Ledermix* For Dental Use

Demeclocycline hydrochloride and Triamcinolone acetonide

PATIENT INFORMATION LEAFLET - INFORMATION FOR THE USER

COMBINATION KIT

Please read all of this leaflet carefully before you receive the medicine.
Keep the leaflet as you may want to read it again.
If you have any further questions please ask your dentist.
If you experience any troublesome side effects or any effects not listed in this leaflet tell your dentist or doctor.

In this leaflet:

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

Sample Only

1. What LEDERMIX is and what it is used for

LEDERMIX is a combination kit which contains a dental paste, a dental cement powder and two dental liquids (slow and fast setting hardeners).

LEDERMIX dental paste contains the active ingredients demeclocycline calcium and triamcinolone acetonide.

LEDERMIX dental cement powder contains the active ingredients demeclocycline hydrochloride and triamcinolone acetonide.

Demeclocycline hydrochloride is one of a group of antibiotics called tetracyclines which is used to treat or prevent infections. Triamcinolone acetonide is a corticosteroid used to reduce swelling or inflammation.

LEDERMIX is used by dentists to treat deep and possibly painful cavities (holes in the teeth) which are close to the nerve or involve the nerve in the tooth, and as a dressing during the treatment of the root canal.

2. Before you receive LEDERMIX

You should not receive this medicine if:

- you are allergic to any tetracycline antibiotic (e.g. oxytetracycline, tetracycline, chlortetracycline, demeclocycline, doxycycline or minocycline) or any of the ingredients in this medicine (see section 6 for more details)
- you have badly infected dental pulp

This medicine must not be used in children under 12 years and should be avoided where possible in children over 12 years of age. The use of tetracyclines in this age group can cause permanent discolouration and incomplete development of hard tooth surface.

Important information about some of the ingredients of LEDERMIX

This medicine contains sodium sulphite anhydrous (E221) which may rarely cause allergic reactions and bronchospasm (difficulty breathing).

Taking other medicines

Before you receive this medicine please tell your dentist if you are taking any other medicines.

Pregnancy and breast-feeding

This medicine should not be used in pregnancy or breast-feeding unless considered essential. The use of this medicine during tooth development in the last half of pregnancy and breast-feeding may cause permanent discolouration and incomplete development of the hard tooth surface.

Driving and operating machinery

There are no known effects of this medicine on your ability to drive or use machinery.

3. How LEDERMIX is used

This medicine will be used by your dentist. The amount of paste or cement used will depend on the individual person's condition. They can be used on teeth with small holes which may be painful or teeth which have no holes, but are painful. Sometimes this pain is caused by an abscess.

They can also be used as a dressing during the treatment of the nerve or root canal.

LEDERMIX dental paste is only a temporary treatment. It is very important that you keep your next appointment with your dentist so that the paste can be properly removed. Sometimes the paste will be used a second time.

LEDERMIX dental cement is a permanent treatment which can be used at the next visit after using the paste.

This medicine must not be used in children under 12 years and should be avoided where possible in children over 12 years of age.

Sample Only

4. Possible Side-effects

As with all medicines LEDERMIX can cause side-effects in some people, although because the medicine is not swallowed or injected unwanted effects are very rare.

Tell your dentist immediately or go to hospital if you experience any of the following symptoms of an allergic reaction:

- swelling of the eyes, mouth and possibly hands, feet and throat
- breathing difficulties
- rash

- hives (raised, often itchy, red patches on the skin)
- itching.

These side effects are very rare but may be serious; if they occur you may need urgent medical attention.

Your dentist will check your teeth regularly to make sure that the pulp or nerve inside the tooth has not been damaged by this medicine and that there is no infection in the tooth.

Tooth discolouration may occur.

Reporting of side effects

If you get any side effects, talk to your doctor or dentist. This includes any possible side effects not listed in this leaflet.

In the UK you can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

In Ireland you can report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5. How to store LEDERMIX

Your dentist will keep and dispose of this medicine for you (see section 6).

6. Further information

What LEDERMIX contains

LEDERMIX 30 mg/g + 10 mg/g dental paste contains the active ingredients demeclocycline calcium (equivalent to demeclocycline hydrochloride 30 mg) and triamcinolone acetonide 10 mg in each gram of paste. The other ingredients are: calcium chloride, zinc oxide, sodium sulphite anhydrous (E221), trolamine, macrogol 3000, macrogol 400, sodium calcium edetate, silica colloidal anhydrous, purified water.

LEDERMIX 20 mg/g + 6.7 mg/g dental cement powder contains the active ingredients demeclocycline hydrochloride 20 mg and triamcinolone acetonide 6.7 mg in each gram of cement. The other ingredients are: zinc oxide, Canada balsam neutral solidified, resin, calcium hydroxide.

LEDERMIX hardener '"F" contains eugenol and turpentine oil, pinus pinaster type.

LEDERMIX hardener "S" contains eugenol, macrogol 4000 and turpentine oil, pinus pinaster type.

Sample Only

What LEDERMIX looks like

LEDERMIX is available in a kit which contains:

- 3 g aluminum tube of grey-yellow LEDERMIX dental paste
- 2 g glass bottle of cream LEDERMIX dental cement powder
- 5 ml glass bottle of colourless to yellow dental liquid hardener "F" with a glass dropper
- 5 ml glass bottle of colourless to yellow dental liquid hardener "S" with a glass dropper

Also available are:

LEDERMIX for Dental Use Refill Kit No. 2 which contains 5 g dental paste

LEDERMIX for Dental Use Refill Kit No. 3 which contains 3 g dental cement powder

LEDERMIX for Dental Use Refill Kit No. 4 which contains 5 ml hardener "F" with a separate glass dropper

LEDERMIX for Dental Use Refill Kit No. 5 which contains 5 ml hardener "S" with a separate glass dropper

Not all pack sizes may be marketed.

Marketing authorisation holder

Henry Schein UK Holdings Ltd.
Medcare House, Centurion Close, Gillingham Business Park, Gillingham, Kent, ME8 OSB, United Kingdom

Manufacturer

Haupt Pharma GmbH,
Pfaffenrieder Strasse 5, D-82515 Wolfratshausen, Germany

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* Trade mark

L12/04-04

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Information for the Dentist

Do not mix Ledermix Dental Paste with calcium hydroxide.

How to store Ledermix

Keep out of the sight and reach of children. Do not store above 25ºC. Store in the original pack. Do not refrigerate. Keep the dental paste tube and dental cement powder bottle tightly closed to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton/bottle label/tube crimp after EXP. The expiry date refers to the last day of that month.

JOB: **Ledermix Combination Kit Label**

CODE: **14016_12**

SIZE: **320mm x 105mm**

DATE: **03/09/2015**

FONTS USED

HEADING/SUB HEADING COPY
HELVETICA BOLD CONDENSED:
SAMPLE Sample
SIZE: 10pt

BODY COPY
HELVETICA CONDENSED:
SAMPLE Sample
SIZE: 9pt

PRINTED COLOURS

(3 colour)

- Pantone 116
- Pantone 5255
- Black
- Cutting Form (Not Printed)

REVISION: 1.4

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