Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

PRED FORTE®

Ophthalmic Suspension

Active ingredient and its concentration:
prednisolone acetate 1% w/v

Inactive ingredients and allergens in the medicine: see section 2, under 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed to treat your illness/for you. Do not pass it on to others. It may harm them, even if it seems to you that their illness/medical condition is similar to yours.

1. What is this medicine intended for?

PRED FORTE is used to treat eye inflammation that responds to steroids and involves the conjunctiva, cornea or the anterior segment of the eyeball.

Therapeutic group: corticosteroids

PRED FORTE belongs to a group of medicines known as steroidal anti-inflammatory drugs. It reduces the irritation, burning, redness and swelling of eye inflammation caused by chemicals, heat, radiation, allergy, or foreign objects in the eye.

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to the substance prednisolone acetate, benzalkonium chloride or any of the other ingredients of this medicine (listed in section 6 'Additional information').
- you suffer from viral, fungal or bacterial eye infections.
- you suffer from tuberculosis of the eye.
- you have injuries or ulcers on the cornea.
- you have previously had herpes simplex.

Special warnings about using this medicine
Before treatment with PRED FORTE, tell your doctor if:

- you suffer from or have ever suffered from eye ulcers, or if you have had a disease or received treatment in the eye that caused the tissue to become thin
- you have glaucoma or are being treated for high pressure within the eye
- you have had surgery for cataract
- you suffer from or have in the past suffered from bacterial, viral or fungal eye infections
- you are using or have used other steroid eye drops, as frequent or long-term use of steroids can result in additional side effects

Contact your doctor if you experience blurred vision or other visual disturbances.

Children
this medicine should not be given to a child younger than 12 years without medical advice, as it contains boron and may impair fertility in the future.

Tests and follow-up
If you use this medicine for more than 7 days, your doctor may ask you to have checkups. These are to make sure that your medicine is working properly and that the dose you are taking is right for you. Your doctor will check your eyes for increased pressure, cataract, infection.

Interactions/Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:
Some medicines may increase the effects of **PRED FORTE** and your doctor may wish to monitor your condition if you are taking these medicines (including certain medicines for HIV [human immunodeficiency virus]: ritonavir, cobicistat).

Pregnancy and breastfeeding:
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine, as steroids may be harmful to the baby.

Driving and using machines
PRED FORTE may cause temporary blurred vision. Do not use machines or drive until the symptoms have disappeared.

Important information about some of this medicine's ingredients
PRED FORTE contains benzalkonium chloride
PRED FORTE contains 0.06 mg benzalkonium chloride in each 1 ml.
Contact lenses -
Benzalkonium chloride may be absorbed by soft contact lenses and may change their color. Remove your contact lenses before using this medicine. You may

only put them back in your eyes 15 minutes after you have finished using this medicine. 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 an abnormal sensation, stinging, or pain in your eye after using this medicine, consult your doctor.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions.
Check with your doctor or pharmacist if you are not sure about the dosage or treatment regimen of this medicine.
The dosage and treatment regimen will be determined by the doctor only.
The recommended dosage of PRED FORTE in adults is usually: one or two drops into the eye(s) two to four times a day.
During the first two days of treatment you may be asked to apply the drops as often as every hour.
Do not exceed the recommended dose.
Do not swallow.

Directions for use:
Do not use the product if the tamper-proof seal on the bottle neck is broken before you first use it.

Apply your eye drops in the following way:

1. Wash your hands. Shake the bottle well before use. Tilt your head back and look at the ceiling.
2. Gently pull the lower eyelid down until there is a small 'pocket'.
3. Turn the bottle upside down so that the dropper points down, and squeeze to release one or two drops into each eye that needs treatment.
4. Let go of the lower eyelid 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 the drop misses your eye, try again.
To avoid eye injury and contamination, do not let the tip of the dropper touch your eye or anything else. Close the bottle tightly with the cap straight after use.
Wipe off any excess liquid from your cheek with a clean tissue. The proper application of your eye drops is very important.

If you have accidentally taken a higher dosage
If you have accidentally applied too many drops in your eye(s), wash your eye(s) with clean water. However, putting too many drops in your eye(s) is unlikely to cause unwanted side effects. Apply your next dose at the scheduled time. If, by accident, anyone drinks this medicine, contact your doctor straight away.

If you forget to take this medicine at the scheduled time
If you forget a dose, apply it as soon as you remember, unless it is time for your next dose, in which case you must skip the forgotten dose. Then apply your next dose according to your normal routine. Do not apply a double dose to make up for a forgotten dose.
Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine
Use PRED FORTE as advised by your doctor. Do not stop using PRED FORTE until your doctor has told you to.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using PRED FORTE may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Contact your doctor immediately if you experience:
- ulcers on the surface of the eye
- severe pain in the eye

Contact your doctor if any of the following effects is troublesome or long-lasting:
Side effects of unknown frequency (the frequency of these effects has not been established yet)
- allergic reaction
- headache
- increased pressure within the eye
- center of the eye becomes cloudy (cataract)
- feeling you have a foreign object in your eye
- eye infection (bacterial, fungal or viral)
- mild stinging or irritation
- red eye
- blurred or poor vision

- pupil dilation
- change in sense of taste
- rash or itching

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting of side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
Do not use the medicine after the expiry date (exp. date). This date is printed on the bottle label and on the bottom of the medicine package. The expiry date refers to the last day of that month.

Storage conditions:
Store below 25ºC, in an upright position. Do not freeze.
Do not use the product if the tamper-proof seal on the bottle neck is broken.
Discard the bottle 28 days after opening, even if some solution remains.

Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
boric acid; sodium citrate dihydrate; sodium chloride; hypromellose; polysorbate 80; disodium edetate; benzalkonium chloride; hydrochloride acid, sodium hydroxide and purified water.

What does the medicine look like and what does the pack contain?
A white, sterile suspension in a plastic bottle. Each bottle is about half full and contains either 5 ml or 10 ml of medicine. Not all pack sizes may be marketed.

Manufacturer's name and address: Allergan Pharmaceuticals Ireland, Castlebar Road, Westport, County Mayo, Ireland.

Registration holder's name and address: AbbVie Biopharmaceuticals Ltd., 4 Haharash St., Hod Hasharon, Israel.

Revised in March 2023 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 118 24 29914