## DEXCHLORMINE SYRUP

Dexchlorpheniramine Maleate (2 mg/5 ml)

#### What is in this leaflet

- 1. What DEXCHLORMINE is used for
- 2. How DEXCHLORMINE works
- 3. Before you use DEXCHLORMINE
- 4. How to use DEXCHLORMINE
- 5. While you are using it
- 6. Side effects
- 7. Storage and Disposal of DEXCHLORMINE
- 8. Product Description
- 9. Manufacturer and Product Registration Holder
- 10. Date of revision

# What DEXCHLORMINE is used for

Indicated for the treatment of

- Allergic rhinitis (hay fever)
- Vasomotor (non-allergic) rhinitis
- Allergic conjunctivitis
   (inflammation of the membrane
   covering the eye)
- Mild, uncomplicated allergic skin manifestations of hives & swelling under the skin.
- Allergic reactions to blood or plasma.

## **How DEXCHLORMINE works**

Dexchlorpheniramine Maleate is an antihistamine. It works by blocking a certain natural substance (histamine) that your body makes during an allergic reaction. The antimuscarinic action provides a drying effect on the nasal lining.

# Before you use DEXCHLORMINE

- When you must not use it
  - In new-born or premature infants because of the possibility of severe reactions such as convulsions.
  - Together with MAOI (monoamine oxidase inhibitor) therapy.
  - To treat lower respiratory tract symptoms.
  - Hypersensitivity to the Dexchlorpheniramine Maleate or other ingredients in this product.

Pregnancy and lactation
It should not be used in the third trimester of pregnancy. Use in pregnancy has not been established. It is not known whether
Dexchlorpheniramine is found in human milk, therefore caution should be exercised when used by

Ask your doctor or pharmacist for advice before taking any medicine.

nursing mothers.

- <u>Before you start to use it</u> You should abstain from alcohol.
- <u>Taking other medicines</u>
  Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

It may enhance the sedative effect of central nervous system depressants including barbiturates, hypnotics, narcotic painkiller, sedatives and tranquillisers. Monoamine oxidase inhibitors (antidepressant) prolong and intensify the effects of antihistamines. The action of oral anticoagulants (prevent blood clots) may be blocked by antihistamines.

#### How to use DEXCHLORMINE

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

### DEXCHLORMINE SYRUP

Adults and children above 12: 1 teaspoonful (5 ml) every 4 - 6 hours.

Children aged 6 - 11 years: ½ teaspoonful (2.5 ml) every 4 - 6 hours.

Children aged 2 - 5 years: <sup>1</sup>/<sub>4</sub> teaspoonful (1.25 ml) every 4 - 6 hours

- When to use it

Use as directed by your doctor or pharmacist.

Can be taken before or after meal.

- How long to use it Continue taking DEXCHLORMINE for as long as your doctor

recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- <u>If you use too much (overdose)</u> Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause hallucinations (hear, smell, taste or feel things that do not exist), excitation, convulsions or death especially in infants and children. The individual should be kept quiet to minimise the excitation which occurs particularly in children.

## While you are using it

- Things you must do
Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking DEXCHLORMINE.

Tell your doctor immediately if you become pregnant while taking this medication.

- <u>Things you must not do</u> Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give DEXCHLORMINE to anyone else, even if they have the same symptoms or condition as you. - Things to be careful of Driving and using machines
It may cause drowsiness and dulling of mental alertness. Individuals undergoing treatment with these medicines should not take charge of vehicles or machinery.

It should be used with caution in individuals with narrow angle glaucoma (increased eye pressure), pyloroduodenal obstruction (obstruction of the outlet of stomach), enlarged prostate gland, bladder neck obstruction and in individuals with a history of asthma, overactive thyroid gland, heart and blood vessel disease and high blood pressure. Antihistamines are more likely to cause dizziness, sedation and low blood pressure in elderly.

### Side effects

Like all medicines, DEXCHLORMINE can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Slight to moderate drowsiness is the most common side effect. Others include:

- General: hives, rash, anaphylactic shock (serious allergic reaction), sensitive to light, excessive perspiration, chills, dryness of mouth, nose and throat.
- Cardiovascular System:
   Headache, pounding of the
   heartbeat, tachycardia
   (abnormally fast heart rate),
   abnormally low blood pressure.
- Nervous System: Sedation, dizziness, feeling of spinning, noises or ringing in the ears, disturbed co-ordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia (sleep disorder), euphoria (excitement), blurred vision and convulsions.
- Gastrointestinal system:
   Epigastric distress, anorexia
   (lack of appetite), nausea, vomiting, diarrhoea, constipation.

- Genitourinary system: Urinary frequency, difficult urination, urinary retention, early menses.
- Respiratory system: Thickening of airway secretions, tightness of chest, wheezing, nasal stuffiness.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

## Storage and Disposal of DEXCHLORMINE

- <u>Storage</u>
Keep out of the reach and sight of children.
Store in dry place below 25°C.
Keep container tightly closed
Protect from light
SHAKE WELL BEFORE USE

#### - <u>Disposal</u>

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **Product Description**

- What it looks like
DEXCHLORMINE SYRUP
Yellow syrup with banana flavour.

- Ingredients
  - Active ingredient Dexchlorpheniramine Maleate
  - Inactive ingredients

    DEXCHLORMINE SYRUP

    Sugar, Liquid Glucose, Methyl

    Paraben, Propyl Paraben,

    Sodium Benzoate, Quinoline

    Yellow, Banana Flavour, &

    Deionised Water.
- <u>MAL number:</u> DEXCHLORMINE SYRUP MAL19910823AZ

### Manufacturer & Product Registration Holder

Dynapharm (M) Sdn. Bhd. 2497, Mk 1, Lorong Perusahaan Baru 5, Kawasan Perusahaan Perai 3, 13600 Perai, Pulau Pinang, Malaysia.

Date of revision 03/07/2017

**Serial Number:** BPFK(R4/1)030717/00164