

FORMANOVA

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912201/03

**Miphtel 20 mg powder and solvent
for solution for intraocular irrigation****(Acetylcholine chloride)****Patient Information Leaflet****Read all of this leaflet carefully before you are given this medicine.**

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or the medical staff looking after you.

In this leaflet:

1. What MIPHTEL is and what it is used for
2. Before using MIPHTEL
3. How to use MIPHTEL
4. Possible side effects
5. Storing MIPHTEL
6. Further information

1. WHAT MIPHTEL IS AND WHAT IT IS USED FOR

The active substance in **MIPHTEL 20mg powder and solvent for solution for intraocular irrigation** is acetylcholine chloride. It belongs to a group of substances called parasympathomimetics (neurohormones) involved with the transmission of nerve impulses in the body.

MIPHTEL is used during cataract surgery and other types of eye surgery to make the pupil (at the front of the eye) contract. This helps the surgeon carry out the surgical procedure. If you have any questions about how MIPHTEL works or why this medicine has been prescribed for you, ask your doctor or the medical staff looking after you. It is available only for hospital use.

NOTE: This is a patient information leaflet. Doctors and other health professionals involved in the administration of MIPHTEL should consult the administration instructions for healthcare professionals before use.

2. BEFORE USING MIPHTEL**You must not be given MIPHTEL:**

If you are allergic (hypersensitive) to acetylcholine chloride or any of the other ingredients (mannitol) of this medicine listed at the beginning of this leaflet.

Children: the use of MIPHTEL in children has not been studied and therefore children must not be given this

medicine.

Take special care with MIPHTEL:

If the answer to any of the following questions is 'yes', talk to your doctor before you are given this medicine:

- Are you taking β -blockers (drugs used to treat high blood pressure and certain heart conditions)?
- Are you taking or have you recently taken non-steroidal anti-inflammatory agents (used to treat pain and swelling)?
- Do you suffer from bronchial asthma?
- Do you suffer from heart disease such as heart failure?
- Do you have an overactive thyroid gland?
- Do you suffer from gastrointestinal complaints?
- Do you have a stomach ulcer?
- Do you have any difficulty passing urine?
- Do you suffer from Parkinson's disease?

Taking other medicines

Tell your doctor if you are taking or have recently taken any other medicines, even those you have bought without a prescription. In particular, you should inform your doctor if you are taking:

- β -blockers (used to treat high blood pressure and certain heart conditions)
- topical non-steroidal anti-inflammatory agents (used to treat pain and swelling).

Pregnancy and Breastfeeding

Tell your doctor if you are or think you may be pregnant.

Tell your doctor if you are breastfeeding.

The doctor will discuss with you the risks and benefits involved.

Driving and using machines

No studies on the effects on the ability to drive

**Miphtel 20 mg powder and solvent
for solution for intraocular irrigation****(Acetylcholine chloride)****INFORMATION FOR THE HEALTHCARE PROFESSIONAL**

Warning: Do not use if the PVC holder or peelable backing is damaged or broken.

How to prepare MIPHTEL

1. Inspect unopened PVC holder to ensure that it is intact. Peel open the holder.
2. Aseptically withdraw the entire content of the solvent ampoule into a sterile syringe. Discard ampoule.
3. Transfer the solvent from the syringe to the powder ampoule.
4. Shake gently to dissolve drug.
5. Visually inspect the reconstituted solution for particulate matter. Do not use solutions containing particulate matter.

The reconstituted solution should be slowly withdrawn

and use machines have been performed. However, the surgical procedure may impair vision. You should not drive or use machines until such disturbances have subsided.

3. HOW MIPHTEL IS GIVEN

This medicine will be given to you only by the surgeon. Your surgeon will work out the correct dose of MIPHTEL for you. In most cases 0.5ml to 2ml of solution is a suitable dose. The solution should be made up just before it is given for intraocular use (i.e. use in the eye). It contains 10mg/ml of acetylcholine chloride (20mg/2ml). Each ampoule of powder and solvent is for single use only.

If too much is given

If you are given more medicine than you need, your doctor may need to give you an injection of either atropine sulphate or adrenaline to control symptoms. Symptoms of overdose may include slow heart rate, low blood pressure, flushing, breathing difficulties and sweating. Because acetylcholine is rapidly broken down by the body, symptoms of overdose are unlikely to occur. If you have any further questions on the use of this product, ask your doctor or the medical staff looking after you.

4. POSSIBLE SIDE EFFECTS

Like all medicines, MIPHTEL can have side effects, even when used as directed.

The following side effects have rarely been reported:

- Slow heart rate
- Low blood pressure
- Flushing
- Breathing difficulties
- Sweating
- Cloudiness of the cornea

If any of these affects you or if you notice any other side effects not mentioned in this leaflet, tell your doctor or the medical staff looking after you.

5. STORING MIPHTEL

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date stated on the label. The doctor should check that the solution is clear

from the ampoule into a suitable sterile syringe and should be administered into the anterior chamber of the eye. The product provides 10mg/ml of acetylcholine chloride when diluted as recommended. In most cases a satisfactory miosis, which will last approximately 20 minutes, is produced within seconds by 0.5-2ml of reconstituted solution. If a prolonged miosis is required a second application may be made. The solution must be prepared just before use, since aqueous solutions of acetylcholine are unstable. Only clear and colourless solutions should be used. The product is sterile until opened and should not be re-sterilised. For single use only. Any unused solution should be discarded.

and colourless before use.
Do not freeze.
Store in the original package.

6. FURTHER INFORMATION

What MIPHTEL contains

Powder ampoule:

Each ampoule contains: acetylcholine chloride 20mg. Also contains: mannitol (E421), sodium hydroxide (for pH adjustment).

Solvent ampoule: Each ampoule contains water for injections 2ml (for ophthalmic use only).

What MIPHTEL looks like and contents of the pack

MIPHTEL is supplied as a powder in a glass container called ampoule that requires reconstitution with the solvent provided in a separate ampoule.

Each pack contains 6 holders each containing one ampoule of powder and one ampoule of solvent.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder: Farmigea S.p.A. - Via G.B. Oliva, 8 - I-56121 Pisa – Italy

Manufacturers responsible for batch release:

Alfasigma S.p.A. - Via Enrico Fermi, 1 - I-65020 Alanno - Pescara – Italy

Farmigea S.p.A. Via G.B. Oliva, 8 - I-56121 Pisa – Italy

This leaflet was last revised in February 2018

How to store MIPHTEL

- Keep out of the reach and sight of children.
- Do not use any pack that is damaged or shows signs of tampering.
- Do not freeze.
- Store in the original package.
- Do not use after the expiry date stated on the label.