SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Lidokain Isdin 40 mg/g cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g cream contains 40 mg lidocaine.
Excipients with known effect:
Propylene glycol 75 mg
Benzyl alcohol 15 mg
Hydrogenated soy lecithin 73.2 mg
Polysorbate 80, 7,5 mg
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream
White to yellowish cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Topical anaesthesia of the skin in association with needle insertions.

4.2 Posology and method of administration

Posology
A thick, even layer of cream should be applied to the skin area being treated.

Children from 6 to 12 years:
The single application dose is 2-3g. Recommended application time is 60 minutes, but no longer than two hours.

Adolescents over 12 years and Adults:
The single application dose is 2-3g. The maximum daily dose is 5 grams. Recommended application time is 60 minutes, but no longer than two hours.

Children from 2 to 6 years:
As there are insufficient data Lidokain Isdin is not recommended in this age group.

Children from 0 to 2 years:
As there are no data available Lidokain Isdin should not be used in this age group.

Method of administration
1 g of cream corresponds to a strand of approximately 2.5 cm.

A dressing is recommended to avoid the cream coming off before the application time is up.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Hypersensitivity to local anaesthetics of the amide type, to soya or peanuts.
Pre-term newborn infants born before the 37th full week of pregnancy.

4.4 Special warnings and precautions for use

In acute inflammation of the middle ear when puncturing the eardrum is necessary, or in other surgical procedures in the auditory canal or inner ear, as there is a risk of damage to the inner ear.

Extensive use should be avoided in patients with serious underlying conditions; in particular impairment of cardiac conduction, non-compensated cardiac insufficiency or cardiogenic or hypovolaemic shock. Patients treated with antiarrhythmics class I and III (e.g. tocainide, mexiletine and amiodarone) should be closely supervised and ECG monitoring should be considered, as the cardiac effects of lidocaine and these antiarrhythmics can be additive.

There are currently no clinical studies of Lidokain Isdin in the treatment of wounds, mucous membranes and skin areas of atopic dermatitis. Lidokain Isdin should therefore only be used on undamaged skin.

Lidokain Isdin should be used with caution near the eyes, as lidocaine may cause eye irritation. In addition, with the loss of protective reflexes, corneal irritation or grazes may occur. If Lidokain Isdin comes into contact with the eyes, they should be rinsed immediately with water or sodium chloride solution and protected until sensation returns.

In order to prevent reduced efficacy of live vaccines, such as BCG, vaccines should not be administered in areas where Lidokain Isdin has already been applied.

Due to an increased risk of high plasma concentrations of lidocaine, Lidokain Isdin should be used with caution in patients with severe hepatic impairment.

Frequent use of high doses of lidocaine is not recommended.

Lidokain Isdin contains propylene glycol, which may cause skin irritations.
Lidokain Isdin contains benzyl alcohol which may cause allergic reactions and mild local irritation.
Polysorbates can cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Increased systemic toxicity should be taken into account if Lidokain Isdin is coadministered with lidocaine therapy given in high doses, as well as other local anaesthetics or substances with similar structure (e.g. class I antiarrhythmic agents such as tocainide and mexiletine).
Specific interaction studies of local anaesthetics and antiarrhythmic active substances class III (e.g. amiodarone) have not been performed but caution is advised.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no adequate data of pregnant women treated with Lidokain Isdin. Animal studies are incomplete in regard to pregnancy, embryonic/foetal development, delivery and postnatal development (see section 5.3). Lidocaine crosses the placenta barrier and may be absorbed in amniotic fluid. The risk to humans is not known. With temporary use of Lidokain Isdin during pregnancy, the benefit is considered to outweigh the possible risks. The lowest possible dose of Lidokain Isdin should be used for the shortest possible time during pregnancy.

Lactation
Lidocaine is excreted in breast milk in small quantities. It is thought unlikely, however, that Lidokain Isdin affects the child. Breast feeding can therefore continue during treatment.

4.7 Effects on ability to drive and use machines

Lidokain Isdin has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Skin and subcutaneous tissue disorders:
Uncommon (≥1/1000 to <1/100)
Local skin reactions, such as pallor and redness in the treated area. These symptoms are caused by a direct effect of the local anaesthetic on the blood vessels and are usually transient and mild.
Skin irritations such as itching and burning may occur, particularly in the beginning of treatment. These symptoms are transient.

