

POLARAMINE® Repetabs (Red and Colour Free), Tablets (Red and Colour Free) and Syrup

Dexchlorpheniramine maleate

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about Polaramine. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking Polaramine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What POLARAMINE is used for

Polaramine relieves symptoms associated with allergic rhinitis (including hayfever), such as sneezing, runny or itchy nose, and burning or itchy eyes.

Polaramine may also be used to relieve symptoms associated with hives (also known as chronic urticaria). These symptoms include itching, redness and lumps on the skin.

Polaramine can also be used to treat drug reactions.

Polaramine belongs to a class of medicines known as antihistamines.

Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine. Histamine is produced by the body in response to foreign substances which the body is allergic to.

Your doctor or pharmacist may have prescribed Polaramine for another reason.

Ask your doctor or pharmacist if you have any questions about why Polaramine has been prescribed for you.

There is no evidence that Polaramine is addictive.

Before you take POLARAMINE

When you must not take it

Do not take Polaramine if:

- **you are allergic to it or any of the ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction may include skin rash, difficulty in breathing or faintness.

- **You are also taking medicines used to treat depression such as monoamine oxidase inhibitor (MAOI).**

Taking Polaramine together with a MAOI may exaggerate the effects of Polaramine and cause a severe drop in your blood pressure.

Do not give Polaramine Syrup to children under 2 years of age.

Do not give Polaramine Tablets and Repetabs to children less than 12 years.

Do not take Polaramine after the expiry date (EXP) printed on the pack.

Do not take Polaramine if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using Polaramine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, any other substances such as foods, dyes or preservatives

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

If you are in the third trimester of pregnancy, you must tell your doctor you are taking Polaramine because newborn babies may have severe reactions to antihistamine.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.

Polaramine may be transferred in breast milk to your baby.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- seizures
- liver or kidney disease
- an overactive thyroid gland
- heart disease
- high blood pressure
- raised pressure in the eye
- prostate problems
- difficulty passing urine
- a narrowing or blockage between the stomach and small intestine which causes vomiting of undigested food
- peptic ulcer

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Polaramine.

Taking other medicines

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

Some medicines should not be taken with Polaramine. These include: monoamine oxidase inhibitor (MAOI).

These medicines may be affected by Polaramine and may cause a decrease in blood pressure.

Polaramine may interfere with other medicines. These include:

- alcohol
- medicines used to treat depression such as tricyclic antidepressants
- strong / narcotic pain killers, such as codeine, morphine and dextropropoxyphene
- some medicines used to help you sleep
- some medicines used to treat anxiety
- some medicines used to stop blood clotting, such as warfarin

These medicines may be affected by Polaramine, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Polaramine.

How to take POLARAMINE

How much to take

Polaramine Tablets (Red or Colour Free)

Adults and children over 12 years: One Polaramine tablet every 6 hours

After initial relief is obtained, dosage may be reduced to 1 tablet as required.

Polaramine Repetabs (Red or Colour Free)

Adults and children over 12 years: One Polaramine Repetab tablet swallowed whole, every 12 hours.

After initial relief is obtained, dosage may be reduced to 1 tablet as required.

Do not give Polaramine Tablets and Repetabs to children under 12 years of age.

Do not crush or chew the Repetabs.

This will affect the slow release timing.

Do not take more than 2 doses of the Repetabs in 24 hours.

Polaramine Syrup

Adults and children over 12 years: 5mL every 6 hours

Children 6 to 12 years: 2 to 4mL every 6 to 8 hours

Children 4 to 6 years: 1.75 to 2mL every 6 to 8 hours

Children 2 to 4 years: 1.25 to 1.75mL every 6 to 8 hours

Do not give Polaramine Syrup to children under 2 years of age.

Take Polaramine exactly as your doctor or pharmacist has told you to.

If you take the wrong dose, Polaramine may not work as well and you may not get relief from your symptoms.

How to take it

Swallow the tablet whole with a glass of water.

Do not crush or chew the Repetabs.

These tablets have a special coating. If you crush or chew them, it will affect the coating and may not work as well.

When to take it

It does not matter if you take Polaramine before or after food.

How long to take it

Continue taking Polaramine until your symptoms have resolved.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking your medicine as you would normally

If you are not sure what to do, ask your doctor or pharmacist

If you have trouble remembering to take your medicine, ask your pharmacist for some hints

If you take too much (overdose)

Immediately telephone your doctor, pharmacist or Poisons Information Centre (13 11 26) for advice, or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much Polaramine

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Polaramine, you may feel dizzy or light-headed and may have difficulty breathing.

While you are taking POLARAMINE

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking Polaramine.

If you become pregnant while taking Polaramine, tell your doctor

Things you must not do

Do not give Polaramine to anyone else, even if their symptoms seem similar to yours.

Do not take Polaramine to treat any other complaints unless your doctor or pharmacist says to.

Do not drink alcohol while taking Polaramine.

The effects of alcohol can be increased by some antihistamine medicines, including Polaramine. If you drink alcohol, the drowsiness, dizziness or light-headedness may become worse.

If you feel tired, drowsy, dizzy or light-headed, do not drive a vehicle or operate machinery.

