UNIFLEX CREAM

Betamethasone 17-Valerate (0.025% w/w, 0.05% w/w, 0.1 w/w)

What is in this leaflet:

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

What is Uniflex Cream used for

To be applied on the skin. For the relief of:

• inflammatory manifestations of corticosteroid responsive skin diseases such as in eczema, dermatitis, some form of psoriasis and intertrigo.

How Uniflex Cream works

Betamethasone is a potent corticosteroid that helps to reduce inflammation and itchiness.

Before you use Uniflex Cream

-When you must not to use it

- Do not use this medicine if you are allergic to Betamethasone or any other ingredients in this medicine.
- Not to be use on mouth areas and around eye, anal and genital where skin is thinner.
- If irritation develops with the use of Uniflex, treatment should be discontinued.
- Topical steroids should not be used in large amounts or for prolonged periods in pregnant women.
- Avoid prolonged use or over large areas of the body particularly with occlusive dressing present.
- Do not use on the face, broken or infected skin, including cold sores, acne and athletes' foot and chicken pox.
- Do not use in your children under 1 year old.

-Before you start to use it

Tell your doctor or pharmacist if you:

- are pregnant or breast-feeding.
- have viral, fungal or bacterial skin infection.

-Taking other medicines

Tell your doctor or pharmacist if you are taking or having recently taken any other medicines. This includes any medicines which you have bought without a prescription especially barbiturates (used for depressants), phenytoin (used for seizure), rifampicin (used for tuberculosis which mainly affects the lungs).

How to use Uniflex Cream

-How much to use

Apply sparingly, a thin film over the affected skin areas 2-3 times daily.

-When to use it

Follow the prescription from your doctor.

-How long to use it

Follow the prescription from your doctor. Ask your doctor or pharmacist before prolonged use of this medicine.

When a favourable response is obtained, reduce application gradually and eventually discontinue.

-If you forget to use it

Use it as soon as you remember. Then, next use it at the usual time.

-If you use too much (overdose)

Excessive application may lead to signs of Cushing's syndrome such as moon face, stretch marks, acne and buffalo hump (excess fats deposition behind the shoulders).

Seek immediate medical attention if you have used too much or are worried with your condition.

While you are using Uniflex Cream

-Things you must do

Always wash your hand before and after using this cream.

-Things you must not do

This cream is for application on skin only. Do not swallow it.

Do not use this medicine by yourself without advice from your doctor or pharmacist.

-Things to be careful of

Be careful of driving or operating machinery until you know how Uniflex Cream affects you.

Avoid indiscriminate use in itching condition as worsen condition may occur when treatment is stopped.

Side Effects

- Cushing's syndrome
- Spread of local infections
- Thinning and/or lightening of skin
- Increased hair growth
- Acne
- Irreversible stretch marks
- Tiny red bumps form around the mouth. Seek immediate medical attention if you experience any side effects or allergic reactions.

Any of the side effects reported following systemic use of corticosteroids including adrenal gland suppression, may also occur following their topical use especially in children and infants.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Consumers→Reporting Side Effects to Medicinal (ConSERF) or Vaccine (AEFI)].

Storage and Disposal of Uniflex Cream

-Storage

Store below 30°C. Protect from light. Keep out of the reach of the children. Do not use this medicine after expiry date.

-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

-How it looks like

White, odourless, water miscible cream. Available in 15g collapsible aluminum tube.

-Ingredients

-Active ingredient Betamethasone Valerate.

-Inactive ingredients

White Soft Paraffin, Cetostearyl Alcohol, Purified Water, Cetomacrogol 1000, Liquid Paraffin, Disodium Hydrogen Phosphate 12-Hydrate, Chlorocresol and Citric Acid Anhydrous.

<u>MAL Number</u>

Uniflex Cream 0.025%w/w: MAL19921156AZ

Uniflex Cream 0.05% w/w: MAL19970673AZ

Uniflex Cream 0.1% w/w MAL19870615AZ

Not all products are marketed

Manufacturer and Registration Holder

Xepa-Soul Pattinson (M) Sdn Bhd 1-5 Cheng Industrial Estate, 75250 Melaka, Malaysia. **Date of Revision**

05/04/2022

Serial Number:

NPRA(R4/1)051218/00364