

PREDNEFRIN® FORTE

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using PREDNEFRIN® FORTE?

PREDNEFRIN® FORTE eye drops contain the active ingredients phenylephrine hydrochloride and prednisolone acetate. PREDNEFRIN® FORTE is used to treat severe inflammation (pain, swelling and redness) of the eye that is NOT caused by an infection and persistent allergy of the eye.

For more information, see Section [1. Why am I using PREDNEFRIN® FORTE?](#) in the full CMI.

2. What should I know before I use PREDNEFRIN® FORTE?

Check the list of ingredients at the end of the CMI. Do not use PREDNEFRIN® FORTE if you have ever had an allergic reaction to any of them.

Talk to your doctor before you use this medicine if he/she is not aware that you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use PREDNEFRIN® FORTE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PREDNEFRIN® FORTE and affect how it works, or PREDNEFRIN® FORTE may interfere with other medicines and affect how they work.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use PREDNEFRIN® FORTE?

- Your doctor will tell you the number of drops to use, when to use PREDNEFRIN® FORTE and how long to use it.

More instructions can be found in Section [4. How do I use PREDNEFRIN® FORTE?](#) in the full CMI.

5. What should I know while using PREDNEFRIN® FORTE

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist,
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	<p>or optometrist you visit that you are using PREDNEFRIN® FORTE®.</p> <ul style="list-style-type: none"> • Follow all your doctor's instructions carefully. • Keep all your follow-up appointments so your condition can be closely checked.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly. • Do not touch the dropper tip against your eye, eye lid or any surface. • Do not use PREDNEFRIN® FORTE while you are wearing contact lenses.
Driving or using machines	<ul style="list-style-type: none"> • Wait for your vision to clear after using PREDNEFRIN® FORTE before you drive or use machines.
Drinking alcohol	<ul style="list-style-type: none"> • There is no information on the effects of using PREDNEFRIN® FORTE with alcohol.

Looking after your medicine	<ul style="list-style-type: none"> • Follow all instructions on the carton and bottle label. • Store upright in a cool dry place, below 25°C, away from moisture, heat, or sunlight. Do not freeze.
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For more information, see Section [5. What should I know while using PREDNEFRIN® FORTE?](#) in the full CMI.

6. Are there any side effects?

Increased pressure in the eye, eye irritation, dilation (widening) of the pupil, dry eye, eye discharge, eye infection, eye pain, foreign body sensation, itchy eye, watery eye(s), eye redness, blurry vision or changes in vision, headache, changes to taste, itchy, red skin rash, severe allergic reaction.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

PREDNEFRIN® FORTE (pred-nef-frin forte)

Active ingredients: [*phenylephrine hydrochloride & prednisolone acetate*] (fen-nil-ef-rin hi-dro-chlor-ride & pred-nis-so-lone as-see-tate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using PREDNEFRIN® FORTE eye drops. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PREDNEFRIN® FORTE.**

Where to find information in this leaflet:

- [1. Why am I using PREDNEFRIN® FORTE?](#)
- [2. What should I know before I use PREDNEFRIN® FORTE ?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use PREDNEFRIN® FORTE?](#)
- [5. What should I know while using PREDNEFRIN® FORTE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using PREDNEFRIN® FORTE?

PREDNEFRIN® FORTE contains the active ingredients phenylephrine hydrochloride and prednisolone acetate.

PREDNEFRIN® FORTE is used to treat severe inflammation (pain, swelling and redness) of the eye that is NOT caused by an infection.

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.

2. What should I know before I use PREDNEFRIN® FORTE?

Warnings

Do not use PREDNEFRIN® FORTE if:

- you are allergic to phenylephrine hydrochloride, prednisolone acetate, or any of the ingredients listed at the end of this leaflet.
- you have **any** infection in or around the eye (bacterial, viral or fungal)
- you have an open sore on the front layer of the eyeball

- you have glaucoma (increased pressure in the eye).

Check with your doctor if you:

- have any condition which might cause thinning of the front layer of the eyeball
- have thickening of the walls of blood vessels (arteriosclerosis)
- have or have had high blood pressure
- have an overactive thyroid
- have an enlarged prostate
- have diabetes
- are susceptible to allergies
- have or have had adrenal suppression (body doesn't make enough hormones, which can make you feel tired and weak)
- have or have had asthma
- take any medicines for any other condition.

The use of steroids after cataract surgery may delay healing.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Make sure your doctor is aware that you are pregnant or plan to become pregnant or are breastfeeding or intend to breastfeed.

Use in children

Use of PREDNEFRIN® FORTE is not recommended in children or adolescents younger than 18 years of age.

3. What if I am taking other medicines?

Tell your doctor, pharmacist or optical practitioner if you are using any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with PREDNEFRIN® FORTE and affect how it works; while PREDNEFRIN® FORTE may affect how other medicines work.

Do not use PREDNEFRIN® FORTE if:

- you are taking specific medicines to treat depression called "monoamine oxidase (MAO) inhibitors," tricyclic antidepressants, or you have taken them in the last 14 days.

There is a small chance that taking certain CYP3A inhibitor medicines, like some antibiotics, antifungal, and antiretroviral drugs, could increase your risk of having side effects.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are using and if these affect PREDNEFRIN® FORTE.

4. How do I use PREDNEFRIN® FORTE?

How much to use

- use one to two drops in the affected eye(s), according to your doctor's instructions.

When to use PREDNEFRIN® FORTE

- Use PREDNEFRIN® FORTE as instructed by your doctor.
- Make sure you understand how frequently you should use it and when to start using it and when to finish using it.

