HYSONE CREAM 1% (W/W)

Hydrocortisone acetate (1% w/w)

What is in the leaflet

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

What Hysone Cream is used for

It is used for symptoms relief of skin conditions like:

- eczema (skin is swelled, itchy, red, dry and cracked)
- contact dermatitis (an allergic skin reaction that develop following exposure to detergents, soaps, metals or cosmetics)
- psoriasis (skin is raised, red and has crusty patches covered with silvery scales)

How Hysone Cream works

This medicine contains Hydrocortisone acetate which belongs to a group of medicine called corticosteroid. It is used to reduce swelling of the skin (anti-inflammation).

Before you use Hysone Cream

- When you must not use it

Do not use Hysone Cream if:

- you are allergic to hydrocortisone or any other ingredients in this medicine
- you have infected skin damage that is not treated
- you have red facial rash, sometimes with small, red pusfilled bumps
- you have rash that develop around your mouth

- you have acne
- you have pre-existing skin thinning

- Before you start to use it

Talk to your doctor or pharmacist before you start using the cream.

- 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.

How to use Hysone Cream

- How much to use

Apply a small amount on the affected area 2 or 3 times a day until improvement occurs.

You may continue to apply the cream once a day or even less often to maintain improvement.

Occlusion of the area under treatment with plastic film may be used to enhance the effect in more resistant cases.

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 further explanations.

When to use it

Use the cream as directed by your doctors or pharmacists.

- How long to use it

Continue using Hysone Cream 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.

- <u>If you take too much (overdose)</u>

If you have applied too much Hysone Cream on the skin, gradual withdrawal (tapering down of dose) is necessary.

If you accidentally ingested a large amount of cream, dilution with fluids are necessary.

Contact your doctor or pharmacists for advice if you think you or anyone else may have applied too much cream.

Do this even there are no signs of discomfort or poisoning.

While you are using it

- Things you must do

Tell your doctor or pharmacist who is treating you that you are using Hysone Cream before you have started with other medicines.

- Things you must not do

Do not stop using Hysone Cream abruptly to avoid recurrence of unwanted skin conditions.

Do not use Hysone Cream if infection (caused by bacteria or viruses) occurs at the affected area.

Discontinue occlusive dressing (if used) and get antimicrobial therapy until the infection is properly controlled.

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

- Things to be careful of

The use of hydrocortisone is likely to cause systemic effects (effects on the whole body) or damage to delicate tissues.

Repeated application of Hysone Cream may result in medicine accumulation in the skin, prolonged exposure and increased side effects.

Side effects

Like all medicines, Hysone Cream can cause side effects, although not everyone gets them.

Prolonged use of Hysone Cream, especially with dressing may cause changes to the skin like stretch mark and secondary skin infection (infection that occurs during or after treatment for another infection).

Hysone Cream can also cause minor side effects such as:

- Itching
- Dryness
- Irritation
- Burning sensation

If irritation (inflammation or other discomfort) occurs at the site of application, stop using Hysone Cream.

Visit your doctor or pharmacist immediately if you experience any side effects after applying the cream.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by visiting the website $\underline{npra.gov.my}$ [Consumers \rightarrow Reporting \rightarrow Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Hysone Cream

- Storage

Keep Hysone Cream in a cool dry place where the temperature stays below 30°C. Protect from light.

Keep the container tightly closed after you use the cream.

Keep it out of reach of children.

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

Use the cream by the expiry date printed on the end flap of the carton box or on the edge of the tube.

- Disposal

Ask your pharmacist how to dispose of cream that is no longer required or has passed its expiry date.

Medicines should not be disposed via wastewater or household waste. This helps to protect the environment.

Product Description

- What it looks like

A white coloured, homogenous cream

Ingredients

- Active ingredient:
 - Hydrocortisone acetate (1% w/w)
- Inactive ingredients:
 - Liquid paraffin
 - White soft paraffin
 - Emulsifying wax
 - Methylparaben
 - Propylparaben
- <u>MAL number(s):</u>
 MAL19860156AZ

Manufacturer

Duopharma Manufacturing (Bangi) Sdn. Bhd. Lot No.2& 4, Jalan P/7, Seksyen 13, Bangi Industrial Estate 43650 Bandar Baru Bangi. Selangor Darul Ehsan.

Product Registration Holder

Duopharma Manufacturing (Bangi) Sdn. Bhd. Lot No.2,4,6,8 & 10 Jalan P/7,

Lot No.2,4,6,8 & 10 Jalan P/7, Section 13, Bangi Industrial Estate, 43650 Bandar Baru Bangi, Selangor Darul Ehsan.

Date of Revision 01/09/2021

Serial Number: NPRA(R4/1)030818/00228