

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### In this leaflet:

- **What is Histafen® topical solution and what it is used for**
- **Before you use Histafen®**
- **How to use Histafen®**
- **How to store Histafen®**
- **Further information**

#### **What Histafen® topical solution is and what it is used for** Histafen® topical solution contains the active ingredient diphenhydramine.

Histafen® temporarily relieves pain and itching associated with:

- Insect bites
- Minor burns
- Sunburn
- Minor skin irritations
- Minor cuts
- Scrapes
- Rashes due to poison ivy, poison oak and poison sumac.

#### **Before you take Histafen®**

##### **Do not use Histafen®**

Do not use Histafen® if you are using any other product containing diphenhydramine, even one taken by mouth.

Do not use Histafen® on large areas of the body

##### **Take special care with Histafen®**

Ask a doctor before using Histafen® on chickenpox or measles

When using Histafen® avoid contact with eyes.

Stop using Histafen® and contact a doctor if:

- Your condition worsens
- Symptoms persist for more than 7 days or clear up and occur again within a few days.

Histafen® is for external use only

##### **Taking other medicines, herbal or dietary supplements**

Do not use Histafen® if you are using any other product containing diphenhydramine, even one taken by mouth.

##### **How to use Histafen®**

###### **Do not use more than directed**

Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily.

Children under 2 years of age: ask a doctor.

##### **How to store Histafen®**

Keep out of the reach and sight of children.

Do not use after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Histafen® topical solution is flammable. Do not store above 30°C. 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.

#### **Further information**

##### **What Histafen® contains**

Histafen® contains the active ingredient Diphenhydramine Hydrochloride. Each gram solution contains 20 mg Diphenhydramine Hydrochloride (2%).

The other ingredients are: Zinc acetate, ethanol, glycerin, povidone and purified water

##### **What Histafen® looks like and contents of the pack**

Histafen® is a clear yellowish solution.

Histafen® topical solution is available in a labeled roll-on tube container which contains 13 ml of the medicated solution, the tube container is enclosed in a carton box along with an insert.

#### **Marketing authorization Holder and Manufacturer**

Dar Al Dawa Development & Investment Co. Ltd (Na'ur – Jordan).

Tel. (+962 6) 57 27 132

Fax. (+962 6) 57 27 776

#### **To report any side effects:**

• Jordan

– Contact marketing authorization holder

• Saudi Arabia

– National Pharmacovigilance and Drug Safety Centre (NPC)

– Fax: + 966 112057662

– Call NPC at + 966 112038222, Exts:

2317-2356-2353-2354-2334-2340

– Toll free phone: 8002490000

– E-mail: npc.drug@sfd.a.gov.sa

– Website: www.sfd.a.gov.sa/npc

• United Arab Emirates

– Pharmacovigilance and Medical Device Section

– Drug Department

– UAE Ministry of Health and Prevention

– Hotline: 800111111

– Email: pv@moh.gov.ae

– P.O. Box: 1853 Dubai UAE

• Sudan

– National Medicines and Poisons Board (NMPB)

– Fax: + 249 183522263

– E-mail: info@nmpb.gov.sd

– Website: www.nmpb.gov.sd

• Other countries

– Please contact the relevant competent authority.

#### **This is a Medicament**

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

