

## **Package leaflet: Information for the user**

### **Unguentum M**

#### **Cream**

The combination of ingredients in this cream work as an emollient (softens and smoothes the skin)

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in in this leaflet:**

1. What Unguentum M is and what it is used for
2. What you need to know before you use Unguentum M
3. How to use Unguentum M
4. Possible side effects
5. How to store Unguentum M
6. Contents of the pack and other information

#### **1. What Unguentum M is and what it is used for**

Unguentum M is formulated to smooth and soften your skin. It replaces oils in your dry skin and stops your skin losing moisture. It will also relieve the itching caused by eczema and dermatitis.

Unguentum M is used to treat dry, cracked and damaged skin caused by conditions like eczema, dermatitis, itchy skin (known as pruritus), or dry harsh scaly skin (known as ichthyosis).

It can also be used for the protection of raw and grazed skin areas.

Unguentum M can also be used to help relieve the symptoms of nappy rash. You can also use Unguentum M instead of soap when washing which will help to prevent the skin drying out.

## **2. What you need to know before you use Unguentum M**

### **Do not use Unguentum M**

- if you are allergic to any ingredients of this medicine (listed in section 6).
- near the eyes or on mucous membranes.

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Unguentum M.

### **Take special care**

Unguentum M **should not** be swallowed. If this happens talk to your doctor or pharmacist.

### **Other medicines and Unguentum M**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

There are no known interactions between Unguentum M and other medicines.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

There are no known harmful effects when this medicine is used in pregnancy or breastfeeding.

### **Driving and using machines**

There are no effects on the ability to drive and use machines when this medicine is used.

**Unguentum M contains sorbic acid (E200), cetostearyl alcohol, propylene glycol (E1520) and white soft paraffin contains butylhydroxytoluene (E321)**

Sorbic acid (E200), cetostearyl alcohol and butylhydroxytoluene (E321) may cause local skin reactions, (e.g. contact dermatitis which can be a rash or irritated skin and irritation to the eyes and mucous membranes).

Propylene glycol (E1520) may cause skin irritation.

### **Warning of fire hazard with emollients**

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

### **3. How to use Unguentum M**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- This medicine should be applied directly to your skin.
- Apply this medicine gently to the affected areas three times a day or as often as you need to.

A good time to do this is after you have had a bath.

- Make sure your hands are clean. Use a small amount of this medicine and apply it gently to the affected area. If you are using the 500 g jar, use a spoon or spatula to take the medicine out as this will help to keep the cream clean.
- If you are using this medicine instead of soap, wet the dry skin, and cleanse the skin with this medicine. Then wash it off with water and pat the skin dry with a towel. Do not rub the skin because you might remove some of the medicine.
- This medicine is easily absorbed and leaves your skin feeling softened and soothed.
- If you have very sore skin, there may be a short tingling sensation when you use this medicine. But your skin should feel soothed afterwards.
- This medicine should be applied as long as your dry skin condition exists.
- When using this medicine as a protective cream apply a small amount before or straight away after coming into contact with a possible source of irritation (e.g. water, detergents, etc.).

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

##### **Rarely (1 in 10 out of 10,000 persons treated)**

- skin irritations such as burning sensation and reddening or allergic contact dermatitis (rash, itching) may occur.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side-effects you can help provide more information on the safety of this medicine

#### **5. How to store Unguentum M**

Keep this medicine out of the sight and reach of children.

Aluminium tubes do not require any special storage condition.

Plastic containers: Do not store above 25°C.

Do not use Unguentum M after the expiry date which is stated on the label after “EXP”.

The expiry date refers to the last day of that month.

After opening: Unguentum M can be used for 6 months.

Do not throw away any medicines via wastewater <or household waste>. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### **6. Content of the pack and other information**

##### **What Unguentum M contains**

The ingredients are white soft paraffin (contains butylhydroxytoluene (E321)), cetostearyl alcohol, polysorbate 40, propylene glycol (E1520), glyceryl monostearate 40-55, liquid paraffin, medium-chain triglycerides, sorbic acid (E200), colloidal anhydrous silica, purified water, sodium hydroxide

##### **What Unguentum M looks like and contents of the pack**

Unguentum M is a white cream.

Unguentum M cream is supplied in:

- aluminium tubes containing 10 g, 15 g, 30 g, 50 g 60 g 80 g and 100 g
- plastic jar containing 500 g
- plastic pump dispenser containing 200 ml

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

Almirall Hermal GmbH

Scholtzstrasse 3, D-21465 Reinbek, Germany

**This leaflet was last revised in 05/2019.**

### **Additional information and explanations for patients**

#### **How else can you help your skin?**

There are many factors that may worsen dry skin conditions. These are for example low humidity (air conditioning, central heating), excessive bathing or showering and contact with soap, detergents or solvents. Try to avoid these factors. For mild cleansing use soapfree products and consider medicinal bath oils.

If you find that your skin problem gets worse when you come in contact with certain things like e.g. special food ingredients, metal jewellery or detergents please talk with your doctor about it. Your doctor will help you to identify and avoid the things that cause a deterioration of your skin problem.

**Other sources of information** Some skin conditions such as eczema are very frustrating. Many people find patient

support groups helpful. The National Eczema Society can give you more information about your condition.

**National Eczema Society**

**11 Murray Street London**

**NW1 9RE**