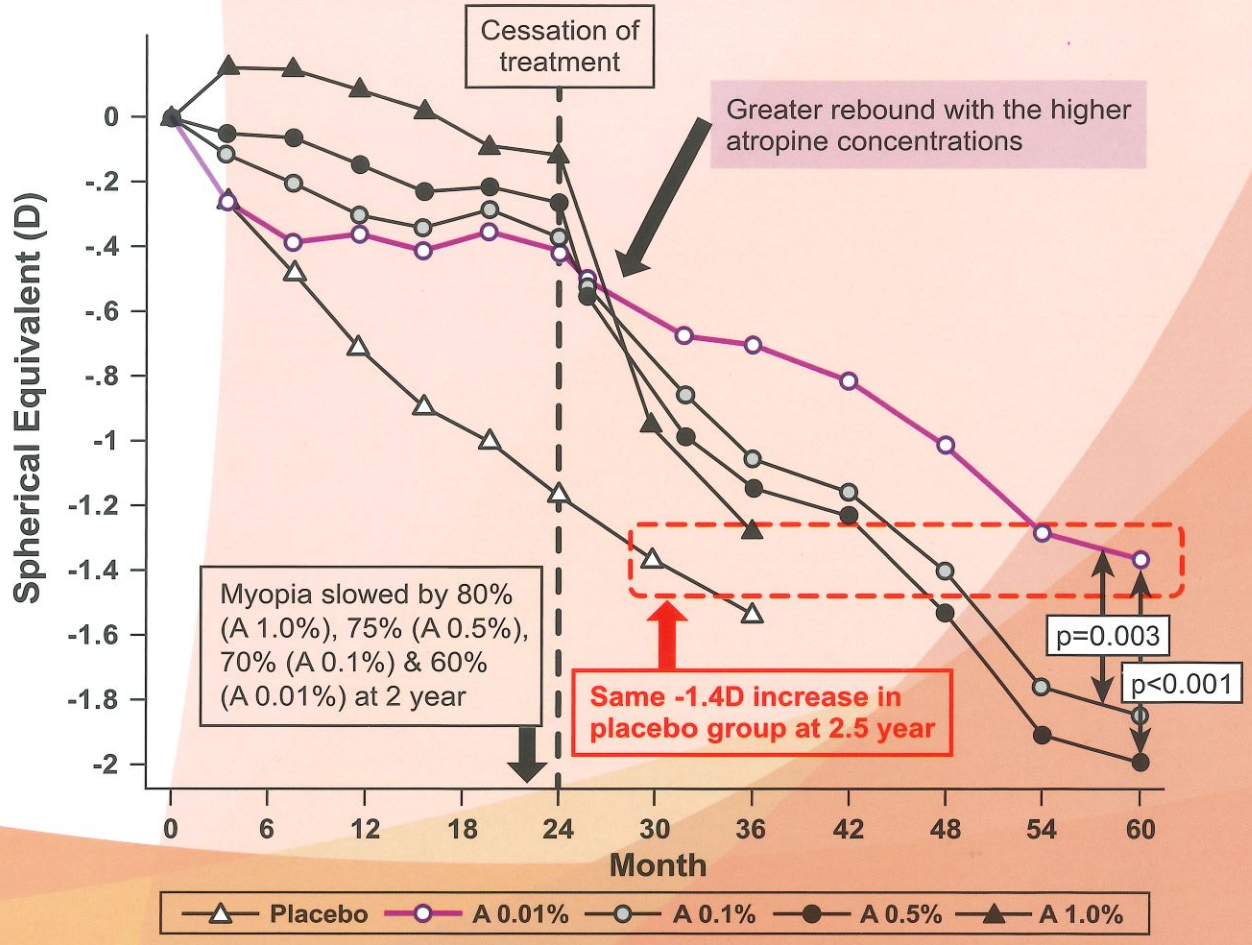
Compared with other concentrations of Atropine eye drops

0.01% was almost as effective as in reducing myopia progression as higher concentrations and less myopic progression after atropine was stopped, resulting in 0.01% being more effective in reducing myopia progression at 3 years.



