Prolid Cream 5% safety card

Therapeutic indication

- Topical anaesthesia of the skin in connection with:
  - needle insertion, e.g. intravenous catheters or blood sampling;
  - superficial surgical procedures; in adults and in the paediatric population.
- Topical anaesthesia of the genital mucosa, e.g. prior to superficial surgical procedures or infiltration anaesthesia; in adults and adolescents ≥ 12 years
- Topical anaesthesia of leg ulcers to facilitate mechanical cleansing/debridement in adults only.

Dosage and administration:

	Dose and administration	Application Time
For needle insertion e.g. insertion of intravenous lines, taking blood samples	½ tube (approx. 2g) per 10 cm2. A thick layer of cream is applied to the skin and covered with an occlusive dressing.	1 hour; Maximum 5 hours
For minor superficial surgical procedures, e.g. curettage of the lesions caused by mollusca contagiosa	1.5-2 g per 10 cm2. A thick layer of cream is applied to the skin and covered with an occlusive dressing.	1 hour; Maximum 5 hours
For more extensive superficial surgical procedures, e.g. split skin grafting	1.5-2 g per 10 cm2. A thick layer of cream is applied to the skin and covered with an occlusive dressing	2 hour; Maximum 5 hours
On large areas of newly shaven skin (in outpatient care)	Maximum recommended dose: 60g. Maximum recommended treatment area: 600 cm2.	1 hour; Maximum 5 hours

Leg ulcers

For cleaning of leg ulcers: approx. 1-2 g per 10 cm2. The cream is applied in a thick layer to the surface of the ulcer, but not more than 10g per treatment procedure. Cover the surface of the ulcer with an occlusive dressing. An opened tube is intended for a single use, and any remaining cream must therefore be discarded after each treatment procedure.
Application time: at least 30 minutes.
For leg ulcers with tissue that is particularly difficult to penetrate the application time may be extended to 60 minutes. Cleaning of the ulcer should begin within 10 minutes after the cream has been removed.

Genital use

Skin

Use prior to injection of local anaesthetics:

Men

1g per 10 cm2. A thick layer of cream is applied to the skin.
Application time: 15 minutes.

Women

1-2 g per 10 cm2. A thick layer of cream is applied to the skin.
Application time: 60 minutes.

Genital mucosa

For removal of condyloma or prior to injection of local anaesthetics: approx. 5-10g, depending on the area to be treated. The whole surface, including the mucosal folds, must be covered.
Application time: 5-10 minutes. The surgery must be begun immediately after removal of the cream.

Children

For needle insertion, curettage of the lesions caused be mollusca contagiosa and other minor surgical procedures:
1g per 10 cm2.

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A thick layer of cream is applied to the skin and covered with an occlusive dressing. The dose should not exceed 1g per 10 cm2 and must be adjusted according to the application area:

Age	Application area	Application time
0-3 months	Maximum 10 cm2 (total of 1 g) (maximum daily dose)	1 hour (note: not longer)
3-12 months	Maximum 20 cm2 (total of 2 g)	1 hour
1-6 years	Maximum 100 cm2 (total of 10 g)	1 hour; maximum 5 hours [1])
6-12 years	Maximum 200 cm2 (total of 20 g)	1 hour; maximum 5 hours[1])

[1]) After a longer application time, the anaesthesia decreases.
Children with atopic dermatitis: reduce application time to 30 minutes.

Elderly
No dose reduction is necessary in elderly patients .
Hepatic impairment
A reduction of a single dose is not necessary in patients with impaired hepatic function .
Renal impairment
A dose reduction is not necessary among patients with restricted renal function.

Precautions :

- Patients with glucose-6-phosphate dehydrogenase deficiency or congenital or idiopathic methaemoglobinaemia are more susceptible to drug-induced methaemoglobinaemia.
- Caution when using near the eyes, as Prolid may cause eye irritation. Also the loss of protective reflexes may allow corneal irritation and potential abrasion. If eye contact occurs, immediately rinse the eye in water or sodium chloride solution and protect until sensation returns.
- Caution when using on areas on skin with atopic dermatitis; the application time should be reduced (15-30 minutes). Application times of longer than 30 minutes in patients with atopic dermatitis may result in an increased incidence of local vascular reactions, particularly application site redness and in some cases petechia and purpura (see section Undesirable effects).
- Prior to removal of mollusca contagiosa in children with atopic dermatitis it is recommended to apply the cream for 30 minutes.
- Patients treated with anti-arrhythmic drugs class III (e.g. amiodarone) should be under close surveillance and ECG monitoring considered, since cardiac effects may be additive.
- Prolid should not be used on damaged tympanic membrane or in other situations where penetration into the middle ear may occur.
- Prolid should not be applied to open wounds.
- Prolid should not be used on the genital mucosa in children on account of incomplete data of absorption.
- Lidocaine and prilocaine have bacteriocidal and antiviral properties in concentrations above 0.5- 2%. For this reason the results of intracutaneous injections of live vaccines (e.g. BCG) should be monitored.
- Until further clinical experience is available, Prolid should not be used for children aged 0-12 months during concomitant treatment with methaemoglobin-inducing drugs (see also Overdose).
- Prolid cream contains macrogol glycerol hydroxystearate which can cause skin reactions.

Contraindication :

- Known hypersensitivity to local anaesthetics of the amide type or to any of the excipients. Prolid must not be

used on premature infants (born before week 37 of pregnancy).

Pregnancy and lactation:

Pregnancy

Although topical application is associated with only a low level of systemic absorption, the use of PROLID Cream in pregnant women should be undertaken with care because insufficient data are available concerning the use of PROLID Cream in pregnant women. Lidocaine and prilocaine cross the placental barrier and may be absorbed by the foetal tissues. It is reasonable to assume that lidocaine and prilocaine have been used in a large number of pregnant women and women of childbearing age. No specific disturbances to the reproductive process have so far been reported, e.g. an increased incidence of malformations or other directly or indirectly harmful effects on the foetus.

Lactation

Lidocaine and, in all probability, prilocaine are excreted into breast milk, but in such small quantities that there is generally no risk of the child being affected at therapeutic dose levels. PROLID Cream can be used during breast-feeding if clinically needed.

(This card focuses on major safety information for medicinal products in order to minimize possible side effects that arise from improper use of medicinal products).

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