10.
STUDY INFORMATION PACK

Myopia Outcome Study of Atropine in Children

MOSAIC
Myopia Outcome Study of Atropine In Children

CONTENTS

INSTRUCTIONS FOR INSERTING EYE DROPS

General information about using the study drug:

- The study drug is intended for study participants only.
- You should not use any other eye drops during this study. Use of artificial tears is allowed but may not be used within 2 hours of administration of study medication.
- If you wear contact lenses, those should be removed at least 15 minutes before using the study drug.
- You must not sleep in contact lenses.
- Wash your hands prior to administering the eye drops

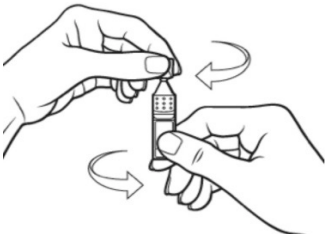
To administer the study drug:

The Eye Drops are to be administered one drop into each eye, each evening at bedtime

Step 1 – Take a foil pouch out of the treatment box.

- Write down your study subject number on the pouch.
- Open the foil pouch and remove the strip of 5 unit dose ampoules.
- Pull off 1 unit dose ampoule from the strip.
- Put the remaining strip of unit dose ampoules back in the foil pouch.

- **Step 2 – Open the unit dose ampoule**
  - Hold the unit dose ampoule upright (the long tab should be on the bottom and the small tab on top).
  - Open the ampoule by twisting off the small tab on top.
  - Make sure that the tip of the ampoule does not touch anything to avoid contamination.



Step 3 – Administer eye drops:

- Drops should be administered in a seated position or lying in a face up position.
- Tilt the head back, gently pull the lower eyelid down, holding the ampoule almost vertically gently squeeze 1 full drop into the eye without letting the ampoule touch the eye
- Using the same ampoule administer 1 full drop into the other eye.

- Keep the eye gently closed after administering the drop. Press your finger into the inner corner of the eye where the upper and lower eyelids meet, next to the nose, and hold for 60 seconds after inserting the drop.
- NOTE: If a full drop is not dropped into the eye, wait approximately 10 to 15 seconds and administer a second drop
- Place the open ampoule and remaining contents in the provided receptacle which will be returned to the study centre for proper disposal.

How should the eye drops be stored?

- You should store the study drug at room temperature (20 – 25 C°).
- Open one foil pouch at a time and use all 5 ampoules (5 day supply) before opening the next foil pouch.
- Store unused ampoules in the foil pouch until time for use.
- Do not allow the study drug to be exposed to extreme temperatures. **Do not refrigerate or leave in a hot car**.

REMEMBER:

- Return all unused eye drops to the Study Centre.
- Remember to make a note for the study centre if an ampoule(s) or foil pouch is destroyed and cannot be returned.

STORAGE INSTRUCTIONS

- Store at room temperature (20°C to 25°C) with excursions permitted
- Caution: Investigational Use Only (we use “FOR CLINICAL TRIAL USE ONLY”)
- Use only as an eye drop, not to be ingested
- **Keep out of Reach of Children**

POTENTIAL SIDE EFFECTS

The eye drop we will use in the trial is called Atropine, which has been used safely for decades by ophthalmologists to treat other eye disorders in children. We will be using a very small dose, 100 times lower than the normal clinical dose. This has been proven in Asia to be the most effective dose for long term myopia control. This lower concentration is also beneficial in terms of greatly reducing potential side effects.

- Atropine is associated with an increase in pupil size (which may cause glare) and a lesser ability to accommodate (which may lead to difficulty reading up close). However, with the diluted low dose of atropine used in this trial the risk of glare is minimised

- Atropine 0.01% may be associated with mild burning and stinging. It is possible that the use of atropine or placebo eye drops over an extended period may cause irritation of the eyes. At each visit to the Centre for Eye Research the examiner will check your eyes for any of these side effects.

- Other, less common and rare ocular side effects of atropine include conjunctivitis, increased intraocular pressure, and swelling of the eyelids. Once again, the examiner will check your eyes for any of these side effects at each study visit. If you have a red and/or sore eye, please report this to the study investigators

- Systemic adverse effects: High doses of atropine (not used in this study) eyedrops have shown effects on heartrate. Heart Rate will be measured every 6 months until month 24. Other possible systemic adverse events include dryness of the mouth, flushing, anhidrosis, heat intolerance or impaired temperature regulation, hypersensitivity-associated skin rashes.

STUDY CONTACT DETAILS

If you do develop any symptoms that you are concerned about, you can contact

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WITHDRAWAL FROM MOSAIC

Participating in MOSAIC aims to not only prevent shortsightedness from getting worse but but also prevents the sight threatening diseases associated with shortsightedness - retinal detachment, myopic maculopathy, glaucoma and cataract. Therefore we encourage you to comply with the study guidelines and remain in the study for the full duration.

However, subjects have the right to voluntarily discontinue study treatment or withdraw from the study at any time for any reason without any consequences. The study investigator has the right to discontinue a subject from study treatment or withdraw a subject from the study at any time if it is in the best interest of the subject.

If a subject withdraws from the study due to a side effect or adverse event, the investigator will arrange for follow-up visits until the adverse event has resolved or stabilised.

If a subject does not attend a study visit, attempts will be made to contact the subject before they are removed from the study.