

PACKAGE LEAFLET : INFORMATION FOR THE USER

Ledermix® Paste for use in dental cavities

Active substances: demeclocycline calcium (1:1) (30.21 mg/g), triamcinolone acetonide (10 mg/g)

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your dentist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the listed side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your dentist or pharmacist. See section 4.

In this leaflet:

1. What Ledermix® Paste is and what it is used for
2. Before you use Ledermix® Paste
3. How to use Ledermix® Paste
4. Possible side effects
5. How to store Ledermix® Paste
6. Further information

1. WHAT LEDERMIX® PASTE IS AND WHAT IT IS USED FOR

Ledermix® Paste is a preparation for the emergency treatment of acute inflammations of the dental pulp. It contains two active substances as a fixed combination for local application in dental cavities:

- an antibiotic constituent of the tetracycline group for the treatment of bacterial infections
- and a corticosteroid for the treatment of inflammatory processes.

Therapeutic indications:

- Emergency management of pulpitis in partial or total acute, non-purulent pulpitis until later regular treatment.

Ledermix® Paste is a medicinal product which is used by a dentist.

2. BEFORE YOU USE LEDERMIX® PASTE

Do not use Ledermix® Paste

- if you are hypersensitive (allergic) to demeclocycline, triamcinolone acetonide, sodium sulfite or any of the other ingredients of Ledermix® Paste;
- if you are hypersensitive to corticoids and tetracyclines (cross-allergy);
- if you have pulpitis purulenta (suppurative inflammation of the dental pulp).

Take special care with Ledermix® Paste

The corticoid content of the water-soluble Ledermix® Paste is released during the entire period of use. Because of the antiproliferative effect of all corticoids, the inlay should not remain in contact with the exposed dental pulp over a prolonged period to prevent the possible pulp necrosis; the possibility of development of chronic pulpitis should also be considered.

Using Ledermix® Paste with other medicines

Please tell your dentist if you are taking / using, or have recently been taking / using, other medicines, including medicines obtained without a prescription.

Not known when used as directed.

Using Ledermix® Paste with food and drink

Not applicable.

Pregnancy and breast feeding

Ledermix should not be used during pregnancy and breast feeding. Triamcinolone should not be used especially in the first 5 months of pregnancy, as animal research has shown evidence of harmful effects for the fetus.

Studies in animals and humans have shown harmful fetal effects of demeclocycline.

The active substances in Ledermix, triamcinolone and demeclocycline, passes into breast milk. Breast feeding should be discontinued if treatment with higher doses or long-term treatment is necessary.

Driving and using machines

No special precautions are necessary.

Important information about some of the ingredients of Ledermix® Paste

None.

3. HOW TO USE LEDERMIX® PASTE

This medicinal product will be used on you by a dentist.

The dosage depends on the nature and severity of the disease. Your dentist will tell you how long Ledermix® Paste has to be used.

Detailed information for dentists is provided in a special section at the end of this leaflet.

If you have any further questions about the use of this medicinal product, please ask your dentist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Ledermix® Paste can cause side effects, although not everybody gets them.

The following categories are used to classify the frequency of undesirable effects:

Very common:	more than 1 in 10 patients
Common:	1 to 10 in 100 patients
Uncommon:	1 to 10 in 1 000 patients
Rare:	1 to 10 in 10 000 patients
Very rare:	fewer than 1 in 10 000 patients
Unknown:	Frequency cannot be estimated based on available data

In very rare cases, allergic reactions and even anaphylactic shock can occur. Attention is drawn to the possibility of a cross-allergy with other tetracyclines.

In rare cases, sodium sulfite can provoke severe allergies and bronchospasms.

Reporting of side effects

If you get any side effects, talk to your dentist or pharmacist. This also includes any possible side effects not listed in this leaflet. You can also report side effects directly to

Bundesinstitut für Arzneimittel und Medizinprodukte
Abt. Pharmakovigilanz
Kurt-Georg-Kiesinger-Allee 3
D-53175 Bonn
Website: <http://www.bfarm.de>

By reporting side effects you can help to provide more information on the safety of this medicine.

5. HOW TO STORE LEDERMIX® PASTE

Keep all medicines out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the box and the tube.

Storage conditions
Do not store above 25 °C.

In-use shelf life
The shelf-life after opening the tube is 2 months.

6. FURTHER INFORMATION

What Ledermix® Paste contains

The active substances are: demeclocycline calcium (1:1) and triamcinolone acetonide.

1 g paste contains 30.21 mg demeclocycline calcium (1:1) (equivalent to 30.00 mg demeclocycline hydrochloride) and 10 mg triamcinolone acetonide.

The other ingredients are: Macrogol 400, Macrogol 3000, zinc oxide, colloidal silicon dioxide, calcium chloride dihydrate, trolamine, sodium calcium edetate (Ph.Eur.), sodium sulfite, purified water.

What Ledermix® Paste looks like and contents of the pack

Greyish-yellow paste

Original pack with 5 g

Marketing Authorisation Holder and Manufacturer

Marketing Authorization Holder

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Email: info@RIEMSER.com

Manufacturer

L-A-W Services GmbH
Leipziger Arzneimittelwerk
Elisabeth-Schumacher-Str. 54/56
04328 Leipzig

This leaflet was last approved in March 2017.

The following information is intended for dentists:

How is Ledermix® Paste used?

A small cotton wool pellet bearing Ledermix® Paste is placed on the punctiform exposed dental pulp and is fitted with a temporary closure of, for example, zinc oxide-eugenol, until commencement of the final treatment.

Ledermix® Paste can also be used quite generally as a medicinal intermediate inlay for any type and method of root canal treatment.

Important

To prevent Ledermix® Paste from hardening at the opening of the tube, always keep the tip of the tube clean and firmly seal the tube after each use. Variations in the colour of Ledermix® Paste have no influence on the efficacy of the product.