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## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

Schedule 4

### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

**PRED FORTE Sterile Eye Suspension, prednisolone acetate 10 mg/ml sterile eye suspension**

### Read all of this leaflet carefully before you start using PRED FORTE Sterile Eye Suspension

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

- The active substance in PRED FORTE is prednisolone acetate 10 mg/ml.
- The other ingredients are benzalkonium chloride 0,004 % m/v as a preservative, disodium edetate, hypromellose, sodium chloride, sodium citrate dihydrate, sodium metabisulphite, polysorbate 80 and purified water.

#### 2. WHAT PRED FORTE IS USED FOR

PRED FORTE belongs to a group of medicines known as steroids. PRED FORTE is used in adults for the short-term treatment of eye inflammation.

#### 3. BEFORE YOU USE PRED FORTE

##### Do not use PRED FORTE:

- If you are hypersensitive (allergic) to prednisolone acetate, benzalkonium chloride or any of the other ingredients of PRED FORTE;
- If you have viral, fungal or bacterial eye infections;
- If you have a mycobacterial infection or tuberculosis of the eye;
- If you have injuries to or ulcers on the cornea;
- If you have glaucoma;
- If you have previously had herpes simplex.

##### Take special care with PRED FORTE

Talk to your doctor before using PRED FORTE if you suffer from, or have in the past suffered from:

- Eye ulcers or have had a disease or treatment to the eye that caused the tissue of the cornea (the see-through layer covering the eye) to become thin;
- You have glaucoma or are being treated for raised pressure within the eye;

- You have had surgery for cataracts;
- Bacterial, viral or fungal eye infections.

Tell your doctor:

- If you are using or have used other steroid eye drops, as frequent or long-term use of steroids can result in additional side effects.

PRED FORTE should not be used for more than 10 days except under strict ophthalmic supervision with regular checks for eye pressure.

PRED FORTE contains sodium metabisulphite, a sulphite that may cause allergic-type reactions, including anaphylactic symptoms, such as shortness of breath, difficulty breathing, hives and itching, and life-threatening or less severe asthmatic episodes. Sulphite sensitivity is seen more frequently in patients that suffer from asthma.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using PRED FORTE.

The safety of PRED FORTE during pregnancy and breast-feeding has not been established.

### **Driving and using machinery**

PRED FORTE may cause temporary blurred vision. Do not drive or use machinery until the symptoms have cleared.

### **Important information about some of the ingredients of PRED FORTE**

PRED FORTE is preserved with benzalkonium chloride. You should undergo regular eye examinations if you are using PRED FORTE for a prolonged period of time. Benzalkonium chloride may cause side effects on your corneal permeability with prolonged or repeated use.

Contact lenses:

- Do not use the drops while your contact lenses are in your eyes. Wait at least 15 minutes after using the eye drops before putting your lenses back in your eyes.
- Benzalkonium chloride, the preservative in PRED FORTE may cause eye irritation and is also known to discolour soft contact lenses.

### **Using other medicines with PRED FORTE**

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

Medicines belonging to a group called CYP3A inhibitors may increase the risk of side effects when used together with PRED FORTE.

#### 4. HOW TO USE PRED FORTE

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

PRED FORTE should not be used for more than 10 days except under strict ophthalmic supervision with regular checks for eye pressure.

Always use PRED FORTE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with PRED FORTE will last. Do not stop treatment early because PRED FORTE should be used as instructed by your doctor to work properly. Do not use PRED FORTE more or less often, or for a longer period, than you are told to by your doctor or pharmacist.

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

##### 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.

Apply your eye drops in the following way:



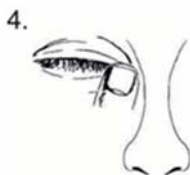
Wash your hands. Shake the bottle well before use.  
Tilt your head back and look at the ceiling.



Gently pull the lower eyelid down until there is a small pocket.



Turn the bottle upside down and squeeze it to release one or two drops into each eye that needs treatment.



