

Package leaflet: Information for the user

PRED FORTE 1% w/v Eye Drops, Suspension prednisolone acetate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Pred Forte is and what it is used for

Pred Forte belongs to a group of medicines known as steroidal (anti-inflammatory drugs). Pred Forte is used in adults for the short-term treatment of eye inflammation when the presence of viral, fungal and bacterial agents have been ruled out.

It reduces the irritation, burning, redness and swelling of the eye caused by chemicals, heat, radiation, allergy, or foreign objects in the eye.

2. What you need to know before you use Pred Forte

Do not use Pred Forte:

- If you are allergic to prednisolone acetate or any of the other ingredients of this medicine (listed in Section 6)
 - (Symptoms of an allergic reaction may include swelling of the face, lips and throat, itching, redness or rash around the eye, body rash, hives, wheeziness, feeling faint or shortness of breath. Contact your doctor or seek medical attention immediately if you experience any of these symptoms)
- If you are suffering from, or have in the past suffered from viral, fungal or bacterial eye infections or tuberculosis of the eye.

Warnings and precautions

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 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

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

Tell your doctor before using Pred Forte, 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.

Steroid eye drops should not be used for more than one week unless under strict ophthalmic supervision to check regularly for intra-ocular pressure (IOP).

Other medicines and Pred Forte

Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines may increase the effects of Pred Forte and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Pregnancy and breast-feeding

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

If you are breast-feeding, the use of Pred Forte is not recommended.

Driving and using machines

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

Pred Forte contains benzalkonium chloride and boric acid

This medicine contains 0.06 mg benzalkonium chloride in each 1 ml.

This medicine contains 10 mg boric acid in each 1 ml.

Contact lenses

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.

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.

3. How to use Pred Forte

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

The recommended dose is 1 or 2 drops into the affected eye(s) 2 to 4 times daily. During the first two days of treatment you may be asked to apply the drops as often as every hour.

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:

- 1.
- 2.
- 3.
- 4.

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 and squeeze it to release one or two drops into each eye that needs treatment.

4. 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.

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

Replace and tighten 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 any questions ask your doctor or pharmacist.

If you use more Pred Forte than you should

Putting too many drops in your eye(s) is unlikely to lead to unwanted side effects. 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 contact your doctor straight away and drink fluids to dilute.

If you forget to use Pred Forte

If you forget 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 the forgotten dose. Then apply your next dose as usual and continue with your normal routine.

Do not take a double dose to make up for a forgotten dose.

If you stop using Pred Forte

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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

You should see your doctor immediately if you experience:

- ulcers on the surface of the eye
- severe pain in the eye

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

Not known (frequency cannot be estimated from the available data)

- allergic reaction
- headache
- increased pressure within the eye
- centre of the eye becomes cloudy (cataracts)
- a feeling that something is in your eye
- eye infections (bacterial, fungal or viral)
- eye irritation
- red eye
- blurred or poor vision
- pupil dilation
- eyelid drooping*
- change in sense of taste
- rash or itching

***long-term use**

Reporting of side effects

If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pred Forte

Keep this medicine out of the sight and reach of children.
Do not store above 25°C. Do not refrigerate or freeze.

Do not use this medicine if the tamper-proof seal on the bottle is broken.

Do not use this medicine after the expiry date which is stated on the bottle label and the bottom of the carton after EXP. The expiry date refers to the last day of that month for an unopened month.

Throw the bottle away 28 days after opening, even if there is solution remaining.

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.

6. Contents of the pack and other information

What Pred Forte contains

- The active substance is prednisolone acetate 1.0% w/v.
- The other ingredients are: benzalkonium chloride - polysorbate 80 - boric acid - sodium citrate dihydrate - sodium chloride - edetate disodium - hypromellose - hydrochloric acid - sodium hydroxide - purified water.

What Pred Forte looks like and contents of the pack

Pred Forte is a dense white sterile microfine eye drop suspension in a plastic bottle. Each carton contains 1 plastic bottle with a screw cap. Each bottle is about half full and contains 5 ml or 10 ml of the eye drops as written on the front of the carton.

Marketing Authorisation Holder

AbbVie Limited
Citywest Business Campus
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Manufacturer

Allergan Pharmaceuticals Ireland
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Westport
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