



PATIENT INFORMATION LEAFLET

Aquadrate[®] 10% w/w Cream urea

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 Aquadrate 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 Aquadrate Cream is and what it is used for**
- 2. Check before you use Aquadrate Cream**
- 3. How to use Aquadrate Cream**
- 4. Possible side effects**
- 5. How to store Aquadrate Cream**
- 6. Further information**

1. What Aquadrate Cream is and what it is used for

Aquadrate 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.

Aquadrate 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 Aquadrate 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 Aquadrate Cream

Do not use Aquadrate Cream:

- if you are allergic (hypersensitive) to urea or any of the ingredients of Aquadrate 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 Aquadrate Cream.

Take special care with Aquadrate Cream

Before you use Aquadrate 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 Aquadrate Cream.

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 Aquadrate 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 Aquadrate Cream

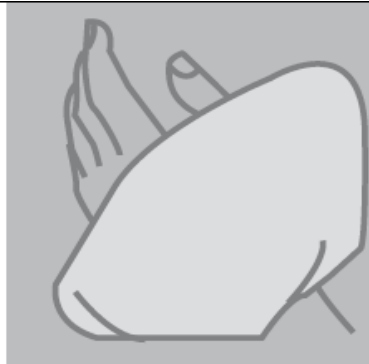
Always use Aquadrate Cream exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

Aquadrate Cream is for external use only and should only be applied to the skin. It should not be used on moist or broken skin.

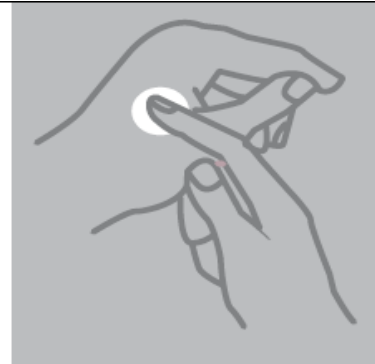
Using Aquadrate Cream is easy, just follow the instructions below:



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 Aquadrate Cream than you should

Using too much Aquadrate 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 Aquadrate Cream

If you forget to use Aquadrate Cream on any occasion, do not worry, just continue as normal.

Some do's and dont's for Aquadrate Cream:

Do

use Aquadrate Cream regularly as directed

Do

wash, rinse and dry affected areas before applying Aquadrate Cream

Do

apply Aquadrate Cream to the whole of the affected area - twice daily

Don't

use Aquadrate Cream if you've had a past reaction to it or any of its ingredients

Don't

use Aquadrate Cream on moist or broken skin

Don't

worry if you occasionally forget to use Aquadrate 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, Aquadrate Cream can cause side effects, although not everyone gets them.

Some people experience local irritation when they apply Aquadrate Cream. If you notice this or any other unusual effect, tell your doctor.

If you use Aquadrate Cream as your doctor tells you, it is unlikely to cause side effects.

If any of the side effects gets worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Aquadrate Cream

Keep out of the reach and sight of children.

Do not use Aquadrate 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 Aquadrate Cream above 30°C.

Do not use Aquadrate 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 Aquadrate 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 Aquadrate Cream looks like and contents of the pack

UK ROI 003v7

Aquadrate Cream is a smooth, unperfumed, non greasy and off white cream.

Aquadrate Cream comes in aluminium tubes of 30g (grams) and 100g. A 30g tube of Aquadrate Cream contains 3g of urea and a 100g tube contains 10g of urea.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder is: Alliance Pharmaceuticals Ltd, Avonbridge House, Chippenham, Wiltshire, SN15 2BB, UK.

Aquadrate Cream is manufactured by: Laboratoires Chemineau, 93 Route de Monnaie, BP 16, 37210 Vouvray, France.

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

This leaflet was last approved: 22nd July 2008.

Alliance, Alliance Pharmaceuticals and associated devices are registered trade marks of Alliance Pharmaceuticals Ltd.

Aquadrate is a registered trade mark of Alliance Pharmaceuticals Ltd.

© Alliance Pharmaceuticals Ltd 2008.