POLARAMINE(R) Syrup, REPETABS(R) & Tablets

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 (hayfever), such as sneezing, runny or itchy nose, and burning or itchy eyes.

POLARAMINE may also be used to relieve symptoms associated with a skin condition called chronic urticaria (also called hives); 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, however, may prescribe POLARAMINE for another purpose.

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 have an allergy to POLARAMINE 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 taking a medicine for depression called a monoamine oxidase inhibitor (MAOI) or

have been taking it within the last 14 days.

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

Ask your pharmacist if you are not sure if you are taking one of these medicines.

* You are in the third trimester of pregnancy or are breastfeeding unless you and your doctor or pharmacist have discussed the risks and benefits involved.

Newborn and premature infants may have severe reactions to medicines like POLARAMINE.

Do not give POLARAMINE to children less than 1 year old without medical advice.

Do not take POLARAMINE after the expiry date 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 pharmacist.

Before you start to take it

You must tell your doctor or pharmacist:

* if you are allergic to any other medicines or any foods, dyes or preservatives

* if you have liver disease, heart disease, asthma, glaucoma or any other medical conditions.

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 and POLARAMINE may interfere with each other.

How to take POLARAMINE

How much to take

POLARAMINE REPETABS

Adults and children over 12 years: One POLARAMINE REPETAB tablet swallowed whole, every 12 hours

Do not crush or chew the REPETABS because this will affect the slow release timing. Do not take more than 2 doses of the REPETABS in 24 hours.

POLARAMINE Tablets

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

Children 6 to 12 years:

Half a tablet every 6 to 8 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

Children 1 to 2 years:

1 to 1.25mL every 6 to 8 hours

Be sure to take POLARAMINE exactly as your doctor or pharmacist has told you to.

If you do not follow their instructions, you may not get relief from your symptoms.

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

How to take it

Tablets and Syrup: Take it with a glass of water.

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.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

If you take too much (overdose)

Immediately telephone your doctor, pharmacist or Poisons Information Centre (13 11 26 in Australia or 0800 764 766 in New Zealand) 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. Keep telephone numbers for these places handy.

While you are taking POLARAMINE

Things you must do

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

Tell your doctor or pharmacist if you become pregnant while you are taking POLARAMINE.

Things you must not do

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

Do not use it to treat any other complaints unless your doctor or pharmacist says to.

Make sure you know how you react to POLARAMINE before you drive a car or operate machinery.

POLARAMINE may cause drowsiness and sleepiness. It may also affect your ability to react quickly, even if you don't feel drowsy or sleepy. If you are drowsy, do not drive a car or work with machinery.

Do not drink alcohol while taking POLARAMINE.

The effects of alcohol can be increased by some antihistamine medicines, including POLARAMINE

Things to be careful of

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

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

Antihistamines may cause dryness of the mouth, nose and throat.

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

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

Antihistamines may interfere with the results of skin tests.

Side effects

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

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

Like other medicines, POLARAMINE can cause some side effects. If they occur, they are most

However, some may be serious and need medical attention.

likely to be minor and temporary.

Ask your doctor or pharmacist any questions you may have.

The most commonly reported unwanted events are:

- * sleepiness
- * thickening of mucus, tight chest, stuffy nose
- upset stomach and loss of appetite

Less common side effects include:

Skin rash, symptoms of sunburn which may occur more quickly than normal, sweating, dry mouth/nose/throat, dizziness, lightheadedness and headache, bleeding or bruising more easily than normal, hallucinations, blurred or double vision,

restlessness/nervousness, tremor, difficult or painful urination.

Other unwanted effects may occur in some people taking POLARAMINE.

Other side effects not listed above may also occur in some patients. If you notice any other side effects, check with your doctor or pharmacist.

After taking POLARAMINE

Storage

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

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

Keep your syrup in the bottle until it is time to take it.

Keep your tablets/syrup in a cool dry place where the temperature stays below 30 degrees C. Do not let the syrup freeze

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

Disposal

If your doctor or pharmacist tells you to stop taking POLARAMINE or the medicine has 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

There are three forms of POLARAMINE - POLARAMINE tablets, POLARAMINE REPETABS and POLARAMINE syrup.

- POLARAMINE tablets (2mg) are dark pink oval tablets. They are available in packs of 25 & 50 tablets.
- POLARAMINE REPETABS (6mg) are red, sugar-coated repeat action tablets available in packs of 20 and 40 tablets.

POLARAMINE Syrup (2mg/5mL) is a red, honey-lemon & peppermint flavoured syrup in a 100mL bottle.

Ingredients

POLARAMINE tablets contain:

Dexchlorpheniramine maleate 2mg

Inactive ingredients:

Lactose, starch-maize, gelatin, magnesium stearate, brilliant scarlet 4R CI6255

POLARAMINE REPETABS contain:

Dexchlorpheniramine maleate 6mg

Inactive Ingredients:

Carnauba wax, white beeswax, erythrosine CI45430, sunset yellow FCF CI45430, zein, gelatin, lactose, starch-maize, magnesium stearate, acacia, calcium sulfate, sucrose, butyl hydroxybenzoate, colophony, oleic acid, purified talc, calcium phosphate, soap eidermere

POLARAMINE syrup contains:

Dexchlorpheniramine maleate 2mg/5mL

Inactive Ingredients:

sodium citrate, sodium chloride, sorbitol, methylhydroxy benzoate, propylhydroxy benzoate, menthol, ethanol, brilliant scarlet 4R CI6255, water, imitation apricot, orange flavour

Supplier

In Australia:

Schering-Plough Pty Limited 11 Gibbon Road Baulkham Hills NSW 2153 AUSTRALIA

In New Zealand: Schering-Plough Pty Limited 33 Whakatiki St Upper Hutt, Wellington NEW ZEALAND

Australian Registration Numbers Tablets, 25s and 50s AUST R 18198 REPETABS, 20s & 40s AUST R 18195 Syrup, 100mL AUST R 18197

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