SCHEDULING STATUS: S0

SPERSATEAR 0,3 % *w/v* eye drops
Hypromellose

Read all of this leaflet carefully because it contains important information for you
SPERSATEAR is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use SPERSATEAR carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SPERSATEAR with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after a few days.

What is in this leaflet

1. What SPERSATEAR is and what it is used for
2. What you need to know before you use SPERSATEAR
3. How to use SPERSATEAR
4. Possible side effects
5. How to store SPERSATEAR
6. Contents of the pack and other information

1. What SPERSATEAR is and what it is used for
SPERSATEAR is an artificial tear used to relieve dry eye conditions.

2. What you need to know before you use SPERSATEAR
Do not use SPERSATEAR:

- if you are hypersensitive (allergic) to hypromellose or any of the other ingredients of SPERSATEAR (listed in section 6).

Warnings and precautions
Take special care with SPERSATEAR:

- If your eye irritation persists or worsens, you have a headache or eye pain, your vision changes, or you have permanently red eyes, stop using SPERSATEAR and contact your doctor immediately.
- If you develop an eye infection while using SPERSATEAR.
- If you are wearing contact lenses.
- If you are using SPERSATEAR for a prolonged period of time. Your doctor may need to monitor your condition.

Other medicines and SPERSATEAR
Always tell your healthcare provider if you are taking any other medicine. (This includes all

complementary or traditional medicines.)
SPERSATEAR may increase the effect of other medicines which are applied to your eyes. Please tell your doctor or pharmacist if you are applying any other type of eye drops or eye ointment before you start to use SPERSATEAR.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using SPERSATEAR.

Driving and using machines
SPERSATEAR may cause a temporary blurring of vision immediately after using the drops. Do not drive or operate machines if you experience any visual disturbance after using SPERSATEAR. Wait until this clears before driving or using machines.

SPERSATEAR contains benzalkonium chloride
SPERSATEAR contains 0,10 mg/ml benzalkonium chloride as preservative.
Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using SPERSATEAR and put them back 15 minutes afterwards.
Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using SPERSATEAR, talk to your doctor.

3. How to use SPERSATEAR
Do not share medicines prescribed for you with any other person.
Always use SPERSATEAR exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

How much to use
The recommended dose is two drops three times a day into each eye or as needed, or as directed by your doctor.
If there is no improvement see your doctor or pharmacist.
SPERSATEAR is for external use only.

Instructions for use
1. Before opening a new bottle of SPERSATEAR, please check that the safety strip on the bottom of the outer cap is unbroken.
2. Twist the outer cap to break the seal.
3. Wash your hands well before use.
4. Remove the outer cap. If you are putting in the drops for yourself, you should use a mirror.
5. Tilt your head back and look up at the ceiling.
6. Pull the lower lid of the eye out to form a small pocket between your eyelid and your eye.

7. Hold the bottle between the thumb and middle finger of the other hand, turn the bottle upside down near to the eye, try not to touch the eye with the nozzle.
8. Apply enough pressure to the container to release two drops, or as directed by your doctor.
9. Blink your eye a few times.
10. If you think that you have missed the eye, then insert another drop.
11. Repeat steps 5-10 for the other eye if you have been told to use SPERSATEAR in both eyes.
12. Replace the outer cap on the container, trying not to touch the nozzle with anything, including the eye or your fingers.
13. Wash your hands.

If you are unsure about how to use SPERSATEAR talk to your doctor or pharmacist. Eye solutions, if handled wrongly, can become contaminated by common bacteria and cause eye infections. If you do develop any other eye condition whilst using this product, see your doctor immediately.

If you use more SPERSATEAR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use SPERSATEAR

Apply the drops as soon as you remember. However, if it is almost time for your next dose, do not take a double dose to make up for a forgotten dose.

If you stop using SPERSATEAR

You should speak to your doctor or pharmacist if you want to stop using SPERSATEAR. If you have any further questions on the use of SPERSATEAR, ask your doctor or pharmacist.

4. Possible side effects

SPERSATEAR can have side effects.

Not all side effects reported for SPERSATEAR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SPERSATEAR, please consult your healthcare provider for advice.

Tell your doctor if notice any of the following side effects:

Frequency not known:

- stinging sensation
- blurred vision
- eye pain
- foreign body sensation in eyes
- eye irritation
- redness of eye.

These effects should wear off after a short time. If these effects persist or get worse, or you

notice any side effects not listed in this leaflet stop using SPERSATEAR and talk to your doctor or pharmacist

Reporting of side effects
If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SPERSATEAR.

5. How to store SPERSATEAR
Store all medicines out of reach of children.
Store in cool place, at or below 30 °C. Protect from light.
Make sure the container is properly closed after each use.
Do not use after the expiry date stated on the label.
Do not use more than 30 days after opening.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What SPERSATEAR contains
- The active substance is hypromellose 3 mg/ml (0,3 % *w/v*).
- The other ingredients are water for injection, borax, boric acid, potassium chloride, sodium chloride, benzalkonium chloride 0,1 mg/ml (0,01 % *w/v*). It may also contain sodium hydroxide or hydrochloric acid.

What SPERSATEAR looks like and contents of the pack
SPERSATEAR is a clear, colourless aqueous, slightly viscous solution supplied in a 20 ml plastic dropper bottle with a tamper evident plastic screw cap.

Holder of Certificate of Registration
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