



LEDERMIX[®] Paste

*Quick and reliable
relief from pain
for your patients*

RIEMSER



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Introduction	4
How does LEDERMIX Paste act?	5
Pharmacokinetics	6-7
Indications	8-10
» Deep carious lesions, symptoms of pulpitis	8
» Infected pulpa, necrosis of the pulpa	9
» Medicinal temporary filling in the scope of root canal treatment	10
» Pain after preparation measures	10
Tips for practical implementation	11-13
List of Literature	14
Your notes	15



Introduction

Cases of acute pain occur in every dental surgery, often in the scope of filling therapies and in acute emergency situations.

Particularly teeth with deep caries are concerned, with or without clinically diagnosable pulpitis. In the case of devitalised teeth with fully developed parodontitis apicalis the patients often complain about unbearable pain which keeps them awake at night and reduces them to despair. In such cases the traditional pain killers are not very effective. Local injections of suitable anaesthetics can either only control this situation in a very limited manner or for a limited period of time.

Apart from the necessary dental therapy required in such cases, the application of a preparation which is used and well known for over 40 years, **LEDERMIX®** Paste, is what is called for.

Due to the active substance triamcinolone **LEDERMIX®** Paste counteracts pain symptoms promptly and quickly and leads to a significant improvement. The wide-spectrum antibiotic demeclocycline that is contained as further active

substance reduces the usually attendant bacterial contamination. This particular combination of active substances allows **LEDERMIX®** Paste to be effective in more ways than one: Quick relief from pain and effective reduction of cariogenic contamination (12) and the simple application make this preparation a very effective one for all the particularly unpleasant situations in which otherwise only less effective therapy measures are at disposal to relieve the patient suffering from pain.

This manual is to supply the practising dental surgeon with the answers: Answers to the questions which have often been posed in connection with the use of **LEDERMIX®** Paste and which could be of importance for the application of this preparation.

How does LEDERMIX® Paste take act?

Damage to the hard tooth tissue often occurs with participation of the pulp tissue. The cause for the possible inflammatory pulp participation are bacterial metabolic products and endotoxins which trigger the typical inflammation reactions in the soft tissue: Swelling, change of the tissue structure with increased blood circulation and pain caused by the swelling. The influence of traditional antiphlogistic agents is very limited for pulpitis diseases.

It is always of primary importance to combat the infection of the hard tooth. However, there are limits to the removal of caries and the reduction of germs: Cariogenic bacteria can be found in the dentine tubules even after the complete removal of the hard tissue effected by the caries and, particularly in the case of deep caries, the removal of this tissue layer is hardly possible without opening the vital pulpa. The method of minimal invasive therapy usually prohibits such a radical procedure as a rule alternative measures have to be found and applied correspondingly.

Thereby combating micro-organisms without destroying the tissue is of particular importance. As it has been noted and confirmed repeatedly, the antibiotic contained in **LEDERMIX®** acts very effectively and eliminates numerous pathogen micro-organisms (12) within a short time.

Particularly pleasant for the patient is the quick pain reduction activity of the second active substance, the corticoid It'santiphlogistic action causes a rapid decline of the oedematous swelling of the inflamed tissue, and thus the symptom of pain subside quickly.

Demeclocycline is a wide-spectrum antibiotic of the tetracycline series and acts bacteriostatically against tetracycline sensitive gram-positive and gram-negative pathogens as well as against chlamydia, mycoplasma, spirochete and rickettsia. Both extra-cellular and intra-cellular pathogens are effected. The mechanism of action is based on the inhibition of bacterial ribosomal protein synthesis.

Triamcinolone acetonide is a fluorised glucocorticoid with distinct anti-allergic, antiphlogistic and membrane stabilising properties. Compared with cortisol, triamcinolone acetonide has a 6-fold increased activity with practically no mineralocorticoid action.

The theoretical basics had already been worked out by Prof. André Schroeder, Bern, and apply today as they had already over 40 years ago. Thus with **LEDERMIX®** Paste a preparation is available that can refer on extremely long and successful clinical experience (10, 11).

Pharmacokinetics of LEDERMIX®

There are reports in literature that the pharmacologically active substances, and also certain bacteria, can penetrate the tooth hard substance via the dentin tubuli. The size and structure of the molecule are decisive for the speed of diffusion (1.2).

Both triamcinolone acetonide as well as demeclocycline are released from the preparation **LEDERMIX®** after application to the tooth cavity or the pulp cavity, resp.. Therefore these substances are available for one to two days at sufficient concentrations to be therapeutically active, as it could be proven by in vitro investigations.

