PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

BESIVANCE™ 0,6 % eye drops, suspension

Besifloxacin

Read all of this leaflet carefully before you start using BESIVANCE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BESIVANCE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What BESIVANCE is and what it is used for

BESIVANCE is an antibiotic eye drop used to treat bacterial conjunctivitis (pink eye) which is inflammation of the conjunctiva - the thin clear membrane that lies over the white part of the eye and lines the inside of the eyelid, in patients of at least one year of age.

2. What you need to know before you use BESIVANCE

Do not use BESIVANCE÷

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

Warnings and precautions

- BESIVANCE should not be injected into the eye or other tissue.
- Your doctor may need to examine your eyes regularly, because the long-term use of BESIVANCE may result in overgrowth of other organisms like fungi. If this occurs, you should stop using BESIVANCE and your doctor will prescribe alternative therapy.
- You should not wear contact lenses if you have an eye infection or while you are using BESIVANCE.

Children

Do not use BESIVANCE in infants below one year of age, because the safety and effectiveness has not been tested in this age group.

Other medicines and BESIVANCE

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Pregnancy, breastfeeding and fertility

No studies were performed on the use of BESIVANCE in pregnant or breastfeeding women.

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 health care provider for advice before using this medicine.

Driving and using machines

You may experience temporary blurred vision or irritation, pain or itching when you instill BESIVANCE into your eye. If you experience blurred vision, wait until your vision clears before driving or using machinery.

BESIVANCE contains benzalkonium chloride

The preservative in BESIVANCE, benzalkonium chloride, may cause certain side effects or damage to your cornea (the clear, front layer of your eye) if it is used repeatedly or for long periods of time. Your doctor may need to examine your eyes regularly.

Benzalkonium chloride may cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear, front layer of your eye). If you feel abnormal eye sensation, stinging or pain in the eye after using BESIVANCE, talk to your doctor.

Your doctor should be extra cautious if you have extensive ocular (eye) surface disease.

3. How to use BESIVANCE

Do not share medicines prescribed for you with any other person.

Always use BESIVANCE exactly as your doctor or pharmacist has told you. Check with our doctor or pharmacist if you are not sure.

Invert the closed bottle and shake once before use.

The usual dose for adults and children aged one year and older is: one drop in the affected eye(s) 3 times a day, 4 to 12 hours apart for 7 days.

Do not let the tip of the bottle touch your eye, fingers or any other surfaces.

Do not stop treatment early, because it is an antibiotic.

If you have the impression that the effect of BESIVANCE is too strong or too weak, tell your doctor or pharmacist.

If you use more BESIVANCE than you should

Overdosage of this medicine is unlikely to occur because it is used in your eyes only.

In the event of overdosage, or if someone accidentally swallowed the eye drops, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use BESIVANCE

Do not instill a double dose into your eyes to make up for forgotten individual doses. Continue with the rest of the doses with the prescribed interval (minimum 4 hours) between doses.

4. Possible side effects

BESIVANCE can have side effects.

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

Tell your doctor if you notice any of the following:

Frequent side effects

- Conjunctivitis (pink eye)
- Blurred vision
- Eye irritation
- Eye pain
- Eye pruritis (itching)
- Headache

Less frequent side effects

- Conjunctival haemorrhage (a small bleed from one of the blood vessels on the surface of the eye)
- Eye discharge
- Eyelid oedema (swelling)
- Hyperaemia (eye redness)
- Punctate keratitis (an eye disorder caused by death of small groups of cells on the surface of the cornea)
- Viral conjunctivitis
- Dry eye
- Increased lacrimation (tearing)

If you notice any side effects not mentioned in this leaflet, please inform 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

You can also report side effects directly to the company, using the following e-mail address: PV-SouthAfrica@bauschhealth.com

By reporting side effects, you can help provide more information on the safety of BESIVANCE.

5. How to store BESIVANCE

Store all medicines out of reach of children.

- Store at or below 30 °C.
- Protect from light.
- Do not use after the expiry date stated on the carton and bottle.
- Do not use more than 28 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 BESIVANCE contains

The active substance is besifloxacin (as hydrochloride) 6 mg per 1 mL (0,6 % *m/v*).

The preservative is benzalkonium chloride 0,1 mg per 1 mL (0,01 % *m/v*).

The other ingredients are polycarbophil, mannitol, poloxamer 407, sodium chloride, edetate disodium, sodium hydroxide (for pH-adjustment), and water for injection.

What BESIVANCE looks like and contents of the pack

BESIVANCE is a sterile, isotonic eye drops suspension. It is an off-white to slightly yellow, opaque liquid.

BESIVANCE is supplied in a round, white low density polyethylene (LDPE) bottle with a white LLDPE controlled dropper tip and beige polypropylene cap.

The 5 mL fill size is supplied in a 7,5 mL bottle, and the 2 mL fill size in a 4 mL bottle. Not all pack sizes may be marketed.

Tamper evidence is provided with a shrink band around the cap and neck area of the package.

Holder of Certificate of Registration

Soflens (Pty) Ltd

254 Hall Street

Centurion

0157

South Africa

Tel: +27 10 025 2100

Manufactured by:

Bausch & Lomb Incorporated

8500 Hidden River Parkway

Tampa, Florida 33637 USA

This leaflet was last revised in

September 2020

Registration number

47/15.1/1186

Access to the corresponding Professional Information

The Professional Information is available on the company website, www.bausch.co.za, or may be requested telephonically: +27 10 025 2100.

NAMIBIA

Scheduling status: NS2

Registration number: 20/15.1/0062

Besivance is a trademark of Bausch & Lomb Incorporated or its affiliates.

© 2020 Bausch & Lomb Incorporated or its affiliates