

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

**P<sup>r</sup>PRED FORTE®**

#### **prednisolone acetate ophthalmic suspension**

Read this carefully before you start taking **PRED FORTE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PRED FORTE**.

#### **What is PRED FORTE used for?**

- PRED FORTE is used to treat inflammation (swelling) of several different parts of the eye.

#### **How does PRED FORTE work?**

PRED FORTE is a type of corticosteroid medicine that treats inflammation. It works by reducing the swelling, irritation, burning, redness and other symptoms seen with eye inflammation.

#### **What are the ingredients in PRED FORTE?**

Medicinal ingredient: prednisolone acetate

Non-medicinal ingredients: benzalkonium chloride, boric acid, edetate disodium, hydroxypropyl methylcellulose, polysorbate 80, purified water, sodium bisulphite, sodium chloride, sodium citrate dihydrate.

#### **PRED FORTE comes in the following dosage forms:**

Ophthalmic suspension, 1% w/v

#### **Do not use PRED FORTE if:**

- you are allergic (hypersensitive) to prednisolone acetate, any other corticosteroids or any of the other ingredients in PRED FORTE (see section **What are the ingredients in PRED FORTE?**).
- you have a viral infection of the eye such as; herpes, vaccinia or chickenpox.
- you have a mycobacterial infection of the eye such as; tuberculosis.
- you have a fungal infection of the eye.
- you have any infection of the eye that causes pus.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PRED FORTE. Talk about any health conditions or problems you may have, including if you:**

- are pregnant or planning to become pregnant
- are breast-feeding or planning to breast-feed
- have asthma
- have glaucoma (increased pressure in your eye)
- have recently had cataract surgery
- have a history of herpes infection in your eye
- have any other eye conditions

**Other warnings you should know about:**

**Use with contact lenses**

- PRED FORTE contains a preservative called benzalkonium chloride which may discolor soft contact lenses. If you wear contact lenses, remove them before using PRED FORTE. Wait 15 minutes after using the drops before you put your lenses back in.

**Serious allergic reactions**

- PRED FORTE contains sodium bisulphite, a sulphite that may cause a serious allergic reaction, that can be life-threatening. If you have asthma you may be more likely to have this type of allergic reaction.
- While you are using PRED FORTE if you develop a rash, hives, swelling of the face, lips, tongue or throat or have difficulty breathing or swallowing stop using PRED FORTE and seek immediate medical help.

**Driving and using machines**

- Using PRED FORTE may temporarily blur your vision. Do not drive or use machines until your vision has cleared.

**Eye and vision problems**

- Using corticosteroids, like PRED FORTE, may cause eye and vision problems, such as blurred vision, vision loss, increased pressure in your eye (glaucoma), cataracts and other serious conditions. Eye drops containing corticosteroids, like PRED FORTE, should not be used for more than 10 days to reduce the risk of eye and vision problems. If you notice any new eye or vision problems while you are using PRED FORTE talk to your healthcare professional immediately.

**Other effects of corticosteroids**

- Using corticosteroids, like PRED FORTE, can affect your how your body handles infections. Infections caused by bacteria, viruses or fungus can be hidden or can get worse when using PRED FORTE. Your body's ability to fight infection can also be reduced making you more likely to get infections in the eye.
- If you notice any symptoms of infection, such as eye swelling and redness that is not getting better, eye discharge, fever and chills or you have extreme fatigue talk to your healthcare professional immediately.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with PRED FORTE:**

- medicines used to treat HIV infection
- antibiotics used to treat bacterial infections such as; clarithromycin, erythromycin
- antifungals used to treat fungal infections such as; ketoconazole, itraconazole, voriconazole, fluconazole
- aprepitant, a medicine used to treat nausea and vomiting
- medicine used to treat high blood pressure and other heart problems such as; diltiazem, verapamil

**How to take PRED FORTE:**

- Always use PRED FORTE exactly as your healthcare professional has instructed you. Do not stop using PRED FORTE or change your dose without talking to your healthcare professional.
- Shake the bottle well before using.
- Do not use the bottle if the tamper-proof seal on the bottle neck is broken before you first use it.
- To help prevent infections, do not let the tip of the bottle touch your eye or anything else. Put the cap back on and close the bottle immediately after you have used it.

Follow these steps to use PRED FORTE properly:

- Wash your hands. Tilt your head back and look at the ceiling. (See Illustration 1)
- Gently pull down the lower eyelid to create a small pocket. (See Illustration 2)
- Turn the bottle upside down and squeeze it gently to release one drop into the eyelid pocket. If a drop misses your eye, try again. (See Illustration 3)
- Let go of the lower lid and close your eye for 30 seconds. (See Illustration 4)



- Repeat steps 1 – 4 in the other eye if both eyes need treatment.

**Usual dose:**

Apply 1 to 2 drops in the affected eye(s) two to four times daily.

**Overdose:**

An overdose of PRED FORTE in the eye can be washed out with warm water. Do not use more PRED FORTE until it is time for your next dose.

If you think you, or a person you are caring for, have taken too much PRED FORTE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you forget to apply your eye drops at your normal time, apply them as soon as you remember. Then go back to the original schedule as directed by your healthcare professional. Don't try to catch up on missed drops by applying more than one dose at a time.

**What are possible side effects from using PRED FORTE?**

These are not all the possible side effects you may have when taking PRED FORTE. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- blurred vision
- change in taste
- eye irritation, eye pain
- feeling like there is something in your eye
- headache
- large (dilated) pupils
- rash, itching
- slow wound healing

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNKNOWN</b>			
<b>Allergic reaction:</b> difficulty breathing or swallowing, hives, rash, swelling of the face, lips, tongue or throat			√
<b>Glaucoma</b> (increased pressure in the eye): blurred vision, eye redness, halos around lights, loss of vision, nausea, severe eye pain, vomiting			√
<b>Eye infection</b> (bacterial, viral or fungal): itching, pain, redness, sensitivity to bright light, swelling, tearing, yellow discharge or crusts around the eye, eyelid ptosis (drooping or sagging of the upper eyelid)		√	
<b>Scleral thinning or perforation</b> (tear in the eye): blurry vision, decreased vision, excessive tearing, redness, sensitivity to light		√	
<b>Cataracts:</b> clouded, blurry or dim vision, fading or yellowing of colours, trouble seeing at night		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

PRED FORTE should be stored in an upright position, at 15 to 25°C. Protect from freezing.

Keep out of reach and sight of children.

### **If you want more information about PRED FORTE:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: ([www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html](http://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html)) the manufacturer's website [www.abbvie.ca](http://www.abbvie.ca)., or by calling 1-888-704-8271.

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