

PATIENT INFORMATION LEAFLET

Urea[®] 10% w/w Cream

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Urea 10% w/w Cream carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

The information in this leaflet has been divided into the following sections:

- 1. What Urea 10% w/w Cream is and what it is used for**
- 2. Check before you use Urea 10% w/w Cream**
- 3. How to use Urea 10% w/w Cream**
- 4. Possible side effects**
- 5. How to store Urea 10% w/w Cream**
- 6. Further information**

1. What Urea 10% w/w Cream is and what it is used for

Urea 10% w/w Cream is an emollient used to treat dry, scaly skin conditions. The cream helps to soften and moisturise your skin.

Dry skin is caused by a lack of water in the outer layer of skin cells known as the stratum corneum (top layer of the skin). When this layer becomes dry it becomes cracked, scaly and sometimes itchy.

The skin dries out when too much water evaporates from its surface. This increases as we get older, and is made worse by washing, because hot water and soap can remove the layer of natural oil on the skin.

Urea 10% w/w Cream contains urea, the skin's natural moisturiser. Urea is a substance that is found naturally in the stratum corneum. It helps the skin retain moisture. Water is also normally retained in the stratum corneum by a thin layer of natural oil (sebum), which slows down evaporation of water from the skin surface.

The urea in Urea 10% w/w Cream is mixed with white soft paraffin which forms a layer of oil on the surface of the skin. This oily layer helps prevent

water from evaporating from the skin's surface which will reduce irritation, restore suppleness and improve the appearance of your skin.

2. Check before you use Urea 10% w/w Cream

Do not use Urea 10% w/w Cream:

- if you are allergic (hypersensitive) to urea or any of the ingredients of Urea 10% w/w Cream (see Section 6 Further information).

If the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you use Urea 10% w/w Cream.

Take special care with Urea 10% w/w Cream

Before you use Urea 10% w/w Cream tell your doctor if:

- you have moist or broken skin.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you use Urea 10% w/w Cream.

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.

Using other medicines

Tell your doctor or pharmacist if you are using or have recently used any other medicines which are applied to the skin as they may interfere with Urea 10% w/w Cream.

Please tell your doctor or pharmacist if you are taking or have recently taken/used any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

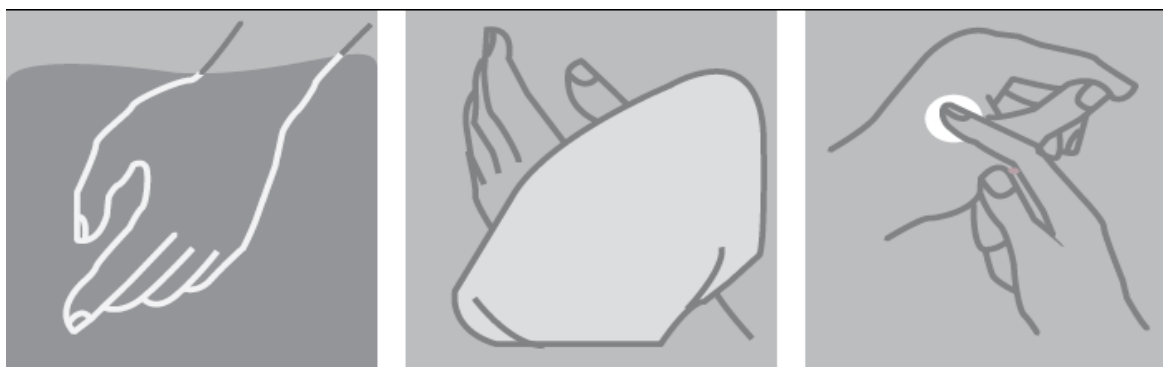
Ask your doctor or pharmacist for advice before taking any medicine.

3. How to use Urea 10% w/w Cream

Always use Urea 10% w/w Cream exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

Urea 10% w/w Cream is for external use only and should only be applied to the skin. It should not be used on moist or broken skin.

Using Urea 10% w/w Cream is easy, just follow the instructions below:



Wash the affected areas well and rinse off any traces of soap

dry

apply a suitable amount of cream twice daily

Your doctor may tell you to cover this with a special “occlusive” dressing (an air tight dressing), but this is not usually necessary.

What to do if you use more Urea 10% w/w Cream than you should

Using too much Urea 10% w/w Cream may cause skin irritation (redness, burning or itching). If this happens to you ask your doctor for advice.

The cream is for external use only and should only be applied to the skin. If you accidentally swallow the cream this may make you feel sick; drink plenty of water or milk. You should tell your doctor at once or contact your nearest accident and emergency department. Show any left-over medicines or the empty container to the doctor.

If you forget to use Urea 10% w/w Cream

If you forget to use Urea 10% w/w Cream on any occasion, do not worry, just continue as normal.

Some do’s and dont’s for Urea 10% w/w Cream:

Do

use Urea 10% w/w Cream regularly as directed

Do

wash, rinse and dry affected areas before applying Urea 10% w/w Cream

Do

Apply Urea 10% w/w Cream to the whole of the affected area - twice daily

Don’t

use Urea 10% w/w Cream if you’ve had a past reaction to it or any of its ingredients

Don’t

use Urea 10% w/w Cream on moist or broken skin

Don’t

worry if you occasionally forget to use Urea 10% w/w Cream - continue using it as before

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

4. Possible side effects

Do not worry. Like all medicines, Urea 10% w/w Cream can cause side effects, although not everyone gets them.

Some people experience local irritation when they apply Urea 10% w/w Cream. If you notice this or any other unusual effect, tell your doctor.

If you use Urea 10% w/w Cream as your doctor tells you, it is unlikely to cause side effects.

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:

UK:

The Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

IE:

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie, E-mail: medsafety@hpra.ie.

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

5. How to store Urea 10% w/w Cream

Keep out of the reach and sight of children.

Do not use Urea 10% w/w Cream after the expiry date which is stated on the carton and on the base of the tube. The expiry date refers to the last day of that month.

Do not store Urea 10% w/w Cream above 30°C.

Do not use Urea 10% w/w Cream if you notice a change in the colour or feel of the cream.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist on how to dispose of medicines no longer required. These measures will help protect the environment.

6. Further information

What is in Urea 10% w/w Cream?

The active ingredient in this medicine is urea 10% w/w contained in white soft paraffin.

The other ingredients are isopropyl myristate, maize starch, glyceryl tribehenate, palmitic acid, sorbitan laurate and polyoxyethylene fatty glyceride.

What Urea 10% w/w Cream looks like and contents of the pack

Urea 10% w/w Cream is a smooth, unperfumed, non greasy and off white cream.

Urea 10% w/w Cream comes in tubes of 30g (grams) and 100g. A 30g tube of Urea 10% w/w Cream contains 3g of urea and a 100g tube contains 10g of urea.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder (UK)

Alliance Pharmaceuticals Ltd, Avonbridge House, Chippenham, Wiltshire, SN15 2BB, UK.

Marketing Authorisation Holder (IE)

Alliance Pharma (Ireland) Ltd, United Drug House, Magna Drive, Dublin, D24 X0CT, Ireland

Urea 10% w/w Cream is manufactured by: Laboratoires Chemineau, 93 Route de Monnaie, BP 16, 37210 Vouvray, France.

The information in this leaflet applies only to Urea 10% w/w Cream. If you have any questions or you are not sure about anything, ask your doctor or a pharmacist.

This leaflet was last approved: July 2019

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