

PREDNEFRIN® FORTE EYE DROPS

(prednisolone acetate and phenylephrine hydrochloride)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PREDNEFRIN® FORTE eye drops, (including how to use the eye drops). It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using PREDNEFRIN® FORTE eye drops against the benefits they expect it will have for you.

If you have any concerns about using/taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What PREDNEFRIN® FORTE eye drops are used for

PREDNEFRIN® FORTE eye drops are used for the immediate treatment of severe non infectious pain, swelling and redness (inflammation) of the eye, inflammation of the coloured part of the eye (iris), inflammation of the iris and ciliary body, inflammation of the white part of the eye and persistent allergy of the eye. PREDNEFRIN® FORTE eye drops can also be used for the treatment of non infectious inflammation following surgery.

Mechanism of action:

The first active ingredient in PREDNEFRIN® FORTE eye drops, prednisolone acetate, belongs to a chemical group called the glucocorticoids, which reduce pain, swelling and redness. The second active ingredient, phenylephrine hydrochloride, is

responsible for reducing swollen blood vessels in the eye and lid.

Your doctor may have prescribed PREDNEFRIN® FORTE eye drops for another reason. Ask your doctor if you have any questions about why PREDNEFRIN® FORTE eye drops have been prescribed for you.

Before you use PREDNEFRIN® FORTE eye drops

When you must not use it

Do not use PREDNEFRIN® FORTE eye drops if you have:

1. an allergy to PREDNEFRIN® FORTE eye drops or any of the ingredients listed at the end of this leaflet.
2. a severe untreated pus forming eye infection.
3. Herpes simplex of the eye.
4. an ulcer on the front layer of the eyeball.
5. viral diseases of the eye.
6. Tuberculosis (mycobacterial infection) of the eye.
7. fungal infections of the eye.
8. glaucoma

Check with your doctor if:

1. you have a condition in which the pressure of fluid in the eye may be high (glaucoma).
2. you have a disease which causes thinning of the front layer of the eyeball.
3. you have a disease of the artery walls (arteriosclerosis).
4. you have high blood pressure (hypertension).
5. you have a condition where your thyroid gland is overactive (hyperthyroidism).
6. you have an enlarged prostate.
7. you have a condition where your blood sugar levels are too high (diabetes).
8. you have received monoamine oxidase (MAO) inhibitor therapy or you are

within 14 days of stopping such treatment.

9. you are susceptible to allergies or you are an asthmatic.
10. you are pregnant or have the intention of becoming pregnant. Like most medicines, PREDNEFRIN® FORTE eye drops are not recommended during pregnancy unless the benefits outweigh the risks.
11. you are breastfeeding or planning to start breastfeeding. It is not known whether your baby may absorb this medicine from breast milk and therefore there is a possibility of harm to the baby.

Do not use PREDNEFRIN® FORTE eye drops if:

- the seal around the cap is broken,
- the bottle/package shows signs of tampering,
- the expiry date on the bottle or carton has passed.

If you use this medicine after the expiry date has passed, it may not work.

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses. The preservative in PREDNEFRIN® FORTE eye drops (benzalkonium chloride) may be deposited in soft contact lenses. You can put your soft contact lenses back into your eyes 15 minutes after you have used PREDNEFRIN® FORTE eye drops.

It is not known if PREDNEFRIN® FORTE eye drops are safe and useful for children and adolescents under 18 years. It is not recommended to be used in children and adolescents under 18 years.

These drops are for topical use only.

If you are not sure whether you should start using PREDNEFRIN® FORTE eye drops, talk to your doctor.

Before you start to use it

Tell your doctor if:

1. you have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.
2. you have or have had any medical conditions, especially a bacterial, viral or fungal disease.

If you have not told your doctor about any of the above, tell them before you use PREDNEFRIN® FORTE eye drops.

Taking other medicines

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

There are no known drug interactions with PREDNEFRIN® FORTE eye drops.

How to use PREDNEFRIN® FORTE eye drops

How much to use

The usual dosage of PREDNEFRIN® FORTE eye drops is one to two drops in the eye(s) two to four times daily. During the initial 24 to 48 hours your doctor may increase the dosage to two drops every hour.

Do not stop using PREDNEFRIN® FORTE eye drops even if you feel well unless instructed by your doctor.

Your doctor will tell you how many drops you need to use each day. Use PREDNEFRIN® FORTE eye drops only as prescribed by your doctor.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

Use PREDNEFRIN® FORTE eye drops every day, at about the

same time each day, unless your doctor tells you otherwise. Using your eye drops at the same time each day will have the best effect on your condition. It will also help you remember when to use the eye drops.

If you are using more than one eye drop product, wait 5 minutes before using the second product.

If you are being changed from one eye drop to another, follow your doctor's instructions carefully as to when to stop the old drops and when to start the new drops.

How to use it

You may find it easier to put drops in your eye while you are sitting or lying down.

If you are wearing soft contact lenses, remove them before putting the drops in your eye.

To open a new bottle of PREDNEFRIN® FORTE eye drops, first tear off the protective seal from the bottle. The seal will break and you can pull it off and then throw it away.

