SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Lidokain GALENpharma 50 mg/g rectal ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g rectal ointment contains 50 mg lidocaine.

Excipient(s) with known effect:
1 g rectal ointment contains 100 mg cetyl alcohol.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Rectal ointment
White, homogenous ointment

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

<Invented name> 50 mg/g rectal ointment is indicated in adults for the treatment of:

- Relief of pain in the anal region before proctological examination,
- Symptomatic treatment of itching and pain in the anal area caused by, for example, haemorrhoids.

4.2 Posology and method of administration

Posology

Adults

<Invented name> is used 2-3 times a day.

The amount of ointment will depend on the areas of skin and mucosa to be treated. A maximum dose of 2.5 grams of ointment (125 milligrams of lidocaine) per single application should not be exceeded.

In adults the “finger-tip unit” can be used to measure the quantity of ointment to be applied. A finger-tip unit corresponds to the amount of ointment applied from an adult’s tip of the index finger to the first crease of the finger. A finger-tip unit corresponds to approx. 0.5 gram of the <invented name> rectal ointment. The maximum dose of 2.5grams corresponds to 5 finger-tip units.

Paediatric population

The safety and efficacy of <invented name> in children aged under 18 years have not yet been established. No data are available.

Before first use

The tube contains a cover in the opening which must be pierced before the first application.
To avoid sharp kinks, it is recommended to roll up the tube from the end after each use so that the front part is always filled to the brim.

Method of administration of <invented name>

The rectal ointment is used in the morning and evening by carefully applying the ointment with a finger in a thin layer around the anal area, preferably before (approx. 30 min) or after a bowel movement. A third application per day is possible.

Directions for use of the applicator

To apply the ointment in the anal canal and adjacent rectum, the included applicator with side openings can be used. With its help, the ointment can be applied specifically where the disease is mainly localized and the pain arises.

The applicator is screwed onto the tube and the top of the applicator is removed. The tube is squeezed to push the ointment into the applicator, where it comes out through the side openings. Then the applicator is carefully inserted into the anus.
Insertion can be made easier by lubricating the applicator with a little ointment. The ointment is introduced into the rectum by squeezing the tube again.
After use, the applicator should be cleaned by squeezing a little ointment through the side openings and wiping the surface dry with a piece of absorbent paper. The top must be screwed on securely again. This prevents the ointment from drying out
If the ointment is not used for a lengthy period of time, the applicator should be unscrewed and cleaned using warm water.

Note

Because of the body temperature, the use of ointments in the anal area may lead to soiling of underclothes. It is therefore recommended to use some form of protection for the underclothes (e.g. a paper handkerchief, cotton, etc.).

4.3 Contraindications

Hypersensitivity to the lidocaine or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

In the case of fungal infestation, the additional use of a locally effective antifungal agent is required.

Cetyl alcohol may cause local skin irritation (e.g. contact dermatitis).

One of the metabolites of lidocaine, 2,6-xylidine, has been shown to be genotoxic and carcinogenic in rats (see section 5.3). Secondary metabolites have been shown to be mutagenic. The clinical significance of these findings is unknown. Therefore, long-term treatment with <Invented name> can only be justified if it has therapeutic benefits for the patient.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of lidocaine in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).

Lidocaine passes the placental barrier. The risk to humans is not known.

<Invented name> must only be used during pregnancy when absolutely necessary.

Breast-feeding

Lidocaine is excreted in breast milk. However, there are no studies on the use of <invented name> in breastfeeding women. As the metabolism of lidocaine is relatively rapid and more or less complete in the liver, it is expected that only very low levels of lidocaine would be excreted in human milk.

<Invented name> must only be used during breast-feeding when absolutely necessary.

Fertility

No data are available on animal or human fertility.

4.7 Effects on ability to drive and use machines

<Invented name> has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

System organ class	**Very common** (≥ 1/10)	**Common** (≥ /100 to < 1/10)	**Uncommon** (≥ 1/1,000 to < 1/100)
Gastrointestinal disorders		diarrhoea	
General disorders and administration site conditions	local hypersensitivity reactions (e.g. itching, burning sensation)		discomfort, redness

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 the national reporting system listed in <to be completed nationally>.

4.9 Overdose

Cases of overdosage or intoxication have not been reported for <invented name>. Since <invented name> is applied locally, overdoses of the active ingredient are not to be expected when used as intended.

Paediatric population

If, by mistake, a small child has ingested the ointment, gastrointestinal poisoning may occur, with stomach pain and nausea. If very high doses of lidocaine are ingested, a reduced level of consciousness, shock, seizures and breathing problems may occur. Please seek emergency medical assistance in any case.

There is no specific antidote to lidocaine.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Agents for treatment of haemorrhoids and anal fissures for topical use, local anaesthetics, ATC code: C05AD01

Mechanism of action
Lidocaine is an acid amide-type local anesthetic. It blocks the formation and transmission of nerve impulses by reversibly reducing the membrane permeability of peripheral nerve cells for sodium ions, which is increased during nerve impulse transmission.

Onset of action is within a few minutes and lasts for several hours. The duration of contact determines the duration of action of the drug.

Pharmacodynamics effects
By inhibiting the excitability of the pain-transmitting sensory end organs, lidocaine locally limits and reversibly reduces pain sensation. Individually to a very different extent, this also applies to the sensation of cold, warmth, touch and pressure.

Clinical efficacy and safety
In a retrospective non-interventional study of 223 consecutive men who underwent prostate biopsy, men that had perianal topical anaesthesia with lidocaine gel reported less pain and discomfort during the insertion of the ultrasound probe compared with men treated with just lubricant gel.

5.2 Pharmacokinetic properties

Lidocaine is one of the moderately potent local anesthetics and is applied topically in the dose range 1-5 %.

Absorption
After application to the skin or mucous membrane, lidocaine is rapidly absorbed.
The bioavailability of lidocaine is approx. 50–70 per cent following rectal administration. Mucous membranes and damaged skin have much higher penetration rates than normal skin.

Distribution
Lidocaine binds up to approximately 70 % to plasma proteins. Lidocaine passes through placenta and the blood-brain barrier.

Biotransformation

In humans, CYP1A2 and CYP3A4 appear to be the main cytochrome P450 isoforms responsible for the conversion of lidocaine to monoethylglycinexylidide and glycinexylidide.

Elimination
The major route of excretion for lidocaine in humans is as metabolites via urine. Up to 80 % of an oral dose of lidocaine were excreted this way.
Terminal half-life following rectal administration is approximately 110-180 minutes.

5.3 Preclinical safety data

In studies of embryofetal development in which rats and rabbits were dosed during organ development, no teratogenic effects were observed. Animal studies are insufficient regarding effects on male and female fertility, parturtion and postnatal development.

Genotoxicity studies of lidocaine were negative. The metabolite 2,6-xylidine has shown genotoxic potential in vitro.

In a carcinogenicity study of rats exposed to 2,6-xylidine in utero, postnatally and throughout their lifetime, tumours in the nasal cavity, subcutaneous tumours and liver tumours were observed. The clinical relevance of tumour findings in relation to short-term/intermittent use of lidocaine in humans is unknown.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetyl alcohol
Macrogol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years
After first opening: 6 months

6.4 Special precautions for storage

No special requirements for storage

6.5 Nature and contents of container

Aluminium tube with screw cap (polyethylene) and applicator (polyethylene)

25 g or 50 g ointment

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

<to be completed nationally>

8. MARKETING AUTHORISATION NUMBER(S)

<to be completed nationally>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<to be completed nationally>

10. DATE OF REVISION OF THE TEXT

03 July 2026