HISTASINTM TABLET

Cetirizine dihydrochloride (10 mg)

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What HISTASIN is used for

HISTASIN is used to relieve symptoms of allergy such as:

- seasonal rhinitis (inflammation of the nasal passages that occurs during specific seasons such as hay fever with sneezing, itchy, runny and blocked nose, red and watery eyes)
- perennial allergic rhinitis
 (inflammation of the nasal
 passages that occurs year round
 such as allergies towards dust or
 pet and cause sneezing, itchy,
 runny and blocked nose, red and
 watery eyes)
- urticaria of allergic origin (an allergic skin condition with symptoms of swelling, redness and itching.)

How HISTASIN works

HISTASIN is an antihistamine medicine that works by blocking the action of histamines in the body. Histamine is a substance produced by the body during an allergic reaction causing itching, sneezing or rashes.

Before you use HISTASIN

- When you must not use it

Do not use HISTASIN if you are allergic to cetirizine, hydroxyzine or any other ingredients listed at the end of this leaflet.

Pregnancy and breastfeeding Tell your doctor if you are pregnant, planning to become pregnant or breastfeeding.

Cetirizine should not be used during the first 3 months of pregnancy.

Cetirizine is contraindicated if you are breastfeeding as it is excreted in breast milk.

- Before you start to use it

Tell your doctor or pharmacist if you are allergic to any other medicines or you have any other health related problems.

- Taking other medicines

Inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription from a pharmacy, supermarket or health food shop.

How to use HISTASIN

- How much to use
- Adults: 10mg once daily.
- Children above 6 years old: 5mg twice daily or 10mg once daily.
- Children 3-6 years old: 2.5mg twice daily or 5mg once daily.
- The daily dose should be reduced by half if you are suffering from kidney disorder.
- If you are affected by side effects, the dose may be taken as 5mg in the morning and 5mg in the evening.

- When to use it

HISTASIN should be taken according to the time advised by your doctor or pharmacist.

It is advisable to take the medicine with a little liquid during the evening meal since the symptoms for which the product is given usually appear during the night.

- How long to use it

HISTASIN should be taken as your doctor advised you to do so.

- If you forget to use it

If you miss a dose of HISTASIN and you are taking it regularly, take it as soon as possible. If it is approaching time for the 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. You may need urgent medical attention.

The symptom of overdose is drowsiness.

While you are using HISTASIN

- Things you must do

Follow your doctor's instruction when you are taking HISTASIN.

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

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

- Things you must not do

Do not stop taking this medicine or change the dosing regimen without instruction from your doctor.

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

- Things to be careful of

Avoid alcohol consumption during the course of treatment with HISTASIN. Avoid driving a car or operating potentially dangerous machinery after taking HISTASIN.

Side effects

HISTASIN may cause headache, dizziness, drowsiness, agitation, dry mouth and gastrointestinal discomfort.

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Please tell your doctor or pharmacist if you experience any other side effects.

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 HISTASIN

- Storage

Store dry below 25°C.

Keep out of the reach and sight of children.

- Disposal

HISTASIN should be disposed when your doctor or pharmacist tells you to stop taking this tablet or it has passed the expiry date. Ask your pharmacist how to dispose medicines that are no longer required. Medicine should not be disposed of via wastewater or household water. These measures will help to protect the environment.

Product Description

- What it looks like

HISTASIN tablet: Film-coated, white to almost white convex, elliptical tablet. Scored on one side.

- Ingredients

- <u>Active ingredient</u> Cetirizine dihydrochloride.
- Inactive ingredients
 Microcrystalline Cellulose,
 Lactose Monohydrate,
 Crospovidone,
 Silica colloidal anhydrous,
 Magnesium stearate,
 Hypromellose,
 Macrogol stearate,
 Propylene glycol,
 Titanium dioxide,
 Purified water.

- <u>MAL number</u> MAL06030814AZ

Manufacturer

ACTAVIS UK LTD Whiddon Valley, Barnstaple North Devon, EX32 8NS UNITED KINGDOM

Product Registration Holder MEPHARM (MALAYSIA) SDN BHD No.15, Jalan USJ 1/19 Taman Subang Permai 47600 Subang Jaya

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24/11/2015

Selangor

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