Immune system disorders:
Rare (≥1/10 000 to <1/1000)
Allergic contact eczema

Very rare (<1/10 000)
Allergic reactions (in severe cases, anaphylactic shock) to
- local anaesthetic of amide type
- hydrogenated soy lecithin

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via <to be completed nationally>

4.9 Overdose

Systemic toxicity is extreme unlikely with normal use of Lidokain Isdin. However, if signs of an overdose are observed, it is to be expected that the symptoms are similar to those described for other local anaesthetics e.g. excitatory CNS symptoms and, in severe cases, CNS depression and myocardial depression. Topical administration of 8.6 – 17.2 mg/kg of lidocaine caused very severe intoxication in small children.

If signs of acute systemic toxicity should occur, administration of the local anaesthetic should be discontinued immediately. Severe neurological reactions (convulsions, CNS depression) require symptomatic treatment such as respiratory supportive and anticonvulsive therapy. In regard to chronic systemic absorption, a patient with symptoms of toxicity should be observed for several hours after treatment of these symptoms.

Accidental oral intake of the cream by children may cause toxic symptoms, depending on the dose.

There is no specific antidote for lidocaine.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Local anaesthetics: amides
ATC code: N01BB02

Lidokain Isdin is a local anaesthetic for surface anaesthesia of the skin in topical surgical procedures.

The active substance, lidocaine, is a local anaesthetic of the amide type. Topical anaesthesia occurs after application through the release of lidocaine in the skin's epidermal and dermal layers, near the pain receptors in the skin and nerve endings. Blocking of the sodium ion channels subsequently occurs, preventing initiation and conduction of the nerve impulse.
The degree of anaesthesia depends on the application time and dose.

Lidokain Isdin causes a transient local peripheral vasoconstriction or vasodilatation in the treated area of skin.
Lidocaine has bactericidal and virus suppressing properties in concentrations above 0.5 – 2 %.

5.2 Pharmacokinetic properties

There are no data on the bioavailability of lidocaine in Lidokain Isdin. The systemic absorption depends on the amount of cream, application time, skin thickness (varies in different parts of the body) and the general condition of the skin.

Absorption of lidocaine after application of Lidokain Isdin on intact skin is very low and increased absorption can therefore be expected after application on mucous membrane of previously damaged skin. There are also insufficient data on the use of Lidokain Isdin on wounds and mucous membranes.

In studies in which Lidokain Isdin was used in children of different ages (3-15 years), the plasma levels of the active substance were very low (0.3 micrograms/ml or less). This was well below toxic plasma levels of the active substance. There are no pharmacokinetics data for Lidokain Isdin in children under 2 years.

The plasma elimination half life of lidocaine is 1.5 – 2 hours after absorption from the tissues.
The distribution volume is 1.5 l/kg and the plasma protein binding is approx. 65 %.

90 – 95 % is metabolised in the liver to the main metabolite 4-hydroxy-2,6-dimethylaniline. The amount of formed 2,6-xylidine, the intermediate metabolite, has not been established. 5 – 10 % of the dose is excreted renally in unchanged form.

The elimination half life in patients with renal insufficiency is 2 – 3 hours and accumulation of active metabolites may occur. In hepatic impairment, the rate of metabolism may decrease from half to 1/10 of the normal.

5.3 Preclinical safety data

Reproduction toxicology
In studies of embryonic/foetal development in which rats or rabbits were dosed during organ development, no teratogenic effects were observed. Embryotoxicity was seen in rabbits at a dose toxic to the mother. In rats, reduced postnatal survival was seen in the young of mothers treated during late pregnancy and lactation with doses which were toxic and influenced the length of the pregnancy.

Genotoxicity and carcinogenicity
Genotoxic studies of lidocaine were negative. 2,6-xylidine, a metabolite of lidocaine has, however, shown genotoxic potential in vitro. In a carcinogenicity study of rats exposed in utero, postnatally and throughout life to 2,6-xylidine, tumours were observed in the nasal cavity, the liver and subcutaneously. High doses of 2,6-xylidine were needed to induce tumours in animal studies. The clinical relevance of the tumour inducing effect of this lidocaine metabolite after intermittent use as a local anaesthetic is unknown.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water
Propylene glycol
Hydrogenated soy lecithin
Benzyl alcohol
Polysorbate 80
Carbomer 940
Trolamine
Cholesterol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 months
After first opening: 6 months

6.4 Special precautions for storage

Do not store above 30°C.
Keep the tube tightly closed

6.5 Nature and contents of container

Aluminium tube: 5 g, 10 g, 20 g, 30 g, 40 g or 50 g cream
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

8. MARKETING AUTHORISATION NUMBER

<[To be completed nationally]>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:
Date of latest renewal: 17 January 2012

10. DATE OF REVISION OF THE TEXT

2025-05-08