

## PACKAGE LEAFLET: INFORMATION FOR THE USER

Lauroderme, 95 mg/g + 5 mg/g, cream  
Zinc oxide + salicylic acid

Lauroderme, 100 mg/ml + 5.26 mg/ml, cutaneous liquid  
Zinc oxide + salicylic acid

Lauroderme, 95 mg/g + 5 mg/g, cutaneous paste  
Zinc oxide + salicylic acid

Lauroderme, 23 mg/g + 2 mg/g, cutaneous powder  
Zinc oxide + salicylic acid

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

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.
- If symptoms worsen or persist, consult your doctor.
- If you experience any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist. See section 4.
- If you don't feel better or get worse, you need to see a doctor.

What's in this leaflet:

1. What Lauroderme is and what it is used for
2. What you need to know before you use Lauroderme
3. How to use Lauroderme
4. Undesirable effects
5. How to store Lauroderme
6. Package contents and other information

### 1. What Lauroderme is and what it is used for

Lauroderme is a medicine from the group of Emollients that is used in the following situations:

- Disinfection and hygiene of the skin and mucous membranes;
- Superficial wounds;
- Diaper dermatitis.

### 2. What you need to know before you use Lauroderme

Do not use Lauroderme

- If you are allergic to zinc oxide and salicylic acid or any of the ingredients of this medicine (listed in section 6).

Warnings and precautions. Talk to your doctor or pharmacist before using Lauroderme.

This is a product for external use only.

Other medicines and Lauroderme

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

#### Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or plan to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

Lauroderme has been used during pregnancy and breastfeeding without harmful effects on the fetus or lactating mother.

#### Lauroderme, 95 mg/g + 5 mg/g, cream

This medicine contains cetyl alcohol. It may cause local skin reactions (e.g. contact dermatitis).

This medicine contains methyl parahydroxybenzoate and propyl parahydroxybenzoate. May cause allergic reactions (possibly delayed).

This medicine contains propylene glycol. This medicine contains 60.5 mg of propylene glycol in each g of cream. Propylene glycol may cause skin irritation. Do not use this medicine in babies under 4 weeks of age with open wounds or large areas of cracked or injured skin (such as burns) without talking to your doctor or pharmacist.

This medicine contains fragrance Lilla Essence (Fleurs sauvages 33508P) with allergens. The allergens Benzyl Alcohol, Cinnamyl Alcohol, Citronellol, Linalool, Lilial, Eugenol, and Isoeugenol can cause allergic reactions.

#### Lauroderme, 100 mg/ml + 5.26 mg/ml, cutaneous liquid

This medicine contains cetyl alcohol. It may cause local skin reactions (e.g. contact dermatitis).

This medicine contains methyl parahydroxybenzoate and propyl parahydroxybenzoate. May cause allergic reactions (possibly delayed).

This medicine contains propylene glycol. This medicine contains 57.92 mg of propylene glycol in each ml of skin fluid. Propylene glycol may cause skin irritation. Do not use this medicine in babies under 4 weeks of age with open wounds or large areas of cracked or injured skin (such as burns) without talking to your doctor or pharmacist.

This medicine contains fragrance Lilla Essence (Fleurs sauvages 33508P) with allergens. The allergens Benzyl Alcohol, Cinnamyl Alcohol, Citronellol, Linalool, Lilial, Eugenol, and Isoeugenol can cause allergic reactions.

#### Lauroderme, 95 mg/g + 5 mg/g, cutaneous paste

This medicine contains lanolin. It may cause local skin reactions (e.g. contact dermatitis).

This medicine contains methyl parahydroxybenzoate. May cause reactions allergic (possibly delayed).

This medicine contains fragrance Lilla Essence (Fleurs sauvages 33508P) with allergens. The allergens Benzyl Alcohol, Cinnamyl Alcohol, Citronellol, Linalool, Lilial, Eugenol, and Isoeugenol can cause allergic reactions.

#### Lauroderme, 23 mg/g + 2 mg/g, cutaneous powder

This medicine contains benzyl alcohol. This medicine contains 0.8 g of benzyl alcohol per 100 g, which is equivalent to 8 mg/g.

Benzyl alcohol may cause allergic reactions and mild local irritation.

This medicine contains fragrance Lilla Essence (Fleurs sauvages 33508P) with allergens. The allergens, Cinnamyl Alcohol, Citronellol, Linalool, Lilial, Eugenol and Isoeugenol can cause allergic reactions.

### 3. How to use Lauroderme

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

On the intact skin, spread a quantity of Lauroderme to cover the entire affected area and massage gently.

In the case of skin lesions, spread in a thick layer, without massaging.

The recommended dose is according to the patient's needs.

If you use more Lauroderme than you should  
Given the route of administration, intoxication is unlikely to occur.

