



PRED FORTE™

1% w/v EYE DROPS, SUSPENSION

Prednisolone acetate

Please read this leaflet carefully before you start to take your medicine.

If you have any questions, or are not sure about anything, ask your doctor or pharmacist.

- The active ingredient in PRED FORTE™ is: Prednisolone acetate 1.0% w/v
- It also contains: benzalkonium chloride, edetate disodium, hypromellose, polysorbate 80, boric acid, sodium citrate, sodium chloride, hydrochloric acid or sodium hydroxide for pH (acidity) adjustment and purified water.
- PRED FORTE™ is a sterile eye drop suspension and each bottle contains 5 ml or 10 ml of the medicine.
- Marketing authorisation holder:
Allergan Pharmaceuticals Ireland, Westport, Co. Mayo, Ireland.
- It is manufactured by:
Allergan Pharmaceuticals Ireland, Westport, Co Mayo, Ireland.
- The active ingredient, prednisolone acetate, is a steroid which is used to treat eye inflammation.

Uses

PRED FORTE™ contains a steroid (anti-inflammatory drug). PRED FORTE™ is used for the short-term treatment of eye inflammation. It reduces the irritation, burning, redness and swelling of eye inflammation caused by chemicals, heat, radiation, allergy, or foreign objects in the eye. It is sometimes used after eye surgery.

Before you take this medicine

Tell your doctor:

- (a) If you have ever suffered from any other eye problem, particularly eye infection, that required treatment from a doctor or specialist.
- (b) If you are pregnant or breast-feeding. PRED FORTE™ should only be used in pregnancy if the potential benefit to the mother outweighs the potential risk to the foetus. This product is not recommended for use in women breast feeding infants.
- (c) If you are taking any other medication, whether it has been purchased from a chemist or pharmacist, or prescribed for you by a doctor.
- (d) If you wear soft ('hydrophilic') 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. A preservative in PRED FORTE™ (called benzalkonium chloride) may cause eye irritation and is also known to discolour soft contact lenses.
- (e) If you are allergic to the preservative benzalkonium chloride or any of the other ingredients. In these cases PRED FORTE™ should not be used.
- (f) If you are suffering from viral, fungal or severe bacterial eye infection or tuberculosis of the eye. In these cases PRED FORTE™ should not be used. Please also tell your doctor if you have a history of these conditions.

Prolonged use may result in the possible growth of other organisms, as well as raised pressure within the eye and thinning or perforation of the outer membranes of the eye.

The safety and effectiveness in children have not been shown.

PRED FORTE™ may cause short-lasting blurring of vision upon instillation. If affected, do not use machinery/ electric tools or drive until vision has returned to normal.

Dosage

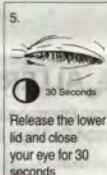
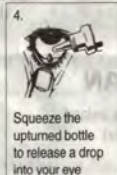
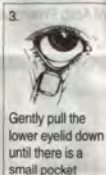
The usual dose of PRED FORTE™ is one or two drops applied two to four times daily. It should not normally be used for longer than one week without review by your doctor. During the first two days of treatment you may be asked to apply the drops as often as every hour. Follow the instructions on your prescription label carefully, and ask your doctor or pharmacist to explain anything that you do not understand.

Do not use this medicine more or less often, or for a longer period, than you are told to by your doctor or pharmacist. Do not stop using PRED FORTE™ until your doctor tells you to.

How to use the product

PRED FORTE™ comes as eye drops. Your prescription label tells you how many drops to use at each dose. Apply your eye drops in the following way:

1.
Shake the bottle well before use



Avoid touching the dropper against your eye or anything else.

Replace and tighten the cap straight after use.

The proper application of your eye drops is very important.

If you have any questions ask your doctor or pharmacist.

Missed doses

If you forget to take a dose apply it as soon as you remember and then apply any remaining doses for that day at evenly spaced intervals. If, however, it is almost time for your next dose, you should omit the missed dose altogether and then follow your normal routine.

Overdosage

If you accidentally place too many drops in your eye(s), wash the eye(s) with water. The application of too many drops is, however, unlikely to lead to unwanted side-effects. If this medicine is drunk by accident by anyone, drink plenty of fluids (e.g. water) to dilute and contact your doctor.

Side Effects

As with all medicines, PRED FORTE™ can cause unwanted effects in some users. You may experience mild stinging and/or burning when the drops are applied and temporary blurred vision. You should see your doctor if these effects prove troublesome or if they are long-lasting. You may possibly experience eye irritation, thinning of the skin and the appearance of fine red lines on the face, formation of cataracts and poorer vision. You may experience thinning or perforation of the outer membranes of the eye. If you experience pressure and pain in the eye you should see your doctor at once. Possible causes of this are e.g. eye infections or glaucoma (raised pressures within the eye).

You should also see your doctor if you experience any other unusual or unexpected effects.

Storage

Keep the medicine in a safe place out of the reach and sight of children.

Do not store above 25°C. Do not refrigerate or freeze.

Warnings

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

The product should not be used after the expiry date. (This is printed on both the label on the bottle and on the bottom of the carton that the bottle is packed in).

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

Prepared: October 2008.

This medicine is for your use only. It can only be prescribed by a doctor. Never give it to anyone else. It may harm them even if their symptoms are the same as yours.

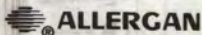
IMPORTANT

This leaflet does not contain complete information about your medicine. If you have any questions, or are not sure about anything, ask your doctor or pharmacist who have access to additional information.

(THIS IS A MEDICAMENT)

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children
Council of Arab health Ministers
Union of Arab Pharmacists



Allergan Pharmaceuticals Ireland
Westport Co. Mayo, Ireland