A= Atropine, D= diopter
Ref. American Academy of Ophthalmology 2016; 123:391-399

Atropine 0.01% has minimal pupil dilation accommodation and near vision loss

	Atropine (A) Dose, Mean (SD)			
	A 0.01%	A 0.1%	A 0.5%	P Value
Spherical equivalent (D)				
mean change over 1 yr	-0.43(0.52)	-0.31(0.50)	-0.17(0.47)	<0.001*,‡
mean change over 2 yrs	-0.49(0.63)	-0.38(0.60)	-0.30(0.60)	0.07*
Accommodation (D)				
mean change over 1 yr	-4.4 (4.9)	-10.9 (4.0)	-12.4 (3.3)	<0.001*,†,‡
mean change over 2 yrs	-4.6 (4.2)	-10.1 (4.3)	-11.8 (4.4)	<0.001*,†,‡
Mesopic pupil size (mm)				
mean change over 1 yr	1.15 (0.78)	2.77 (1.03)	3.50 (1.05)	<0.001*,†,‡
mean change over 2 yrs	1.15 (0.71)	2.71 (1.12)	3.56 (1.14)	<0.001*,†,‡
Near vision (logMAR)				
mean change over 1 yr	-0.01 (0.10)	-0.10 (0.16)	-0.32 (0.19)	<0.001*,†,‡
mean change over 2 yrs	-0.02 (0.08)	-0.06 (0.13)	-0.25 (0.19)	<0.001*,†,‡

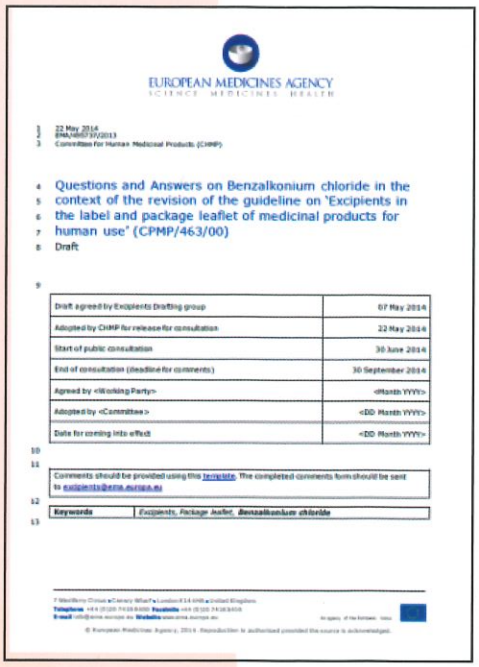
SD =standard deviation.
Myopia progression: change from second baseline; other parameters: change from initial baseline. P values for test of global null hypotheses of all groups being the same are shown. Pairwise comparison P values are represented by*significant (P 0.05) difference between atropine 0.01% and 0.5%;†significant difference between atropine 0.01% and 0.1%; and‡significant difference between atropine 0.1% and 0.5%. Ref. American Academy of Ophthalmology 2012; 119:347-354

Approximately 74% of ophthalmic preparation contain benzalkonum chloride (BAC) as a preservative.

European medicines agency stated that BAC has been reported to cause :

- Punctate keratopathy and/ or toxic ulcerative keratopathy.
- Eye irritation.
- Discolour soft contact lenses.
- Increase conjunctival inflammation and may affect the cornea.
- Abnormal tearing and/or ocular surface disease.

* Ref. EMA/495737/2013, CPMP/463/00



EUROPEAN MEDICINES AGENCY

Questions and Answers on Benzalkonium chloride in the context of the revision of the guideline on 'Excipients in the label and package leaflet of medicinal products for human use' (CPMP/463/00)

Draft

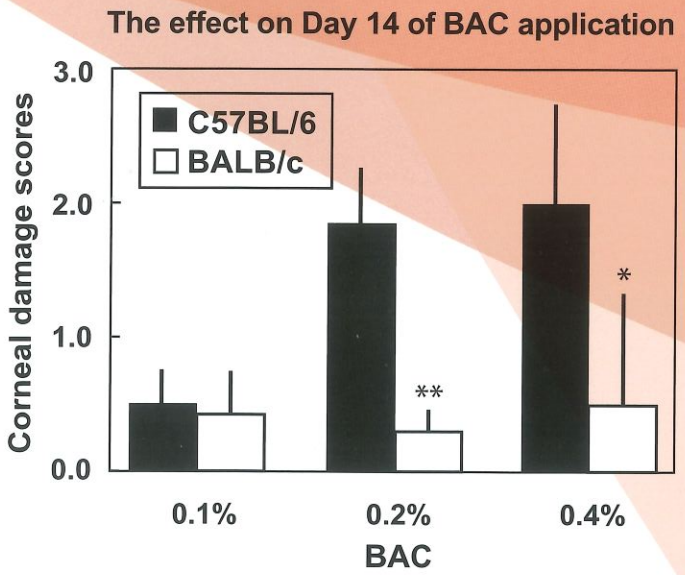
Draft agreed by Excipients Drafting group	07 May 2014
Adopted by CHMP for release for consultation	22 May 2014
Start of public consultation	30 June 2014
End of consultation (deadline for comments)	30 September 2014
Agreed by <Working Party>	<Month YYYY>
Adopted by <Committee>	<DD Month YYYY>
Date for coming into effect	<DD Month YYYY>