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

### 4. Possible undesirable effects

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

No relevant references were found in the published scientific literature on this point.

Occasionally, skin irritation reactions may occur, which disappear with discontinuation of the application of the drug.

If any of the side effects get serious or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

#### Reporting of undesirable effects

If you experience any side effects, including possible side effects not listed in this leaflet, talk to your pharmacist. You can also report undesirable effects directly to INFARMED, I.P. through the contacts below. By reporting side effects, you are helping to provide more information about the safety of this medicine.

Website: <http://www.infarmed.pt/web/infarmed/submissaoram>  
(preferably)

or through the following contacts:

Direção de Gestão do Risco de Medicamentos  
Parque da Saúde de Lisboa, Av. Brazil 53  
1749-004 Lisboa  
Tel: +351 21 798 73 73  
Drug Line: 800222444 (free of charge)  
Email: [farmacovigilancia@infarmed.pt](mailto:farmacovigilancia@infarmed.pt)

### 5. How to store Lauroderme

Do not store above 30°C.

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

Do not use Lauroderme after the expiry date which is stated on the carton. The expiry date corresponds to the last day of the month indicated.

Do not use this medicine after the expiry date which is stated on the carton after EXP: . The expiry date corresponds to the last day of the month indicated.

Do not dispose of any medicines in the sewer or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

## 6. Package contents and other information

What Lauroderme contains

Lauroderme, 95 mg/g + 5 mg/g, cream

- The active substances are: zinc oxide and salicylic acid. Each gram of cream contains 95 mg of zinc oxide and 5 mg of salicylic acid.

- The other ingredients are: glyceryl monomyristate, cetyl alcohol, isopropyl myristate, silicone oil, decyl oleate, propylene glycol, methyl parahydroxybenzoate, propyl parahydroxybenzoate, retinol, cholecalciferol, lilla essence (contains benzyl alcohol, cinnamyl alcohol, citronellol, linalool, lillial, eugenol and isoeugenol) ethanol 96%, hexadecyl dihydrogen phosphate and purified water.

Lauroderme, 100 mg/ml + 5.26 mg/ml, cutaneous liquid

- The active substances are: zinc oxide and salicylic acid. Each milliliter of skin fluid contains 100 mg of zinc oxide and 5.26 mg of salicylic acid.

- The other ingredients are: self-emulsifying glyceryl monostearate, steareth-10, liquid paraffin, propylene glycol, cetyl alcohol, medium-chain triglycerides, silicone oil, methyl parahydroxybenzoate, xanthan gum, propyl parahydroxybenzoate, citric acid monohydrate, lilla essence (contains benzyl alcohol, cinnamyl alcohol, citronellol, linalool, lillial, eugenol and isoeugenol) and purified water.

Lauroderme, 95 mg/g + 5 mg/g, cutaneous paste

- The active substances are: zinc oxide and salicylic acid. Each gram of skin paste contains 95 mg of zinc oxide and 5 mg of salicylic acid.

- The other ingredients are: methyl parahydroxybenzoate, egg albumin, retinyl palmitate, cholecalciferol, ethanol 96%, lanolin, liquid paraffin, talc, lilla essence (contains benzyl alcohol, cinnamyl alcohol, citronellol, linalool, lillial, eugenol and isoeugenol) and purified water.

Lauroderme, 23 mg/g + 2 mg/g, cutaneous powder

- The active substances are: zinc oxide and salicylic acid. Each gram of skin powder contains 23 mg of zinc oxide and 2 mg of salicylic acid.

- The other ingredients are: zinc peroxide, hydrated colloidal silica, wheat starch, talc, lilla essence (contains benzyl alcohol, cinnamyl alcohol, citronellol, linalool, lillial, eugenol and isoeugenol) and benzyl alcohol.

What Lauroderme looks like and contents of the pack

Lauroderme, 95 mg/g + 5 mg/g, cream

30 g and 100 g tubes of cream.

Lauroderme, 100 mg/ml + 5.26 mg/ml, cutaneous liquid  
150 ml bottles of cutaneous liquid

Lauroderme, 95 mg/g + 5 mg/g, cutaneous paste  
Tubes of 30 g, 50 g and 100 g cutaneous paste.

Lauroderme, 23 mg/g + 2 mg/g, cutaneous powder  
50 g and 100 g bottles of cutaneous powder.

#### Marketing Authorization Holder

Baldacci - Portugal, S.A.  
Rua Cândido de Figueiredo, 84-B  
1549-005 Lisboa  
Portugal  
Tel: 217783031  
Fax: 217785457  
Email: [medico@baldacci.pt](mailto:medico@baldacci.pt)

#### Manufacturer

Baldacci - Portugal, S.A.  
Avenida de Santa Iria da Azóia, Bloco B/C  
2695-381 Santa Iria da Azóia  
Portugal

This leaflet was last revised in November 2021