

Package leaflet: Information for the user

Dubine 10 mg/g cream Ozenoxacin

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you use Dubine
3. How to use Dubine
4. Possible side effects
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6. Contents of the pack and other information

1. What Dubine is and what it is used for

Dubine contains the active substance Ozenoxacin, which belongs to the group of antibiotics for dermatological use.

Dubine is used to treat a bacterial infection, affecting small areas of skin, in adults, adolescents, children, and infants aged six months and older. The infection is called non-bullous impetigo and starts with tiny blisters and gradually a crust will cover the infected area.

2. What you need to know before you use Dubine

Do not use Dubine:

- if you are allergic to ozenoxacin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Treatment with Dubine is not recommended in the following situations:

- If the blisters are larger and affecting a larger area, without formation of crust (bullous impetigo),
- For adults and adolescents: if the extension of the lesions is higher than 100 cm².
- For children under 12 years of age: if the affected body surface is bigger than a 2% of all the skin surface of the whole body or if it surpasses the 100cm².

If you notice any worsening of the infection or develop increased redness, irritation or other signs and symptoms at the site of application, you should stop using Dubine and tell your doctor. See also section 4 of this leaflet.

Take special care if you have a skin condition, e.g. rosacea or seborrhoeic dermatitis, since deterioration of already present skin conditions may occur.

Eye contact and contact with mucous membrane with Dubine must be avoided.

Ingestion should be avoided, take special care with children who have lesions around the mouth.

Talk to your doctor if there is no improvement in your infection after three days of treatment.

Children and adolescents

Dubine should not be used on children who are less than six months old.

Other medicines and Dubine

Tell your doctor if you are using, have recently used or might use any other medicines.

Do not apply other ointments, creams or lotions to the area being treated with Dubine unless specifically instructed to do so by your doctor.

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.

Although no clinical studies have been conducted in pregnant women, no effects during pregnancy are anticipated, since uptake of ozenoxacin into the blood is negligible. Dubine can be used during pregnancy. No effects on the suckling child are anticipated since the systemic exposure of the breast-feeding woman to ozenoxacin is negligible. Dubine can be used during breast-feeding but, as a precaution, nursing mothers should not apply ozenoxacin cream to the breast area to protect the suckling infant from unintentional oral drug uptake.

Driving and using machines

Dubine is not expected to affect your ability to drive or use machines.

Dubine contains:

- Propylene glycol which may cause skin irritation.
- Stearyl Alcohol which may cause local skin reactions (e.g. contact dermatitis).
- Benzoic acid which may be irritant to the skin, eyes and mucous membranes and may increase the jaundice in pre-term and full-term jaundiced neonates because of its absorption through the skin. The amount of benzoic acid per each gram of cream is 1 mg.

3. How to use Dubine

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

Apply a thin layer of cream on the infected skin twice a day for five days. The treated area may be covered by a sterile bandage or gauze dressing, if desired. Wash your hands before and after applying the cream. Dubine is for use on the skin only. It must not be put in the eyes, on the mouth or lips, inside the nose or inside the female genital area. If the cream accidentally gets on to these areas, wash the area with water and consult your doctor if you experience discomfort.

If you use more Dubine than you should

Carefully wipe off the extra cream

If you accidentally swallow Dubine

Contact your doctor or pharmacist for advice.

If you forget to use Dubine

Apply the cream as soon as you remember, and apply the next dose at the usual time.

If you stop using Dubine

If you stop using Dubine too soon, the bacteria may start to grow again and your infection may come back. Do not stop using this medicine before talking to your doctor or pharmacist.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you develop a severe skin reaction or an allergy:

- Stop using Dubine
- Carefully wipe off the cream
- Contact your doctor or pharmacist immediately

The following side effects have occurred on the skin where Dubine has been applied.

Uncommon side effects (may affect up to 1 in 100 people):

- Itching (pruritus) or irritation at the application site.

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 Dubine

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 tube and carton after "EXP". The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

You may use the cream for up to 45 days after opening. The tube can be re-used for a second treatment, provided that those 45 days after opening are not exceeded.

Do not throw away any medicines via wastewater 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 Dubine contains**

- The active substance is ozenoxacin: Each gram of Dubine contains 10 mg of ozenoxacin
- The other ingredients are macrogol stearate ethylene glycol monopalmitostearate, , oleoyl macrogol glycerides, octyldodecanol, stearyl alcohol, propylene glycol, benzoic acid (E-210), purified water. Some of these ingredients can cause a skin reaction; see section 2 of this leaflet.

What Dubine looks like and contents of the pack

Dubine is a pale yellow cream, and is available in an aluminium tube with a white screw cap.

Pack size:

Tubes containing 10 g of cream.

Marketing Authorisation Holder

Ferrer Internacional, S.A.
Gran Vía Carlos III, 94
08028 – Barcelona (Spain)

Manufacturer

Ferrer Internacional, S.A.
Joan Buscallà 1-9
08173-Sant Cugat del Valles, Barcelona (Spain)

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium:	Ozadub 10 mg/g crème
Finland:	Dubine 10 mg/g emulsiovoide
Germany:	Dubine 10 mg/g Creme
Greece:	Dubine 10 mg/g κρέμα
Ireland:	Dubine 10 mg/g cream
Italy:	Dubine
Poland:	Dubine
Portugal:	Ozanex 10 mg/g creme
The Netherlands:	Ozanex 10 mg/g crème
Spain:	Ozanex 10 mg/g crema
Sweden:	Ozanex 10 mg/g kräm
United Kingdom:	Ozadub 10 mg/g cream

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