AMYDRAMINE PAEDIATRIC SYRUP

Diphenhydramine HCl/ Sodium Citrate/ Menthol (7mg/28.5mg/0.55mg per 5ml).

WHAT IS IN THIS LEAFLET:

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

What Amydramine is used for

Amydramine is indicated for the treatment and relief of cough and alleviation of nose and bronchial (tubes that carry air into the lungs) congestion for children 2 years and over.

How Amydramine works

Diphenhydramine HCl works by blocking a certain natural substance (histamine) that your body makes during an allergic reaction. Its drying effects on such symptoms as watery eyes and runny nose are caused by blocking another natural substance made by your body (acetylcholine)

Menthol has mild local anaesthetic (decrease or eliminate the feeling of pain) and decongestant properties. It is known to be used in upper respiratory tract disorders to relieve symptoms of bronchitis (inflammation of the air passage that carry air to the lungs), sinusitis (inflammation of sinus) and similar conditions.

Sodium citrate and menthol are added in the formula of Amydramine Paediatric as demulcent agents (soothing and mollifying).

Before you use Amydramine

- When you must not use it

Do not take Amydramine if you are hypersensitive to antihistamines.

Pregnancy and lactation

Do not take Amydramine if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Amydramine if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Not to be used in children less than 2 years of age.

To be used with caution and on doctor's or pharmacist's advice in children 2 to 6 years of age.

This medicine may cause drowsiness. If affected, do not drive motor vehicles or operate machinery. Avoid taking alcoholic drinks or other drugs that may produce drowsiness.

- Taking other medicines

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.

Some medicines and Amydramine Pediatrics Syrup may interfere with each other. These include:

- Hypnotics, sedatives and tranquilizers (to treat anxiety or sleeping disorders)
- Monoamine oxidase inhibitors (MAOIs), for depression.
- Aminoglycosides (a group of antibiotics)
- Antimuscarinics

How to use Amydramine

- 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.

Children 2 – 5 years:

One teaspoonful (5ml) three to four times a day. Not to exceed 20ml in 24 hours.

Children 6 years and over:

Two teaspoonful (10ml). Dose to be repeated every 3 hours, or as directed by the physician.

- When to use it

Use as directed by your doctor or pharmacist.

May be taken with or without food.

- How long to use it

Continue taking Amydramine 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.

- If you use too much (overdose)

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.

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 Amydramine.

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

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Amydramine to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the medicine makes you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Amydramine 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.

Antihistaminic side effects include sedation, dizziness, noise or ringing in the ears (tinnitus), lassitude (lack of energy), incoordination, fatigue, blurred vision, double vision (diplopia), euphoria, nervousness, insomnia and tremors.

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 portal.bpfk.gov.my (Consumers → Reporting)

Storage and disposal of Amydramine

- Storage

Keep medicine out of the reach and sight of children.

Store at room temperature below 25°C and protect from light.

- Disposal

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

Almost clear and orange color syrup with banana flavor.

- Ingredients

- Active ingredients
 Each teaspoonful (5ml) contains
 Diphenhydramine HCl 7.00 mg
 Sodium Citrate 28.50 mg
 Menthol 0.55 mg
- Inactive ingredients Sodium benzoate, Citric acid, Sorbitol 70% Solution, Glycerol, Banana flavour, Sodium saccharin, Sunset Yellow, Sucrose and Purified water.

- <u>MAL number:</u> MAL08021486A

Manufacturer

Gulf Pharmaceutical Industries (Julphar) Digdaga, Airport Street P.O.Box 997, Ras Al Khaimah, United Arab Emirates

Product Registration Holder

Averroes Pharmaceuticals Sdn. Bhd. 11E, Level 5, Block 1 Worldwide Business Center Jalan 13/50, Section 13 40000 Shah Alam, Selangor Malaysia

Date of revision

24/07/2015

Serial number

BPFK(R4/1)230715/00220