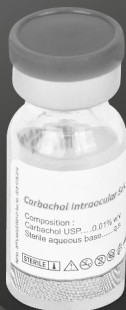




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DEVINE MEDITECH

CARBACHOL INTRAOCULAR SOLUTION



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INSTRUCTION FOR USE

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DESCRIPTION

Carbachol is a direct acting miotic agent administered ophthalmologically to decrease intraocular pressure after cataract surgery, and to induce miosis during surgery. It is a potent cholinergic agent and produces constriction of the iris and ciliary body resulting in reduction of intraocular pressure. Carbachol solution (0.01%) is supplied in sterile aqueous base solution, which is terminally steam sterilized, for intraocular use. The pH of the solution is 5.0 to 7.5.

ACTIVE INGREDIENT

Carbachol is supplied as 1 ml of 0.01% solution and Each ml of solution provides 0.1mg of Carbachol dissolved in sterile aqueous base solution.

HOW SUPPLIED

Carbachol is supplied in the syringe or the vial with volume of 1ml as sterile, non-pyrogenic solution supplied in a prefilled syringe or glass vial. The Carbachol solution is aseptically filled in the container and is terminally sterilized by steam sterilization. The container may be placed individually in a dry, heat sealed Tyvek pouch/blister. Or multiple units may be packed in one box.

INDICATIONS

Carbachol solution is indicated for intraocular use for obtaining miosis during surgery. It also reduces the intensity or intraocular pressure elevations in the first 24 hours after cataract surgery. It is intended for intraocular use only.

CONTRAINDICATIONS

- Carbachol solution should not be used in patients who show hypersensitivity to any of the components of the preparation.

INSTRUCTIONS FOR USE

- The device is to be used by a qualified and trained ophthalmic surgeon only.

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- First check the date of expiry of on the box and make sure that the expiry of the device is still valid.
- To use the solution from a pre-filled syringe, carefully peel open outer pouch/blister and remove container case in sterile environment. Attach the supplied cannula to the leur-lock of the syringe by puncturing the rubber seal with a sterile cannula and aspirating the contents. And then affix a cannula to the syringe as mentioned.

WARNINGS

- Do not use the package if the integrity of the sterile package is compromised
- The device is for intraocular use only
- The device is for singly use only.
- The device is not to be placed in the direct sunlight or temperature exceeding 40°C.
- DO not re-sterilize the device
- Ensure safe and proper disposal or used/ discarded product and packaging to avoid adverse effect to environment, children and stray animals.

STORAGE

- Store at controlled room temperature and a relative humidity less than 65% & Protect from freezing.
- Do not expose containers to direct sunlight.
- During transportation, avoid temperatures above 500 Celsius and below 00 Celsius and use appropriate packaging protecting the device.
- Expiry date showed on the pack indicates the period within which the device has to be used during surgery.

RETURN OF DAMAGED PRODUCT

- Return the product in its original container identified by the LOT number, our purchase reference and reason for the return.

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