DEMAZIN COLD RELIEF Syrup, Clear Syrup, Infant Drops and Clear Infant Drops

Chlorpheniramine Maleate and Phenylephrine Hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DEMAZIN COLD RELIEF Syrups and Infant Drops. 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 DEMAZIN COLD RELIEF 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 DEMAZIN COLD RELIEF is used for

DEMAZIN COLD RELIEF provides relief of upper respiratory congestion associated with common cold, nasal allergy, hayfever, and sinusitis.

DEMAZIN COLD RELIEF contains a combination of two medicines, an antihistamine and a decongestant.

Antihistamines help reduce allergic symptoms such as sneezing, runny or itchy nose, and burning or itchy eyes, 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.

Decongestants produce narrowing of blood vessels. This leads to clearing of stuffy or blocked noses.

Your doctor or pharmacist, however, may have given you DEMAZIN COLD RELIEF for another purpose.

Ask your doctor or pharmacist if you have any questions about why this medicine has been given to you.

DEMAZIN COLD RELIEF can be used in adults and children.

Before you take DEMAZIN COLD RELIEF

When you must not take it

Do not take DEMAZIN COLD RELIEF if:

• you have an allergy to DEMAZIN COLD RELIEF or to any of the ingredients listed at the end of this leaflet

Do not give DEMAZIN COLD RELIEF to newborn or premature infants.

Do not take DEMAZIN COLD RELIEF if you have, or have had, any of the following medical conditions:

- narrow angle glaucoma
- difficulty passing urine
- severe high blood pressure
- severe blood vessel disease
- an overactive thyroid gland

Do not take DEMAZIN COLD RELIEF if you are taking or within 14 days of discontinuing monoamine oxidase inhibitors (MAOIs), medicines used to treat depression. Do not take DEMAZIN COLD RELIEF if you are pregnant or breastfeeding unless you and your doctor or pharmacist have discussed the risks and benefits involved.

Do not take DEMAZIN COLD RELIEF after the expiry date printed on the pack.

Do not take DEMAZIN COLD RELIEF if the packaging is torn or shows signs of tampering.

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, preservatives or dyes

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

- eye problems (such as high pressure in the eye or glaucoma)
- stomach ulcer
- intestinal obstruction
- prostate or urinary bladder problems
- heart disease
- diabetes
- if you are 60 years of age or older (older adults may be more sensitive to the effects of this medicine)

Do not give DEMAZIN COLD RELIEF to children who have breathing problems (e.g. chronic bronchitis) and children with asthma, liver disease or seizure disorders unless under the direction of your doctor.

If you have not told your doctor or pharmacist about any of the above, tell them before you take DEMAZIN COLD RELIEF, or before you start giving this medicine to a child.

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 DEMAZIN COLD RELIEF. These include:

- monoamine oxidase inhibitors, medicines used to treat depression
- some medicines used to treat heart or blood pressure
- antidepressants
- medicines to prevent blood clots
- antacids / kaolin
- appetite suppressants

These medicines may be affected by DEMAZIN COLD RELIEF, 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.

How to take DEMAZIN COLD RELIEF Syrup: Adults

15mL every 6 hr Children 12 years & over: 15mL every 6 hr 6-12 years: 8-15mL every 6-8 hr

- 4-6 years: 6-8mL every 6-8 hr
- 2-4 years: 4-6mL every 6-8 hr

Infant Drops with Dropper:

Children

1-2 years: 3.5-4mL every 6-8 hr

6-12 months: 2.5-3.5mL every 6-8 hr

3-6 months: 2-2.5mL every 6-8 hr

1-3 months: 1.5-2mL every 6-8 hr

Use the dropper to measure the correct amount in infants. Rinse the dropper with hot water after use.

DEMAZIN COLD RELIEF can be taken with or without food.

Be sure to take DEMAZIN COLD RELIEF exactly as your doctor or pharmacist has told you to. If symptoms persist for more than 48 hours or are accompanied by high fever, consult your doctor.

Do not take more DEMAZIN COLD RELIEF than recommended by your doctor or pharmacist.

Nervousness, dizziness or sleeplessness may occur at higher dose.

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 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 DEMAZIN COLD RELIEF. 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 DEMAZIN COLD RELIEF

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking DEMAZIN COLD RELIEF.

Tell your doctor or pharmacist if you become pregnant while you are taking DEMAIN COLD RELIEF.

Things you must not do

Do not give DEMAZIN COLD RELIEF 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.

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Things to be careful of

DEMAZIN COLD RELIEF may cause drowsiness. Make sure you know how you react to this medicine before you drive a car or operate machinery.

DEMAZIN COLD RELIEF contains sorbitol which may have a laxative effect or cause diarrhoea in some people.

Stop taking DEMAZIN COLD RELIEF 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 using DEMAZIN COLD RELIEF.

DEMAZIN COLD RELIEF helps most people, but it may have unwanted effects in a few people.

Like other medicines, DEMAZIN COLD RELIEF can cause some side effects. If they occur, they are most likely to be minor and temporary.

Ask your doctor or pharmacist to answer any questions you may have.

Most unwanted effects seen with DEMAZIN COLD RELIEF have been mild to moderate. These include:

- drowsiness
- hives / rash
- increased sensitivity to sunlight
- excessive sweating
- chills
- dry mouth, nose and throat
- nausea
- dizziness
- weakness
- fast or irregular heart beats
- trouble sleeping
- dilated pupils
- excitability in children

Other unwanted effects may also occur in some people taking DEMAZIN COLD RELIEF. Tell your doctor or pharmacist if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using DEMAZIN COLD RELIEF

Storage

Keep your syrup in a cool dry place where the temperature stays below 30°C. Do not store it or any other medicine in the bathroom or near a sink.

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

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half meters above the ground is good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking DEMAZIN COLD RELIEF or the syrup has passed the expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

DEMAZIN COLD RELIEF and DEMAZIN COLD RELIEF CLEAR Syrups and Infant Drops have an aromatic odour and sweet taste, and are vanilla and peach flavoured. DEMAZIN COLD RELIEF Syrup and Infant

Drops are blue-coloured syrups.

DEMAZIN COLD RELIEF CLEAR Syrup and Infant Drops are colourless syrups.

The Infant Drops are supplied with a dropper.

Ingredients

Active ingredients:

- chlorpheniramine maleate 1.25mg/5mL
- phenylephrine hydrochloride 2.5mg/5mL

Other ingredients:

- sucrose
- sorbitol
- vanillin
- benzaldehyde
- menthol
- ethanol
- artificial peach flavour

• water

Preservatives:

- methyl hydroxybenzoate
- propyl hydroxybenzoate

Artificial colourings (DEMAZIN COLD RELIEF SYRUP and DEMAZIN COLD RELIEF Infant Drops only):

- quinoline yellow
- brilliant blue FCF

Supplier

In Australia:

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

In New Zealand: Schering-Plough a division of

Schering-Plough Animal Health Limited 36 Kitchener Street Auckland

NEW ZEALAND

Australian Registration Numbers

Syrup: AUST R 18813 Infant Syrup: AUST R 116393 Clear Syrup: AUST R 57378 Clear Infant Syrup: AUST R 63198

Date of Preparation

May 2007

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