

Summary of Product Characteristics

1. NAME OF THE MEDICINAL PRODUCT

Aquadrade 10% w/w Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Aquadrade contains urea Ph Eur 10% w/w.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of ichthyosis and hyperkeratotic skin conditions associated with atopic eczema, xeroderma, asteatosis 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

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

4.8 Undesirable effects

May produce local irritations (including erythema, burning or pruritus) and oedema when applied to sensitive, moist or fissured skin.

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 has a therapeutic effect in chronic dry skin conditions through its hydrating, keratolytic and anti-pruritic properties.

5.2 Pharmacokinetic properties

There is no information available on the pharmacokinetics of urea.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The cream also contains white soft paraffin, maize starch, isopropyl myristate, syncrowax HR-C, palmitic acid, sorbitan laurate and arlatone G.

6.2 Incompatibilities

None known.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Store below 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

A patient leaflet is provided with details of use and handling of the product.

7. MARKETING AUTHORISATION HOLDER

Alliance Pharmaceuticals Ltd

Aquadrate SPC UK 005

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8. MARKETING AUTHORISATION NUMBER

PL 16853/0061

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 September 1991

10. DATE OF REVISION OF THE TEXT

5th December 2008