As with some other antihistamine medicines, Polaramine may cause tiredness, drowsiness, dizziness or light-headedness in some people.

Things to be careful of

Protect your skin when you are in the sun, especially between 10am and 3pm.

If you are outdoors, wear protective clothing and use a 30+ sunscreen.

Polaramine may cause your skin to be more sensitive than it is normally.

If your mouth continues to feel dry for more than 2 weeks check with your doctor or dentist.

Antihistamines may cause dryness of the mouth, nose and throat

Stop taking Polaramine 48 hours before you have any skin tests.

Antihistamines may interfere with the results of skin tests

Side effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the times they are not. Your doctor or pharmacist has weighed the risk of using this medicine against the benefit they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

All medicines have side effects. You may need medical treatment if you get some of the side effects

Ask your doctor or pharmacist any questions you may have.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Polaramine.

It helps most people with allergies, but it may have unwanted side effects in a few people.

If you are over 60 years of age you may have an increased chance of getting side effects

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- sleepiness
- upset stomach
- loss of appetite
- thickening of mucus
- stuffy nose
- tight chest
- dry mouth, nose or throat

These are mild side effects of medicines, and usually short lived.

Tell your doctor immediately if you notice any of the following:

- wheezing or being short of breath
- fast, pounding or irregular heart beats
- skin rash
- tiredness, headache, dizziness, spinning sensation, with yellowing of the skin and/or eyes
- unable or difficulty passing urine
- passing urine more often than usual
- hallucinations
- tingling or numbness in the hands or feet, also known as 'pins and needles'

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop taking Polaramine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- chest pain
- sudden signs of allergy such as rash, hives
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- convulsions, fits or seizures
- coma

These are very serious side effects. You may need urgent medical attention or hospitalisation.

All of these side effects are very rare.

Other side effects not listed above may also occur in some patients.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After taking POLARAMINE

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take your tablets out, they will not keep well.

Keep the medicines in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car on hot days.

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

Disposal

If your doctor or pharmacist tells you to stop taking the tablets, Repetabs or the Syrup, or they have passed the expiry date, ask your pharmacist what to do with any that are left over.

Product description

Polaramine can be bought without a doctor's prescription.

What it looks like

Polaramine comes in three forms:

Tablets (Red or Colour Free)

Repetabs (Red or Colour Free)

Syrup

Polaramine Tablets 2mg Red are dark pink, oval tablets with the Flask and Bowl logo embossed on one side, in blister packs of 25 and 40 tablets.

Polaramine Colour Free Tablets 2mg are off-white, round, bevelled tablet with Flask and Bowl logo on one side, and scored on the other side, in blister packs of 25 and 50 tablets.

Polaramine Repetabs 6mg Red are red, oval sugar coated tablets, with a white Flask and Bowl logo on one side, in blister packs of 20 and 40 tablets.

Polaramine Colour Free Repetabs 6mg are white to off white oval coated tablets, in blister packs of 20 and 40 tablets.

Polaramine Syrup 2mg/5mL is a clear, red syrup with an orange like flavour in a 100 mL bottle.

Ingredients

Polaramine tablets contain:

Active ingredient: 2mg dexchlorpheniramine maleate

Inactive ingredients:

- lactose
- starch-maize
- gelatin
- magnesium stearate
- brilliant scarlet 4R

Polaramine Colour Free Tablets contain:

Active ingredient: 2mg dexchlorpheniramine maleate

Inactive ingredients:

- lactose
- starch-maize
- starch-pregelatinised maize
- magnesium stearate

Polaramine Repetabs contain:

Active ingredient:

6mg dexchlorpheniramine maleate

Inactive Ingredients:

- carnauba wax
- beeswax - white
- zein
- gelatin
- lactose
- starch-maize
- magnesium stearate
- acacia
- calcium sulfate
- sucrose

- butyl hydroxybenzoate
- colophony
- oleic acid
- talc - purified
- calcium phosphate
- neutral white soap
- erythrosine
- sunset yellow FCF.

Polaramine Colour Free Repetabs contain:

Active ingredient: 6mg dexchlorpheniramine maleate

Inactive ingredients:

- carnauba wax
- beeswax-white
- zein
- gelatin
- lactose
- starch-maize
- magnesium stearate
- acacia
- calcium sulfate
- colophony
- sucrose
- oleic acid
- talc - purified
- calcium phosphate
- neutral white soap
- methyl hydroxybenzoate.

Polaramine Syrup contains:

Active ingredient:

2mg/5mL dexchlorpheniramine maleate

Inactive Ingredients:

- sodium citrate
- sodium chloride
- sucrose
- sorbitol
- methyl hydroxybenzoate
- propyl hydroxybenzoate
- menthol
- ethanol
- water
- brilliant scarlet 4R
- apricot flavour
- blood orange flavour

Sponsor

Schering-Plough Pty Limited
Level 4, 66 Waterloo Road
North Ryde NSW 2113
AUSTRALIA

Australian Registration Numbers

Red Tablets: AUST R 18198
Red Repetabs: AUST R 18195
Syrup: AUST R 18197

Colour Free tablets: (currently not marketed)

AUST R 154653

Colour Free Repetabs: (currently not marketed)

AUST R 154654

Date of Preparation

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