Let go of the lower lid, and close your eye.  
Press your finger against the corner of your eye (the side where your eye meets your nose) for one minute.

If a drop misses your eye, try again.

To avoid contamination with germs, do not let the tip of the dropper touch your eye or anything else.

To avoid spreading the infection, do not share the same bottle with another person.

Replace and tighten the cap straight after use.

Wipe off any excess liquid from your cheek with a clean tissue.

If you use PRED FORTE for more than 10 days, your doctor may ask you to have check-ups.

These are to make sure that PRED FORTE is working properly and that the dose you are taking is right for you. Your doctor will check your eyes for:

- An increase in pressure;
- Cataracts;
- Infection.

The proper application of your eye drops is very important. If you have any questions ask your doctor or pharmacist.

#### **If you use more PRED FORTE than you should**

If you have placed too many drops in your eye(s), wash your eye(s) with clean water. Apply your next dose at the normal time.

If, by accident, anyone drinks this medicine, the person should drink fluids to dilute it. Consult your doctor or pharmacist straight away.

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

#### **If you forget to use PRED FORTE**

If you forget to apply a dose, apply it as soon as you remember, unless it is almost time for your next dose, in which case you should miss out on the forgotten dose. Then apply your next dose as usual and continue with your normal routine.

Do not use a double dose to make up for forgotten individual doses.

#### **Effects when treatment with PRED FORTE is stopped**

PRED FORTE should be used as advised by your doctor.

Do not stop using PRED FORTE until your doctor has told you to.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

### **5. POSSIBLE SIDE EFFECTS**

PRED FORTE can have side effects. Not all side effects reported for PRED FORTE are included in this leaflet. Should your general health worsen or if you experience any untoward

effects while using PRED FORTE, please consult your doctor, pharmacist or other health care professional for advice.

**You should see your doctor immediately if you experience:**

- Ulcers on the surface of the eye (symptoms include eye pain, light sensitivity, involuntary closing of the eyes and tearing);
- Severe pain in the eye.

**You should see your doctor if any of the following effects prove troublesome or if they are long-lasting:**

- Allergic reaction (symptoms may include rash and itching of the surrounding skin);
- Headache;
- Glaucoma (increased pressure within the eye);
- Cataracts (centre of the eye becomes cloudy);
- Eye infections;
- Redness of the eye(s);
- Foreign body sensation;
- Stinging or irritation;
- Eye pain;
- Blurred or poor vision;
- Pupil dilation;
- Change in sense of taste;
- Rash or itching.

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

## **6. STORING AND DISPOSING OF PRED FORTE**

- Store at or below 25 °C. Do not freeze.
- Store in an upright position.
- Store all medicines out of reach of children.
- Do not use the product after the expiry date. This is the date printed on the label of the bottle and on the bottom of the outer carton. The expiry date refers to the last day of that month for an unopened bottle.
- Do not use the product if the bottle has been open for longer than 30 days, even if there is solution remaining.
- Do not use PRED FORTE if you notice the tamper-proof seal is broken.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## **7. PRESENTATION OF PRED FORTE**

PRED FORTE Sterile Eye Suspension is supplied in sterile plastic dropper bottles containing 5

ml suspension.

For topical use only, under supervision of a medical practitioner.

## **8. IDENTIFICATION OF PRED FORTE**

Dense, white microfine suspension.

## **9. REGISTRATION NUMBER**

J/15.2/77

## **10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION**

Allergan Pharmaceuticals (Pty) Ltd  
30 New Road (entrance off Bavaria Road)  
Randjespark Ext 11, Midrand, 1682  
Johannesburg, Gauteng  
South Africa

Tel: +27 11 545 6600

## **11. DATE OF PUBLICATION**

Date of registration: 23 December 1976

Date of revision of the patient information leaflet: 28 November 2014

Professional Information can be accessed via <http://www.allergan.co.za/en-za/products>

In case of an adverse event please contact +27 11 545 6600 or send an e-mail to [SA\\_Complaints@allergan.com](mailto:SA_Complaints@allergan.com)