

## **XBETA, Betamethasone sodium phosphate eye/ear and nose drops 0.1% w/v**

### **Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

### **In this leaflet:**

- a) What XBETA EYE/EAR AND NOSE DROPS is and what it is used for
- b) Before you use XBETA EYE/EAR AND NOSE DROPS
- c) How to use XBETA EYE/EAR AND NOSE DROPS
- d) Possible side effects
- e) How to store XBETA EYE/EAR AND NOSE DROPS
- f) Further information

#### **a) What XBETA EYE/EAR AND NOSE DROPS is and what it is used for**

XBETA eye/ear and nose drops contains Betamethasone sodium phosphate, which belongs to a group of medicines called corticosteroids. These are used to relieve redness and swelling.

XBETA eye/ear and nose drops are used to treat redness and swelling of the eyes, nose and ears.

#### **b) Before you use XBETA EYE/EAR AND NOSE DROPS**

**DO NOT** use XBETA eye/ear and nose drops if you are allergic to any of the ingredients.

#### **Take special care**

Do not use in your eyes if you:

- have a viral infection of the eye
- have a fungal infection of the eye
- have tuberculosis of the eye
- have an eye infection that is producing pus
- suffer from raised pressure in your eye(s) (glaucoma)
- suffer from herpes in your eye(s)
- have undiagnosed red eye(s)

- are wearing soft contact lenses. These should be removed whilst you are using XBETA eye/ear and nose drops.

Do not use in your ears if you have:

- a hole in your ear drum

If any of the above apply please tell your doctor or pharmacist.

Take special care with XBETA eye/ear and nose drops

- Do not use XBETA eye/ear and nose drops for a prolonged period of time (more than 7 days) as this may cause serious side effects, particularly in children. (See **section d** of this leaflet)
- You should be aware that if you are using XBETA eye/ear and nose drops in your eyes, your doctor may need to check your eyes frequently during your treatment.
- if the patient has an untreated nasal infection, has pulmonary tuberculosis or after nasal surgery.

### **Other medicines and XBETA eye/ear and nose drops**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, before you use this medicine.

If you have any doubts about whether this medicine is suitable for you, consult your doctor or pharmacist.

### **Pregnancy and breast feeding**

This medicine should be avoided if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor has recommended it.

### **Effects on ability to drive and use machines**

XBETA eye/ear and nose drops can cause temporary blurring of vision after application to the eye.

Wait until your vision is clear whilst driving or using machines.

### **XBETA eye/ear and nose drops contains benzalkonium chloride**

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 this medicine 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 this medicine, talk to your doctor.

## **c) How to use XBETA eye/ear and nose drops**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### **How much to use.**

**For adults, the elderly and children.**

**For use in the eye:**

The usual starting dose is one or two drops to be put into the eye every two hours.

Your doctor may reduce the dose once the condition of your eye has begun to improve.

**For use in the ear:**

The usual starting dose is two or three drops put into the ear every three to four hours.

Your doctor may reduce the dose once the condition of your ear has begun to improve.

**For use in the nose:**

The usual dose is two or three drops into each nostril twice daily or as required.

**If you get any side effects**, talk to your doctor, pharmacist or healthcare provider. This includes any possible side effects not listed in this leaflet.

**Instructions for use**

You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first use it.

Using the drops for the first time: These eye drops come in a bottle with a coned shaped nozzle and screw cap.

The inside of the screw cap contains a spike. The screw cap is fitted to the bottle in such a way that there is no contact between the spike and the top of the nozzle of the bottle. In order to open the bottle, it is necessary to tighten the screw cap further, so that the edge of the screw cap and the nozzle edge are totally aligned. At this point the screw cap spike will pierce the top of the nozzle of the bottle, which will open the bottle. Once the bottle has been opened in this way, unscrew the screw cap fully to remove it from the bottle and apply the drops.

To avoid contamination, do not touch or allow the dropper tip touch the eye, areas around the eye or any surface. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision.

**If you use more XBETA eye/ear and nose drops than you should**

If you are at all concerned that you have used too much of this medicine, contact your doctor or pharmacist.

XBETA eye/ear and nose drops are for external use only.

If you have swallowed or you suspect someone else has swallowed any, contact your doctor or pharmacist.

**If you forget to use XBETA eye/ear and nose drops**

If you have just missed using your dose and it is a long time until your next dose is due, put in the missed dose now and continue the course of treatment. If it is near the time for using your next dose wait and use this dose at the correct time.

Do not take a double dose to make up for one you have missed.

**If you stop using XBETA eye/ear and nose drops**

You should keep using XBETA eye/ear and nose drops for as long as your doctor has instructed. Your treatment is helping your condition, even if you have not noticed a difference in how you feel. Should you need to stop your treatment, your doctor will advise you how to do this.

#### **d) Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following side effects you should tell your doctor immediately. These are symptoms of an allergic reaction.

- difficulty in breathing with or without swelling of the face, lips, tongue and/or throat
- swelling of the face, lips tongue and/or throat, which may cause difficulty in swallowing
- severe itching of the skin (with raised lumps)

Other possible side effects include:

- irritation, burning, itching and stinging in the area. This may occur after treatment has stopped.
- raised pressure in the eye (only when used in the eye)
- pupil dilation, drooping of the eyelid, corneal inflammation, sneezing, headache, light headedness, nausea, nosebleeds, rebound congestion, nasal discomfort, disturbance to sense of smell, disturbance to sense of taste, stunted growth in children.

Where you suffer from a disease (other than that for which you are using XBETA eye/ear and nose drops) that causes thinning of the surface of the eye, serious damage may be caused.

Prolonged use of this medicine (for more than 7 days) can lead to cloudiness of the lens of the eye (cataracts), it is therefore advised that the lens of the eye is checked frequently during use of this medicine.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

#### **e) How to store XBETA EYE/EAR AND NOSE DROPS**

Keep out of reach of children.

Store below 30°C, but do not freeze.

Do not use after the expiry date which is stated on the bottle after “Expiry”. The expiry date refers to the last day of that month.

Dispose of this medicine 4 weeks after opening.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

**f) Further information**

**What XBETA EYE/EAR AND NOSE DROPS contains**

The **active** ingredient is betamethasone sodium phosphate 0.1% w/v.

The **other** ingredients are benzalkonium chloride solution, disodium edetate, sodium chloride and water for injections.

**What XBETA EYE/EAR AND NOSE DROPS looks like and the contents of the pack**

XBETA eye/ear and nose drops are a clear, colourless to faintly yellow solution supplied in a plastic dropper bottle with a cap. Each bottle contains 5 or 10ml of the solution.

**Marketing authorization holder and manufacturer**

Abacus Parenteral Drugs Limited

Block 191, Plot no.114, Kinga Mukono

P. O. Box 31376, Kampala, Uganda.

Phone: +256-312 380 800

Fax: +256-312 380 820

Email: [apdl@abacuspharma.com](mailto:apdl@abacuspharma.com)

For any information about this medicinal product, please contact the local representative of the supplier:

Name: Gihanda John Davis

Address: Kigali City Market, B1-R85, Kigali, Rwanda

Tel: +250 788218527

e-mail: [aplrw.pharmacist@abacuspharma.com](mailto:aplrw.pharmacist@abacuspharma.com)

This leaflet was last revised in.