

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT- INSTRUCTIONS FOR USE

Curaderm^{BCC}

What Curaderm^{BCC} is and what it is used for

Decades of scientific research about the anti-tumoral properties of natural glycoalkaloids actives derived from the *Solanaceae* plant group have led to the formulation of Curaderm^{BCC} a treatment that incorporates the keratolytic action of salicylic acid, lactic acid and urea to remedy cellular proliferation activity also by the cytoprotective action of the glycoalkaloids. Moreover, Curaderm^{BCC} allows the entry of other therapeutic agents, including molecules with pharmacological actions.

Intended use: Topical treatment with keratolytic action, adjuvant in the healing of localized basal cell carcinoma of the skin.

What you need to know before you use Curaderm^{BCC}

Do not use Curaderm^{BCC} If you are allergic to solasodine glycosides or any of the other ingredients of this treatment.



Warnings and precautions Avoid contact with eyes. In the event of accidental contact, remove the cream by rinsing with plenty of water and seek medical assistance as soon as possible. Do not swallow this remedy. Drink plenty of water if you accidentally swallow this cream and seek medical assistance.

Make sure that your skin has healed from any other treatments or surgery before using this remedy.

Do not apply Curaderm^{BCC} on open-wounds or damaged skin. Do not apply this treatment internally, to the area near the eyes, to the inside of the nostrils, the inside of the ear or on the lips. Avoid sunlight as much as possible (including sunlamps and tanning beds). This remedy is intended to treat one large basal cell carcinoma of maximum 25 cm² or multiple smaller basal cell carcinomas until complete healing is obtained. Do not use in cases of suspected spinocellular carcinoma, melanoma or other skin neoplasms other than basal cell carcinoma. Do not apply more cream than your doctor has advised. You should expect to get local skin reactions, such as reddening and swelling, during treatment with this treatment. Contact your doctor if these local skin reactions get severe.

Other treatments and Curaderm^{BCC} Tell your doctor or pharmacist if you are using, have recently used, or might use any other medicines. If you have previously used Curaderm^{BCC} or other similar remedies tell your doctor before starting the treatment.

How to use Curaderm^{BCC} Always use this remedy exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Instructions for use:

- Wash the lesion and the surrounding area with a mild non-irritating soap
- Rinse with water
- Dry thoroughly
- Unscrew the lid of the Curaderm^{BCC} tube and remove the protective seal on the lid of the tube
- Apply Curaderm^{BCC} to the lesion, just enough to cover the lesion. Do not apply the cream in large quantity and do not extend the cream more than 0.5 cm onto the apparently normal skin surrounding the edge of the lesion
- Apply the cream to the lesion by gently squeezing the tube
- Cover the lesion with an occlusive dressing such as Micropore, Leukopor or Duoderm, but not a band-aid, until the next application of Curaderm^{BCC}
- Apply the cream to the lesion at least twice daily, i.e. at least every 12 hours
- If the treatment period is more than 12 weeks, please contact your doctor or pharmacist



Possible side effects This treatment can cause side effects, although not everybody gets them. By using this treatment, the skin where you apply it is likely to get red and ulcerate. This effect may occur within one day after the first and second application. The effect may get worse for up to 2 weeks during treatment. The lesion will appear to become larger during the initial stages of treatment, this is normal. Pain (including application site burning) may occur. Treatment should continue until the lesion is eliminated. Infection of the skin in the treatment area is very rare.

Reporting of side effects If you get any side effects, please communicate this immediately to the Manufacturer and corresponding Health Authorities in your territory. This includes any possible side effects not listed in this leaflet

How to store Curaderm^{BCC} Keep this medical device out of the sight and reach of children. Do not use this medicine after the expiry date, which is stated on the crimp of the tube above . The expiry date refers to the last day of that month.

Store below 25°C. (2°C-8°C in refrigerator after opening of tube).

For multiple use.

What Curaderm^{BCC} contains

Aqua, salicylic acid, paraffinum liquidum, petrolatum, lactic acid, cetearyl alcohol, cetareth-20, urea, propylene glycol, solasodine rhamnoside, xanthan gum, p-chlorocresol



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