PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ZYMAR® gatifloxacin 3,0 mg/ml eye drops (ophthalmic solution)

Read all of this leaflet carefully before you start using ZYMAR®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ZYMAR® 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.

1. WHAT ZYMAR® CONTAINS

- The active ingredient is 3 mg/ml gatifloxacin.
- The other ingredients are benzalkonium chloride as preservative, edetate disodium, purified water and sodium chloride. May contain hydrochloric acid and/or sodium hydroxide.

2. WHAT ZYMAR® IS USED FOR

ZYMAR® is an antibiotic ophthalmic solution and is used for the treatment of conjunctivitis caused by bacteria.

3. BEFORE YOU USE ZYMAR®

Do not use ZYMAR®

- If you are hypersensitive (allergic) to gatifloxacin, other quinolones or to any of the components in this medication.
- Do not use in infants under the age of one year.

Take special care with ZYMAR®

NOT SUITABLE FOR INJECTION

As the possibility of adverse effects on the corneal permeability, and the danger of disruption of the corneal epithelium with prolonged or repeated usage of

benzalkonium chloride preserved ophthalmological preparations, cannot be excluded, regular ophthalmological examination is required. Caution should be exercised in the use of benzalkonium chloride preserved topical medication over an extended period in patients with extensive ocular surface diseases.

Before using ZYMAR®, tell your doctor:

- If you have allergies to any medicines;
- If you wear contact lenses.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using ZYMAR®.

If you are pregnant or breastfeeding your baby, you should not use ZYMAR®. It is not known whether ZYMAR® is excreted in human milk.

Driving and using machinery

Your sight may become blurred for a short time after using ZYMAR®. You should not drive or use machines until your sight is clear again.

Important information about some of the ingredients of ZYMAR®

Benzalkonium chloride: Special care should be taken if you have an extensive eye surface disease. Do not use ZYMAR® for a prolonged period of time and have regular eye examinations.

If you wear soft contact lenses, remove your contact lenses before using ZYMAR®, and wait at least 15 minutes after using ZYMAR® before reinserting your contact lenses. The preservative in ZYMAR®, benzalkonium chloride, may be absorbed by and cause discolouration of soft contact lenses.

Using ZYMAR® with other medicines

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

4. HOW TO USE ZYMAR®

Do not share medicines prescribed for you with any other person.
Always use ZYMAR® exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is:
Days 1 and 2: Instil one drop every two hours in the affected eye(s) while awake, up to 8 times daily.
Days 3 through 7: Instil one drop up to four times daily while awake.

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

Things to be careful of:
- ZYMAR® solution should not be injected into the eye or any other part of the body.
- Avoid contaminating the applicator tip with material from the eye, fingers or other source.
- Do not wear contact lenses if you have signs and symptoms of bacterial conjunctivitis, and while using ZYMAR®.

If you use more ZYMAR® than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

The eye(s) should be flushed with water. If you have questions or concerns, or are not sure about something, please consult your doctor or pharmacist.

If you forget to use ZYMAR®
- Use the eye drops as soon as you remember, and then go back to using them as you would normally.
- If it is almost time for your next dose, ignore the dose you missed and put the drops in when you are meant to.
- Do not take a double dose to make up for the dose that you missed.
- If you have missed several doses, consult your doctor.
- If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

5. POSSIBLE SIDE EFFECTS

ZYMAR® can have side effects.

If you experience inflamed or itchy skin, swelling or redness of the skin, or hives (urticaria) stop using ZYMAR® and contact your doctor or hospital immediately. You may be experiencing an allergic reaction to ZYMAR® which may be serious. You may need urgent medical attention.

Not all side effects reported for ZYMAR® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using ZYMAR®, please consult your doctor, pharmacist or other health care professional for advice.

You may experience the following effects:

Frequent side effects:

- inflammation, bleeding or other disorders of the see-through layer covering the surface of the eye (conjunctiva)
- inflammation of the surface of the eye (cornea)
- red and painful eyes
- watery eyes
- eyelid swelling
- decreased vision
- eye irritation
- eye discharge
- dry eye
- skin redness
- headache
- taste disturbances

Less frequent side effects:

- swelling of the see-through layer which covers the surface of the eye
- red and itchy skin

Side effects of unkown frequency:

- inflamed eyelids
- eye redness
- blurred vision

- itchy eyes
- eye swelling
- nausea
- allergic reactions
- severe allergic reactions (anaphylactic reactions)
- swelling of the skin including the throat, mouth and face
- difficulty breathing
- itchy skin
- rash
- hives

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

You can report side effect to SAHPRA via “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publication: https://www.sahpra.org.za/Publications/Index/8
By reporting side effects, you can help provide more information on the safety of **ZYMAR**.

You can also report side effects to AbbVie (Pty) Ltd by sending an e-mail to MEAPV@abbvie.com

6. STORING AND DISPOSING OF ZYMAR®

Store below 25 °C. STORE ALL MEDICINES OUT OF REACH OF CHILDREN. Do not use more than 30 days after opening. Discard any unused portion. Store in the original eye drop bottle. To avoid contamination of the solution, keep container tightly closed and do not touch dropper tip to any surface. Contents are sterile if seal is intact. Do not put the eye drops in the freezer. Return all unused medicines to your pharmacist. Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF ZYMAR®

ZYMAR® is supplied sterile in a white, plastic bottle with a controlled dropper tip and a beige cap in a 5 ml pack size.

8. IDENTIFICATION OF ZYMAR®

ZYMAR® is a sterile, clear, pale yellow coloured solution.

9. REGISTRATION NUMBER

A39/15.1/0367

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Abbvie (Pty) Ltd

Abbott Place

219 Golf Club Terrace

Constantia Kloof 1709

South Africa

Tel: 011 831 3261

11. DATE OF PUBLICATION

Date of registration: 20 October 2007

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For the professional information please email medicalinfo.za@abbvie.com