SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Miovisin 20 mg/2ml powder and solvent for solution for intraocular injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ampoule of freeze dried Miovisin contains 20 mg of acetylcholine chloride.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder and solvent for solution for intraocular injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Miovisin is indicated only as a preparation for topical intraocular irrigation during eye surgery procedures requiring miosis.

4.2 Posology and method of administration

Miovisin is a medicinal product for intraocular use only.

Posology

In most cases, 0.5 to 2.0 ml (from part to all of the contents of the ampoule) are enough to obtain satisfactory miosis. After administration of the 1% solution, miosis is rapid and persists for up to approximately 20 minutes.

Method of administration

Administer freshly prepared solution into the anterior chamber of the eye during surgical procedures. The reconstituted medicinal product is a clear, colourless solution. As aqueous solutions of acetylcholine chloride are unstable, they must be prepared immediately before use.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Generally contraindicated in pregnancy (see section 4.6).

4.4 Special warnings and precautions for use

Intra-ocular acetylcholine must be administered with caution in patients with cardiac insufficiency, bronchial asthma, hyperthyroidism, urinary tract obstruction or Parkinson's disease.
For intraocular use only.
All anatomic obstructions, such as anterior and posterior synechia, must be removed from the eye before administration.
Intraocular irrigation must be slow, as a strong jet of solution could cause hyaloid membrane rupture, vitreous detachment or iris damage or perforation.
Dissolve the content of one ampoule of lyophilisate with one containing solvent, immediately before use.
To open the ampoule, hold the neck and press on the white spot with your thumb.
Keep out of the reach and sight of children.

4.5 Interaction with other medicinal products and other forms of interaction

Acetylcholine may be ineffective as a miotic when used in patients pre-treated with non-steroidal anti-inflammatory drugs (NSAIDs).
Severe bronchospasm has been reported after intraocular injection in patients treated with methoprolol.

4.6 Fertility, pregnancy and lactation

The safety and efficacy of Miovisin during pregnancy and breast-feeding has not been confirmed.

This medicine may only be administered to pregnant women if effectively necessary and under direct medical supervision.

4.7 Effects on ability to drive and use machines

Miovisin may cause moderate alterations in the ability to drive and use machines. Temporary effects such as blurred vision due to the osmotic effect of mannitol may affect some patient's ability to drive and/or use machines.

4.8 Undesirable effects

Ocular adverse events (eye disorders) following topical administration of choline esters in the eye include:

• Corneal opacity, decompensated corneal oedema persistent bullous keratopathy and postoperative iritis. As with all miotics, retinal detachment may occur in particularly sensitive subjects.

• Atrophy of the iris (following excessively high concentrations of acetycholine).

• Transient opacity of the lens (following intraocular administration) that can be attributed to the osmotic effect of the mannitol 5% present in the preparation administered.

Cardiac disorders

• Severe bradycardia and hypotension, hot flushes (rarely, after intraocular administration)

Respiratory, thoracic and mediastinal disorders

• Breathing difficulties.

General disorders and administration site conditions

• Perspiration

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reaction using the national reporting system.

4.9 Overdose

Atrophy of the iris may occur if excessively high concentrations of acetylcholine are administered. In the event of overdose, administer parenteral atropine sulphate.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: parasympathomimetic miotic, ACT code: S01EB09.

Acetylcholine is a potent cholinergic (parasympathomimetic) agent.

Acetylcholine mediates nerve impulse transmission in all cholinergic sites of the autonomic and somatic nerves. Once it has been administered to the anterior chamber of the eye, it causes short, fast miosis and a contraction of the ciliary muscle (cycloplegia); it reduces intraocular pressure.

5.2 Pharmacokinetic properties

Acetylcholine is rapidly hydrolysed by its specific enzyme (cholinesterase) and it therefore has a short duration of action. When administered as eye drops, penetration into the anterior chamber of the eye is poor, due to deactivation when passing through the cornea.

5.3 Preclinical safety data

For topical or intraocular administration the incidence of toxicity is rare. When administered systemically (intravenously) at high doses, symptoms include lacrimation, conjunctival congestion, nystagmus, hypotension, bronchoconstriction and bradycardia.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol and water for injections.

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products.

6.3 Shelf-life

2 years. As aqueous solutions of acetylcholine chloride are unstable, they must be prepared immediately before use.

6.4 Special precautions for storage

No special precautions.

6.5 Nature and content of the container

Box of 6 white glass ampoules containing 20 mg of lyophilisate + 6 white glass ampoules containing 2 ml of solvent solution.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

FARMIGEA SpA, Via G. B. Oliva 6/8, 56121 – Pisa

8. MARKETING AUTHORISATION NUMBER(S)

MA 028930016

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12 July 1996
Date of latest renewal: 12 July 2011

10. DATE OF REVISION OF THE TEXT

03 Aprile 2024