

PRED FORTE® STERILE OPHTHALMIC SUSPENSION

prednisolone acetate (1% w/v)

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What PRED FORTE® is used for

PRED FORTE® is used for the treatment of eye inflammation.

How PRED FORTE® works

Prednisolone acetate works by limiting inflammatory substances in the eyes, thereby reducing redness, swelling and irritation.

Before you use PRED FORTE®**- When you must not use it**

Do not use **PRED FORTE®**:

- If you are allergic (hypersensitive to prednisolone acetate, benzalkonium chloride or any of the other ingredients of **PRED FORTE®**. (for a full list of ingredients, see section "PRODUCT DESCRIPTION").
- If you suffer from viral, fungal or bacterial eye infections

- Pregnancy and lactation

Ask your doctor or pharmacist for advice before taking any medicine. Tell your doctor if you are pregnant or planning to become pregnant. Do not use **PRED FORTE®** if you are pregnant unless your doctor considers it necessary.

Do not use **PRED FORTE®** if you are breast-feeding. Ask your doctor for advice before taking any medicine during breast-feeding.

- Children

The use of **PRED FORTE®** in children below the age of two years has not been studied.

- Before you start use it

Take special care with **PRED FORTE®**. If any of the following apply, talk to your doctor before using **PRED FORTE®** if you suffer from, or have in the past suffered from:

- Disease or treatment to the eye that caused the eye surface to become thin
- Glaucoma or are being treated for raised pressure within the eye or had surgery for cataracts.
- Herpes simplex

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.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use PRED FORTE®**- How much to use**

Instill 1 to 2 drops into the eye two to four times a day. During the initial 24 to 48 hours the dosage may be safely increased to 2 drops every hour. Do not stop therapy before talking to a doctor.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- Instructions for use

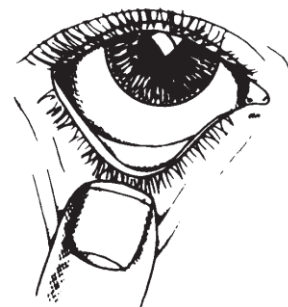
You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first use it.

Apply your eye drops in the following way:

1. 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.



If a 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.

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 any questions, ask your doctor or pharmacist.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue using **PRED FORTE**[®] for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

If you use more **PRED FORTE**[®] than you should, it is unlikely to cause you any serious harm. If accidentally ingested, you should drink fluids to dilute.

Take your next dose in at the usual time. If you are worried, talk to your doctor or pharmacist.

While you are using it

- Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking **PRED FORTE**[®].

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not take any new medicines without consulting your doctor.

Do not give **PRED FORTE**[®] to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines:

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

Using contact lenses:

PRED FORTE[®] contains benzalkonium chloride as a preservative, which is known to discolour soft contact lenses and can cause eye irritation. If you wear soft contact lenses you must remove them before using **PRED FORTE**[®] eye drops and wait at least 15 minutes before putting your lenses back in.

Other things to take note:

1. In those diseases causing thinning of the eye surface, puncture has been reported with the use of topical steroids.
2. Serious eye infections may be masked or enhanced by the use of topical steroids. Prolonged use may suppress the host immune response in eye tissues and thus increase the possibility of secondary eye infections.
3. Eye drops containing corticosteroids should not be used

for more than 10 days except under strict ophthalmic supervision with regular checks of intra-ocular pressure (IOP).

4. The use of the bottle or tube by more than one person may spread infection. Keep bottle or tube tightly closed when not in use.
5. The possibility of adrenal suppression should be considered with prolonged, frequent, use of high dose topical steroids, particularly in infants and children.

Side effects

Like all medicines, **PRED FORTE**[®] can cause side effects, although not everybody gets them.

These side effects include:

- Allergic reaction, headache, increased eye pressure, loss of part of the usual field of vision, cloudy lens inside the eye, a feeling that something is in the eye, secondary eye infections from fungi, bacterial or viruses, irritation of the eye, eye pain, blurred or poor vision, change in sense of taste, rash or itching, piercing of the white of the eye (the white layer covering part of the eye bulb), delayed wound healing and eyelid drooping (*eyelid ptosis*).

It can also cause inflammation inside the eye. Enlarged pupil, loss of accommodation and droopy eyelids have occasionally been reported following local use of corticosteroids. Systemic side effects may occur with extensive use of steroids.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel:

03-78835490, or visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (conSERF) or Vaccines (AEFI)].

hydrochloric acid, sodium hydroxide and purified water
- *MAL number:*
MAL19890346ARZ

Storage and Disposal of PRED FORTE®

- *Storage*

Store upright. Keep out of the reach and sight of children. **Shake well before use.**

Do not use **PRED FORTE®** after the expiry date which is stated on the bottle label and the bottom of the carton after EXP.

Store below 30°C. Protect from freezing. For topical ophthalmic use only.

- *Disposal*

Discard unused contents 4 weeks after opening.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

PRED FORTE® is a dense, white, microfine suspension in a plastic bottle.

Each carton contains 1 plastic bottle with a screw cap in the following pack sizes: 5 ml or 10 ml.

Not all pack sizes may be marketed.

- *Ingredients*

- Active ingredient
prednisolone acetate

- Inactive ingredients
benzalkonium chloride, polysorbate 80, boric acid, sodium citrate, sodium chloride, edetate disodium, hydroxypropyl methylcellulose,

Manufacturer

Allergan Pharmaceuticals Ireland
Castlebar Road
Westport
County Mayo
Ireland

Product Registration Holder

ABBVIE SDN BHD
9th Floor Menara Lien Hoe
No.8, Persiaran Tropicana
Tropicana Golf & Country Resort
47410 Petaling Jaya Selangor, Malaysia

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