



Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Aquadrade 10% w/w Cream.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Aquadrade cream contains Urea 10% w/w

For excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream

A smooth, unperfumed, non-greasy, off-white cream for topical administration.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the management of ichthyosis, xeroderma, hyperkeratosis and other chronic dry skin conditions.

4.2 Posology and method of administration

Aquadrade is applied topically. Wash affected areas well, rinse off all traces of soap, dry, and apply sparingly twice daily. Occlusive dressings may be used but are usually unnecessary because of the self-occlusive nature of the cream.

4.3 Contraindications

Known hypersensitivity to the product.

4.4 Special warnings and precautions for use

Avoid application to moist or broken skin.

4.5 Interaction with other medicinal products and other forms of interaction

Aquadrade may increase the penetration through the skin barrier of other topically applied medicaments.

4.6 Pregnancy and lactation

Animal reproduction studies have not been conducted with Aquadrade. Aquadrade should only be used if the anticipated benefits outweigh the risks.

4.7 Effects on ability to drive and use machines

Aquadrate does not interfere with the ability to drive or use machines.

4.8 Undesirable effects

May cause local irritations (including erythema, burning or pruritus) and oedema when applied to sensitive skin. If the condition is aggravated or there is no improvement, the doctor should be consulted.

4.9 Overdose

Topical applications of excessive amounts of Aquadrate might cause skin irritation but no other effects would be expected. Ingestion of a large amount of Aquadrate would be expected to result in gastrointestinal irritation (nausea and vomiting). Symptomatic and supportive care should be given. Liberal oral administration of milk or water may be helpful.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Urea acts as a hydrating and keratolytic agent.

5.2 Pharmacokinetic properties

Urea is primarily excreted in the urine. A small amount is also eliminated in sweat.

5.3 Preclinical safety data

In man, doses of up to 80g/day iv or 100g/day p.o urea are considered safe.

Whilst only very limited preclinical data is available, there is no evidence to suggest that urea would have teratogenic, carcinogenic or mutagenic potential in therapeutic use.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The cream also contains:

White soft paraffin
Maize starch
Isopropyl myristate
Glyceryl tribehenate
Palmitic acid
Sorbitan laurate
Polyoxyethylene fatty glyceride.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Aquadrate is available in tubes of 30g and 100g.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Alliance Pharmaceuticals Limited
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8. MARKETING AUTHORISATION NUMBER

PA 943/5/1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

7th January 1975 / 7th January 2005

10. DATE OF REVISION OF THE TEXT

January 2008