Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Quinoderm 10% w/w + 0.5% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzoyl Peroxide, hydrous 10.0% w/w
Potassium Hydroxyquinoline Sulfate 0.5% w/w

Excipient(s) with known effect
Cetostearyl alcohol 5.25 % - 6.375 % w/w
Macrogol 40 castor oil 0.75 % - 1.5 % w/w

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.
White, astringent vanishing cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Acne vulgaris, acneform eruptions, folliculitis.

4.2 Posology and method of administration

Posology

Adults, Children and the Elderly
By gentle massage over all the affected area two or three times daily.
A single course of treatment should not extend beyond three months unless there is clear evidence of response.

Method of administration
For topical use only.

4.3 Contraindications

Acne Rosacea.Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Avoid contact with eyes, mouth and mucous membranes. May bleach hair or dyed fabrics. Avoid exposure to excessive sunlight.

In the few isolated cases, overreaction to Quinoderm Cream may occur. To minimise this possibility, select a small area of skin behind the ear, apply the cream and leave for twelve hours. If severe irritation or pronounced redness occurs, do not proceed with treatment and a doctor or pharmacist should be consulted.

The product should only be used with caution in areas of thin or sensitive skin. Fair skinned individuals are likely to be particularly sensitive to irritation.

Benzoyl Peroxide should not be used in patients with fair or sensitive skin if there is extensive exposure to sunlight or ultraviolet light.

Where local irritation or inflammation may result, use should be interrupted or frequency reduced. If itch or rash occur treatment should cease and a doctor or pharmacist consulted (See section 4.8 Undesirable effects).

Quinoderm cream contains cetostearyl alcohol and macrogol 40 castor oil:
Cetostearyl alcohol may cause local skin reactions (e.g contact dermatitis).
Macrogol 40 castor oil may cause skin reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Benzoyl Peroxide is an oxidising agent. Hence, Quinoderm Cream should not be used at the same time as other topical agents which would react with an oxidising agent.
Zinc oxide inhibits the antibacterial and antimycotic effects of hydroxyquinoline. Concurrent use of zinc oxide is not recommended.

Concurrent administration with oral isotretinoin should be avoided.

If combination topical treatment is required with tretinoin, isotretinoin, or tazarotene, the products should be applied at different times of the day (e.g., one in the morning and the other in the evening) to minimise irritation and maximise efficacy.

4.6 Fertility, pregnancy and lactation

Pregnancy:
There are limited data on the use of topical benzoyl peroxide or potassium hydroxyquinoline sulfate in pregnant women.
Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).

Quinoderm Cream should be used during pregnancy only if the expected benefit justifies the potential risk to the foetus.

Breast-feeding:
There is insufficient information on the excretion of benzoyl peroxide or potassium hydroxyquinoline sulfate into human milk after topical administration.

Quinoderm Cream should be used during lactation only if the expected benefit justifies the potential risk to the infant.

If used during lactation, ensure that the infant's skin does not come into direct contact with the areas of skin that have been treated.

Fertility:
No data on human fertility is available.

4.7 Effects on ability to drive and use machines

Quinoderm Cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Undesirable effects are listed by MedDRA System Organ Classes.
Assessment of undesirable effects is based on the following frequency groups:
Very common: ≥1/10 common: ≥1/100 to <1/10
Uncommon: ≥1/1,000 to <1/100
Rare: ≥1/10,000 to <1/1,000
Very rare: <1/10,000
Not known: frequency cannot be estimated from the available data.

Immune system disorders	Frequency Not known: Hypersensitivity including local irritation or inflammation
Skin and subcutaneous tissue disorders	Frequency Not known: Itch Rash Dry skin

	Peeling
General disorders and administration site conditions	Frequency Not known: Application site erythema

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Symptoms are unlikely to arise after ingestion of this product. It is possible that nausea and vomiting or diarrhoea may occur.

Gut decontamination or other specific management is unlikely to be required. Treat symptomatically. A glass of milk or water may be helpful.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Benzoyl Peroxide, combinations
ATC code: D10A E51

The combination of the mild keratolytic properties of benzoyl peroxide and the antibacterial and antifungal properties of potassium hydroxyquinoline sulfate in a specially formulated bland water-miscible base make this preparation valuable in the treatment of acne vulgaris, acneform eruptions and folliculitis.

5.2 Pharmacokinetic properties

Approximately 5% of benzoyl peroxide is absorbed following topical application.

Any absorbed drug appears to be metabolised in the skin to benzoic acid and rapidly excreted in the urine.

5.3 Preclinical safety data

Data from mutagenicity studies, carcinogenicity studies and a photo co-carcinogenicity study indicate that benzoyl peroxide is neither a carcinogen nor a photocarcinogen.

No reproductive toxicity data is available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White Soft Paraffin
Cetostearyl Alcohol
Sodium Cetostearyl Sulfate
Macrogol 40 Castor Oil
Edetic Acid
Sodium dihydrogen phosphate dihydrate
Maize Starch
Lactic Acid
Purified Water

6.2 Incompatibilities

Any topical agent that would react with an oxidising agent.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate.

6.5 Nature and contents of container

Quinoderm Cream is available in heat-sealed low-density polyethylene tubes with flush-fitting polypropylene cap containing 25 g and 50 g of product. Each tube is cartoned.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

UMIP Limited
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Rathcoole
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8 MARKETING AUTHORISATION NUMBER

PA25405/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th April 1981

Date of last renewal: 24th April 2006

10 DATE OF REVISION OF THE TEXT

July 2025