

Package leaflet: Information for the patient

“DUAL ACTION” LOGO

Quinoderm®
10% w/w + 0.5% w/w Cream
benzoyl peroxide, hydrous /
potassium hydroxyquinoline sulfate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 months.

What is in this leaflet

1. What Quinoderm Cream is and what it is used for
2. What you need to know before you use Quinoderm Cream
3. How to use Quinoderm Cream
4. Possible side effects
5. How to store Quinoderm Cream
6. Contents of the pack and other information

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

Quinoderm Cream belongs to a group of medicines called peroxides. It contains two active ingredients; benzoyl peroxide, which provides a peeling action, and potassium hydroxyquinoline sulfate, which has antimicrobial and antifungal properties.

Quinoderm Cream is used for the treatment of acne vulgaris (common acne), acneform eruptions (an acne like rash) and folliculitis (a mild infection of the hair follicles).

2. What you need to know before you use Quinoderm Cream

Do not use Quinoderm Cream if:

- you are allergic to benzoyl peroxide or potassium hydroxyquinoline sulfate or any of the other ingredients of this medicine (listed in section 6)
- you have acne rosacea, a skin condition of the face where the nose and cheeks are usually red.

Warnings and precautions

- Avoid contact with eyes, mouth and mucous membranes (such as nose or throat)
- Caution is required when applying to thin or sensitive skin
- May bleach hair or dyed fabrics. If accidental contact occurs, rinse thoroughly with warm water
- Avoid exposure to excessive sunlight.

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.

In a few isolated cases an over-reaction to Quinoderm Cream may occur. If you have not used this medicine before, perform the sensitivity test described in section 3. If you experience mild irritation or inflammation use Quinoderm Cream less often, for example once a day or every few days. If severe irritation or pronounced redness occurs, stop treatment and tell your doctor or pharmacist.

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.

Other medicines and Quinoderm Cream:

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

Quinoderm Cream should not be used at the same time as any other skin preparation that would react with benzoyl peroxide, which is an oxidising agent.

Zinc oxide inhibits the antibacterial and antifungal effects of hydroxyquinoline. The use of zinc oxide at the same time is not recommended.

The use of oral isotretinoin should be avoided at the same time as Quinoderm Cream.

If you are using topical treatment 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 reduce skin irritation and to provide maximum effect.

Pregnancy and breast-feeding:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. If you have been advised by your doctor to use Quinoderm Cream whilst you are breast-feeding, you should ensure that the infant's skin does not come into direct contact with the areas of skin that have been treated.

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.

3. How to use Quinoderm Cream

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is: apply two or three times daily.

For external use only.

Sensitivity Test:

If you have not used Quinoderm Cream before, perform the following test. Select a small area of skin behind the ear, apply the cream and leave for 12 hours. If severe irritation or pronounced redness occurs, do not proceed with the treatment and tell your doctor or pharmacist.

Application – adults, children and the elderly:

- Spread thinly over all the affected areas and gently massage until no trace of the cream remains.
- It is important that the whole area is treated, not just individual spots or blemishes.
- After application, wash your hands thoroughly.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Not known: (frequency cannot be estimated from the available data)

- hypersensitivity (allergic reaction) including local irritation or inflammation
- itch
- rash
- dry skin
- peeling
- redness of skin.

It is common for some slight redness of the skin to occur during the early weeks of treatment. This should gradually disappear as your skin becomes accustomed to the treatment.

Stop using the medicine and tell your doctor or pharmacist:

- if your original symptoms do not improve within 3 months
- if the original condition worsens
- if any side effect gets serious
- if you notice any side effects not listed in this leaflet

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 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 Quinoderm Cream

- Keep this medicine out of the sight and reach of children.

- Do not use this medicine after the expiry date which is stated on the carton and the tube after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Do not refrigerate.
- Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Quinoderm Cream contains:

The active substances are benzoyl peroxide, hydrous 10% w/w and potassium hydroxyquinoline sulfate 0.5% w/w.

The other ingredients are lactic acid, white soft paraffin, edetic acid, sodium dihydrogen phosphate dihydrate, maize starch, cetostearyl alcohol, sodium cetostearyl sulfate, macrogol 40 castor oil and purified water.

What Quinoderm Cream looks like and contents of the pack:

Quinoderm Cream is a white vanishing cream. It is presented in a printed carton containing a printed tube with a cap, and an information leaflet. Each tube contains either 25g or 50g of product.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

UMIP Limited
Landscape House
Baldonnell Business Park
Dublin 22
D22 P3K7
Ireland

Manufacturer: Ecolab Ltd., Lotherton Way, Garforth, Leeds, LS25 2JY, UK.

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