In some instances, PREDNEFRIN® FORTE needs to be used with other eye drops. Your doctor will let you know which drops, how to use them and how long to use them.

Wait at least 5 to 10 minutes after using PREDNEFRIN® FORTE before using other eye drops.

How to use PREDNEFRIN® FORTE

1. If you wear contact lenses, remove them before using PREDNEFRIN® FORTE.
2. Wash your hands well with soap and water.
3. Shake the bottle well.
4. Tear off the protective seal on any new bottle and throw the seal away. Remove the lid/cap.

5. Hold the bottle upside down in one hand between your thumb and index finger.
6. Using your other hand, gently pull down your lower eyelid to form a pouch or pocket.
7. Tilt your head back and look up. This might be easier if you are sitting or lying down.
8. Put the tip of the bottle close to your lower eyelid. Do not let the tip touch your eye or eyelid.
9. Release one drop into the pouch or pocket formed between your eye and eyelid by gently squeezing the bottle.
- 10 If a drop misses your eye, try again, and wipe off any excess that runs down your cheek.
- 11 Close your eye. Do not blink or rub your eye or eyelid.
- 12 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.
- 13 Replace the lid/cap, sealing it tightly.
- 14 Wash your hands again with soap and water.
- 15 If you wear contacts, wait 15 minutes before replacing your contact lenses.

If you forget to use PREDNEFRIN® FORTE

It is important that you use PREDNEFRIN® FORTE according to your doctor's instructions.

If you forget to use PREDNEFRIN® FORTE and 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.

Do not use double the number of drops to make up for the dose you missed.

If you use too much PREDNEFRIN® FORTE

Immediately rinse your eyes with warm water.

If PREDNEFRIN® FORTE is accidentally swallowed, you should immediately:

- **phone the Poisons Information Centre (by calling 13 11 26), or**
- **contact your doctor, or**
- **go to the Emergency Department at your nearest hospital.**

You should do this even if there appears to be no signs of discomfort or poisoning.

5. What should I know while using PREDNEFRIN® FORTE?

Things you should do

- **Follow all of your doctor's instructions carefully.**

- If you wear soft contact lenses, remove them before using PREDNEFRIN® FORTE, and wait at least 15 minutes before inserting them again. The preservative in PREDNEFRIN® FORTE eye drops (benzalkonium chloride) may be absorbed and cause discolouration of soft contact lenses.
- Keep all your follow-up appointments with your doctor so your eye(s) can be checked.
- Use all the medication prescribed to treat your eye condition.
- Keep the bottle tightly sealed to avoid contaminating the eye drops.

Call your doctor straight away if:

- you develop an eye infection, receive an eye injury, or have eye surgery
- you develop blurred vision or you notice any changes in your vision
- you become pregnant while using PREDNEFRIN® FORTE
- your eye(s) seem(s) to be getting worse or is/are not improving.

Remind any doctor, dentist, pharmacist, or optometrist you visit that you are using PREDNEFRIN® FORTE.

Things you should not do

- Do not touch the dropper tip against your eye, eyelid, or anything else, to avoid contaminating the eye drops. 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.

- Do not stop using this medicine suddenly without checking with your doctor.

Driving or using machines

Wait for your vision to clear after using PREDNEFRIN® FORTE before you drive or use machines.

Looking after your medicine

Follow the instructions on the carton and bottle label on how to take care of your medicine properly.

Store PREDNEFRIN® FORTE upright.

Store it in a cool dry place away from moisture, heat or sunlight; for example:

- do not store it in the bathroom or near a sink, or
- do not store it in the car or on window sills.

Do not freeze the eye drops.

Keep it where young children cannot reach it.

When to discard your medicine

Discard the bottle 4 weeks after first opening it.

Getting rid of any unwanted medicine

If your doctor advises that you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not open a new bottle to use it if the expiry date has passed.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Effects on the eye: <ul style="list-style-type: none">• increased pressure in the eye• eye irritation• dilation (widening) of the pupil• dry eye• eye discharge	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> • eye pain • foreign body sensation • itchy eye • watery eye(s) • eye redness • droopy eye lid <p>Effects on the body as a whole:</p> <ul style="list-style-type: none"> • headache • changes to taste • itchy, red skin rash. 	

Serious side effects

Serious side effects	What to do
<p>Effects on the eye:</p> <ul style="list-style-type: none"> • eye infection • blurry vision or changes in vision. 	<p>Call your doctor straight away, if you notice any of these serious side effects.</p>
<p>Effect on the body as a whole:</p> <ul style="list-style-type: none"> • severe allergic reaction, including swelling of the tongue, lips and throat, difficulty breathing. 	<p>Go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop using any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What PREDNEFRIN® FORTE contains

Active ingredients (main ingredients)	<ul style="list-style-type: none">• phenylephrine hydrochloride• prednisolone acetate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• boric acid• disodium edetate• hydrochloric acid

	<ul style="list-style-type: none"> • hypromellose • phenazone • polysorbate 80 • purified water • sodium chloride • sodium citrate dihydrate • sodium hydroxide • sodium metabisulfite
Potential allergens	<ul style="list-style-type: none"> • benzalkonium chloride

Do not use this medicine if you are allergic to any of these ingredients.

What PREDNEFRIN® FORTE looks like

PREDNEFRIN® FORTE is a milky suspension. It is supplied in a plastic dropper bottle containing 10 mL of liquid. (Aust R 23235).

Who distributes PREDNEFRIN® FORTE?

PREDNEFRIN® FORTE is distributed in Australia by:

AbbVie Pty Ltd

Mascot NSW 2020

Australia

Toll-free: 1800 252 224

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