### Patient Information Leaflet

# Dexasalvl®

### This is a medicament

Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instruction of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

### What is Dexasalvl and when is it used?

Dexasalyl is indicated for external application in the treatment of certain skin diseases. The main active substance (dexamethasone) has anti-inflammatory and anti-allergic properties and alleviates itching. Dexasalyl also contains salicylic acid - an active substance that stimulates the stratum corneum (horny layer) and loosens scales. Dexasalyl is prescribed by your doctor for the treatment of mild and moderately severe cases of chronic skin diseases associated with a thickened, flaky stratum corneum and dry, itchy skin such as all forms of chronic eczema, neurodermatitis and psoriasis, etc. Dexasalyl ointment is very greasy and makes the skin soft. Dexasalyl solution can be used on body regions that are covered in hair because it is not greasy and does not adhere or leave residues.

### When must Dexasalyl not be used?

Dexasalyl must not be used in the case of skin infections such as tuberculosis of the skin, syphilis, viral skin infections (chicken pox, herpes zoster) or vaccination reactions. Do not use if you are hypersensitive to one of the ingredients contained in the preparation such as salicylic acid or dexamethasone (very rare). Dexasalyl is not suitable for the treatment of severely inflamed, weeping conditions. Specific medical supervision is required when the product is used for children, especially young children. The preparation must not be used for infants, Face/genital region: if possible, do not use. Damaging thinning of the skin may occur within a matter of days. Consult your doctor if symptoms are exacerbated or if no response is elicited during treatment. An allergy or infection may be the cause.

## When should caution be applied during application of Dexasalyl?

Do not exceed the treatment period and area of application recommended by your doctor. Inform your doctor or pharmacist if you are suffering from other conditions, have allergies or are taking or applying other medicines (even non-prescription (over-the-counter) medicines). Dexasalyl is a highly potent agent. Do not exceed the treatment period of normally 2 - 3 weeks advised by your doctor as skin damage may otherwise occur.

Application to large areas (more than 10 % of the body surface) and to highly absorbent areas of skin (open wounds, damaged skin, between folds of skin in the joints as well as between the fingers and toes, skin/mucous membrane layers, around the eyes) should be avoided. Use Dexasalyl only for the current skin condition for which the medicinal product has been prescribed and not for other subsequent skin disorders. Do not give Dexasalyl to other persons,

# Can Dexasalyl be used during pregnancy or whilst breast-feeding?

Although no adverse events have been reported in the unborn child following application of Dexasalyl during pregnancy, laboratory animal studies indicate a risk of deformity at very high dose levels. For these reasons, Dexasalyl should not, where possible, be used during pregnant cy, especially during the first trimester. Nursing mothers should only apply the preparation for short periods and to small areas. In all cases, seek medical advice and inform your doctor if you become pregnant before or during treatment.

### How should Dexasalyl be applied?

Unless otherwise prescribed by your doctor, apply Dexasalyl thinly to the affected area 1 - 2 times a day. An occlusive dressing should only be applied on your doctor's recommendation. Do not change the dosage. Consult your doctor or pharmacist if you think that Dexasalyl is too weak or too strong.

## What are the possible side effects of Dexasalyl?

Local side effects such as skin irritation, a burning sensation, itching and dryness as well as hypersensitivity reactions may occur. The skin may become thin and discoloured with some bleeding. The smaller, superficial blood vessels may become dilated and blue-red striae (wheals) may appear. Irritation, inflammation of the hair follicles and increased hair formation very occasionally occur. Increased sensitivity to sunlight. A transient burning sensation may be experienced upon administration of the solution to irritated skin. This is due to the alcohol content of the preparation and is of no significance. In children, particularly young children, it should be noted that the active substance is increasingly absorbed by the circulation such that long-term application may lead to growth disorders.

### Other points to note?

Keep all medicines out of reach of children. The solution must be refrigerated (2 °C - 8 °C). Do not store the ointment above 30 °C. Use Dexasalyl only up to the date indicated by "EXP" on the container. The package should be returned to the pharmacy for disposal once treatment has ended or the expiry date has elapsed. Further information is available from your doctor or pharmacist, both of whom have detailed product information (Summary of Product Characteristics) at their disposal.

### What does Dexasalvl contain?

Dexasalyl ointment contains the following per 1 g: 1.2 mg dexamethasone acetate and 30 mg salicylic acid in a wool wax/vaseline/paraffin base (no preservatives) and other excipients. Dexasalyl solution contains the following per 1 g: 1.2 mg dexamethasone and 20 mg salicylic acid in an alcohol-aqueous solution with 440 mg isopropanol, propylene glycol and other excipients (no preservatives).

# Where can you obtain Dexasalvl?

What pack sizes are available?

Dexasalyl is available from pharmacies only on prescription. Ointment 20 g, solution 30 ml.

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