1. Wash your hands well with soap and water.
2. Shake the bottle gently.
3. Remove the cap.
4. Hold the bottle upside down in one hand between your thumb and forefinger or index finger.
5. Using your other hand, gently pull down your lower eyelid to form a pouch or pocket.
6. Tilt your head back and look up.
7. Put the tip of the bottle close to your lower eyelid. Do not let it touch your eye.
8. Release one drop into the pouch or pocket formed between your eye and eyelid by gently squeezing the bottle.
9. Close your eye. Do not blink or rub your eye.
10. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from

where it can be absorbed into other parts of your body. Ask your doctor for more specific instructions on this technique.

11. Replace the cap, sealing it tightly.
12. Wash your hands again with soap and water to remove any residue.

Wait 15 minutes before replacing your contact lenses.

Be careful not to touch the dropper tip against your eye, eyelid or anything else to avoid contaminating the eye drops. Contaminated eye drops may give you an eye infection.

How long to use it

Continue using PREDNEFRIN® FORTE eye drops for as long as your doctor prescribes.

PREDNEFRIN® FORTE eye drops contain a corticosteroid. Corticosteroid eye drops should not be used for more than 10 days, except under strict supervision by your doctor.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use the drops as soon as you remember, and then go back to using/taking them as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not use double the amount to make up for the dose that you missed.

If you use too much (overdose)

If you accidentally put several drops in your eye(s), immediately rinse your eye(s) with warm water.

If you think that you or anyone else may have swallowed any or all of the contents of a bottle of PREDNEFRIN® FORTE eye drops, drink fluids to dilute and immediately telephone your doctor or Poisons Information Centre

(telephone 13 11 26) for advice, or go to casualty at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are using PREDNEFRIN® FORTE eye drops

Things you must do

If you develop an eye infection, receive an eye injury, or have eye surgery tell your doctor.

Your doctor may tell you to use a new container of PREDNEFRIN® FORTE eye drops because of possible contamination of the old one, or may advise you to stop your treatment with PREDNEFRIN® FORTE eye drops.

If you become pregnant while using PREDNEFRIN® FORTE eye drops tell your doctor immediately.

If you wear soft contact lenses, remove them before using PREDNEFRIN® FORTE eye drops. Leave your lenses out for at least 15 minutes after putting in the eye drops.

Tell your doctor if your condition gets worse or does not get better while using PREDNEFRIN® FORTE eye drops.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are using PREDNEFRIN® FORTE eye drops.

Things you must not do

Do not give PREDNEFRIN® FORTE eye drops to anyone else, even if they have the same condition as you.

Do not stop using PREDNEFRIN® FORTE eye drops without first talking to your doctor.

Things to be careful of

Your vision may blur for a short time after you put in your PREDNEFRIN® FORTE eye drops. If this happens you should

wait until you can see well again before you drive or use machinery.

PREDNEFRIN® FORTE eye drops may cause the pupils to get dilated (get bigger) or transient blurring of vision which may impair the ability to drive a car or operate machinery. Wait until your vision has cleared. Be careful driving or operating machinery until you know how PREDNEFRIN® FORTE eye drops affect you.

Use of PREDNEFRIN® FORTE eye drops after cataract surgery may delay healing and increase the likelihood of blister formation on the eye.

If you experience blurred vision or other visual disturbances while using PREDNEFRIN® FORTE eye drops, tell your doctor immediately.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using PREDNEFRIN® FORTE eye drops. PREDNEFRIN® FORTE eye drops help most people with severe inflammation of the eye, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Some side effects of PREDNEFRIN® FORTE eye drops are:

- increased pressure in the eye
- formation of cataract, i.e. blurred vision
- viral, bacterial or fungal infections of the eye
- perforation of the tissues of the eye
- eye irritation

- vision blurred/vision disturbances
- dilation of the pupil
- dry eye
- eye discharge
- eye pain
- foreign body sensation
- eye pruritus (itchy eye)
- increased flow of tears
- ocular hyperemia (red eye)
- droopy eyelid (ptosis)

There can also be effects on the body as a whole such as allergy, rash, headache, altered taste and itching.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects and they worry you.

After using PREDNEFRIN® FORTE eye drops

Storage

Keep your eye drops in a cool place where the temperature stays below 25°C. Store upright. Do not freeze the eye drops.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Do not carry the eye drops in pockets of your clothes. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not leave the top/lid off the bottle for any length of time to avoid contaminating the eye drops.

Disposal

Write the date on the bottle when you open the eye drops and throw out any remaining solution after four weeks.

Eye drops contain a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle. After this time there is a

greater risk that the drops may become contaminated and cause an eye infection. A new bottle should be opened.

If your doctor tells you to stop using the eye drops or they have passed their expiry date, ask your pharmacist what to do with any remaining solution.

Product description

What it looks like

The eye drops come in a 10 mL sterile plastic bottle.

Ingredients

Active ingredients: Prednisolone acetate 10 mg/mL (1%) and phenylephrine hydrochloride 1.2 mg/mL (0.12%).

Inactive ingredients: benzalkonium chloride 0.04 mg/mL (0.004%), phenazone, polysorbate 80, boric acid, sodium citrate, sodium chloride, sodium metabisulfite, disodium edetate, hypromellose, and purified water.

Manufacturer/Supplier

*AbbVie Pty Ltd
Mascot NSW 2020
AUSTRALIA*

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