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| CLIENTE / Customer : | Farmigea S.p.A. | | |
| BOZZA / Proof date : | n° 1 | del | dd - mm - yyyy |
| PRODOTTO / Product : | XXXXXXXXXX | CODICE / Code : | 000000/00 |
| COD. LAETUS : | IIIIIXXXXX | (0000) | G/MQ / g/smq : 50 |
| F.TO POSA STESA / Size flat : | 135 X 425mm | POSA PIEGATA / Size folden : | 135 X 28mm |
| STAMPA SU LATO / Printing : | BIANCA / Top side : | <input checked="" type="checkbox"/> | VOLTA / Reverse side : <input checked="" type="checkbox"/> |
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FARXP162KPC

Atropine sulfate 1% w/v eye drops solution in single dose container

atropine sulfate

Read all this leaflet carefully before you start using your medicine. It contains a summary of the information available on your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist. Remember this medicine is for you. Do not give it to someone else.

In this leaflet:

1. What Atropine Eye Drops are and what they are used for
2. Before you use your eye drops
3. How to use your eye drops
4. Possible side effects
5. How to store your eye drops
6. Further information

1. What Atropine Eye Drops are and what they are used for

Atropine Eye Drops contain a mydriatic and cycloplegic agent. It is used to enlarge the pupil of your eye. Your doctor or eye specialist may use it to examine your eye more closely, or as part of a treatment program. This medicine is indicated for children, adults and the elderly.

2. Before you use your eye drops

Do not use these drops if

- you are allergic to the active substance (atropine sulphate) or any of the ingredients (refer to the end of this leaflet).
- you have history of closed angle glaucoma (with your eyes likely to develop sudden increased internal pressure when the pupil is enlarged).

If you are pregnant, may be pregnant, or are breastfeeding
Tell your doctor or eye specialist, he/she may decide to use these drops or to prescribe you an alternative.

Contact lenses
Your doctor will ask you to remove your contact lenses prior to the administration of the drops. Do not wear your contact lenses until the effects of the drops have completely worn off.

Driving and using machines
As with all eye drops, your vision may be blurred after putting the drops in. Wait until your vision is clear before driving or using machines.

3. How to use your eye drops

The drops are for single use only and provided in single dose containers, to treat both eyes if necessary. Once opened, use immediately. Discard any unused portion.

Dosage
The normal dose is one drop in each eye. If necessary, your doctor or eye specialist will tell you to use more than one drop.

Method of administration
The doctor or eye specialist will normally put the drops in your eye for you, but if you are putting the eye drops in yourself, then follow these instructions carefully:

1. Wash your hands.
2. Use a mirror, this will help you to see what you are doing.
3. Carefully dry your eyes using a tissue, and twist open the cap from the single dose container.
4. Pull your lower eyelid down gently, and then carefully place 1 drop inside your lower eyelid.
5. Close your eye and blink a few times to make sure your eye is covered by the liquid.
6. Close the eyelids. It is advisable to press gently on the inner corner of your eyelid for 3 minutes. This will help stop the solution draining into your nose and throat. This is especially advisable in children, the elderly and population at risk.
7. Repeat steps 4, 5 and 6 for the other eye if necessary, then throw away the single dose container, even if some solution remains.

If you use more Atropine Eye drops than you should, an overdose is very unlikely to occur. If you suddenly feel unwell after receiving the drops, tell your doctor or eye specialist or contact your nearest emergency department immediately.

4. Possible side effects

The following side effects may occur occasionally:

- the skin around the eyes can be sore. Your eyes can be swollen, red and itchy. This is more likely to happen if the drops are used more than once.
- dry mouth
- flushing of the skin
- increased body temperature
- constipation
- difficulty in passing urine
- fast heartbeat.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard, or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store your eye drops

Keep out of the sight and reach of children.
Do not use the eye drops after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.
Do not store above 25°C. Do not freeze. Store in original package in order to protect from light.
The drops are for single use only and provided in single use units, to treat both eyes if necessary. Once opened, use immediately. Discard any unused portion.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What do your eye drops contain
The active ingredient is atropine sulphate. Each single dose container contains approximately 0.5 ml eye drops solution of atropine sulphate 1% w/v.
The other ingredients are hydrochloric acid and sodium hydroxide (for pH adjustment) and water for injection. This medicine does not contain a preservative as it is a sterile single use unit.

Contents of the pack
Each carton contains 20 single-dose containers packed in sachets.

Customer: FRG **Originated by:** DOB (AWG)

Product: Atropine Sulfate Eye Drops

Dimensions: 135mm x 425mm

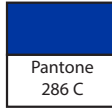
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Marketing Authorisation Holder:

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Manufacturer

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