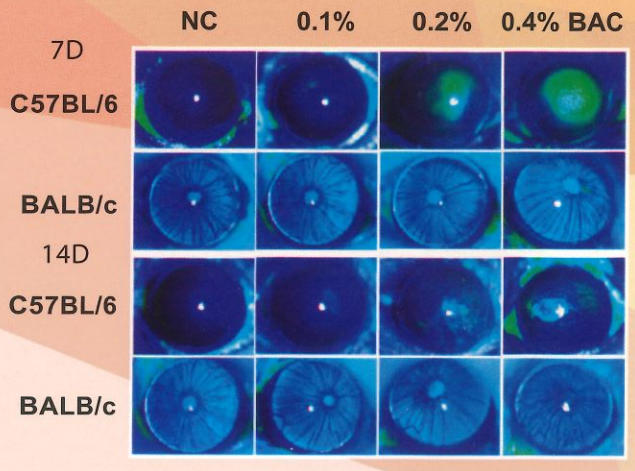
Comments should be provided using this template. The completed comments form should be sent to excipients@ema.europa.eu

Keywords: Excipients, Package leaflet, Benzalkonium chloride

Preservative free single dose eye drops to avoid secondary damage to human eyes

Topical application of BAC can dramatically disrupt the ocular surfaces of mice





* Ref. Int J Mol Sci. 2017 Feb 26

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【DESCRIPTION】Atropine Eye Drops 0.01% is anticholinergic agent as a sterile topical ophthalmic solution.

【COMPOSITION】Each mL contains : Atropine Sulfate 0.1mg

【INDICATION】Mydriasis、cycloplegia.

【DOSAGE & ADMINISTRATION】Administer one or two drops topically to the eye(s) two to four times daily, or as directed by doctor.

CONTRAINDICATION	WARNING
Contraindicated in persons with primary glaucoma or a tendency toward glaucoma, e.g., narrow anterior chamber angle, and in those persons showing hypersensitivity to any component of this preparation.	Patient should be advised not to drive or engage in other hazardous activities while pupils are dilated.

【PRECAUTIONS】

1. This preservative-free medicine can be re-capped and must be disposed after 24 hours of opening
2. Please wash your hands thoroughly before use
3. Please use as directed by your doctor

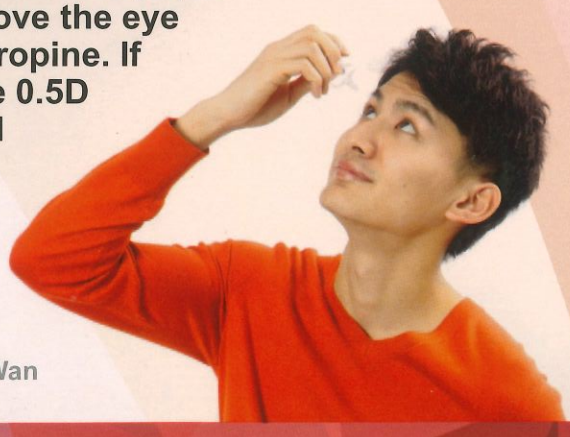
※※※※※※※※ Atropine For Myopia Control ※※※※※※※※

Atropine is long-acting anticholinergic agent. It is the only effective medication for myopia control. It may cause mydriasis, photophobia and blurred Vision. Low dose concentration is recommend for first treatment options.

(1) When using 0.01%, atropine eye drops, administer one drop to both eyes before going to bed every night. Record the symptoms of allergic, photophobia, and blurred vision.

(2) Patient will have to return to the clinic for eye examination after one month. Ask patient to record the symptoms of allergic and photophobia daily if any. If the situation is stable and continues to receive medication, check up can be done every three months. It is advisable to have a optometry test once every six months or one year. The aim of treatment is to maintain the myopia progression below 0.5D per year.

(3) If the degree of myopia increases by 0.5D per half year or increases by 1D per year, it shows that atropine may not be effective in myopia control. It is recommended to examine and improve the eye caring habits or increase the concentration of atropine. If the degree is unstable, e.g. the increase is above 0.5D every six months or one year, it is recommended to increase the concentration of atropine in the order of 0.1%, 0.25%, 0.5%, and the highest is 1%.



REFERENCE :
Children's vision screening and correction guidelines-Health promotion Administration Ministry of Health and Welfare, TaiWan

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