Active substance penetration of through the root dentin - medium average release rates from LEDERMIX® Paste

After application of radioactively marked **LEDERMIX®** Paste into the prepared root canal of freshly extracted teeth, a high level of active substance release through the root dentin, both of demeclocyclin and of triamcinolone acetone, were recorded for the period up to 8 hours. After one hour the release rates found were 253 pmol/min for demeclocycline and 11 pmol/min for triamcinolone acetonide. While the demeclocycline release was continuous, there was a slight increase in the release for the corticoid over the period of the first 8 hours. For both substances a release rate of 3-6 pmol/min could be detected after 3 days (Fig.1)

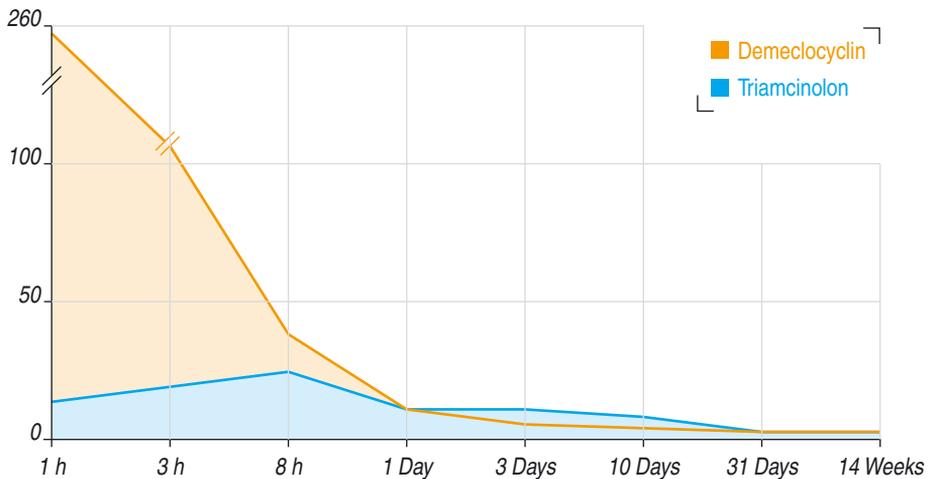


Fig. 1: Average release rates of active substances in pmol/min (n= 20 teeth) of **LEDERMIX®** Paste through root dentin (1)

As result of the calculation of the release rates it was found that demeclocycline reached concentrations of 200 mg/ml in the first days in the dentin close to the root canal and in remoter dentin regions of 17 mg/ml. After one week concentrations of approx. 21 mg/ml, or 1.7 mg/ml respectively, were detected. Thus the demeclocycline penetrating from the **LEDERMIX**[®] Paste reaches concentrations, both in the root canal and in the dentin tubuli, which are effective against bacteria (1).

*Active substance penetration through the crown dentin - average substance release rates from **LEDERMIX**[®] Paste*

Even after application of **LEDERMIX**[®] Paste in a cavity in the tooth crown area triamcinolone acetonide and demeclocycline can penetrate through the crown dentin. There was a maximum demeclocycline release rate of 47 pmol/min after 2 hours which dropped to 10 pmol/min after one day. Triamcinolone acetonide reached maximum release rate of approx. 60 pmol/min in the period 2 to 8 hours after **LEDERMIX**[®] application, after one day 23 picomol/minute and after 2 days 10 picomol/minute (Fig. 2).

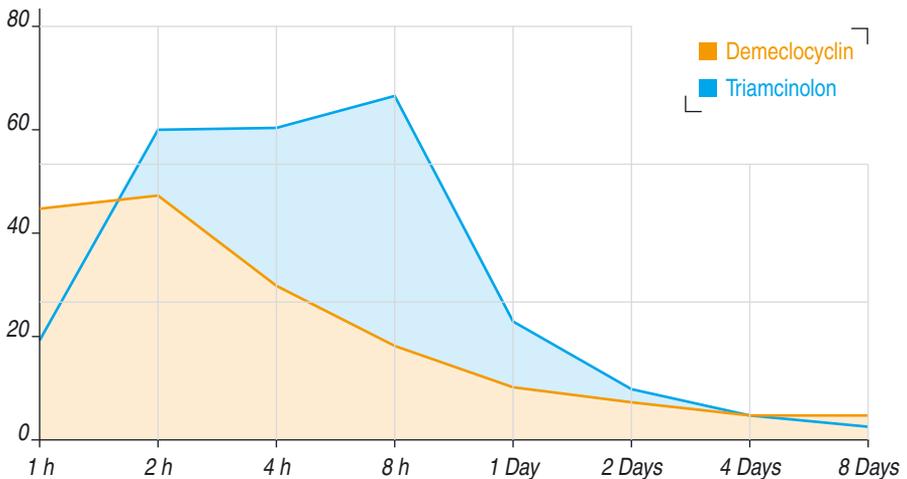


Fig. 2: Average release rates of active substances in pmol/min (n= 20 teeth) of **LEDERMIX**[®] Paste through crown dentin (2)

Indications

LEDERMIX® Paste is applied by small cotton-wool pellets covered with **LEDERMIX®** Paste to the exposed pulpa and temporary capped with, e.g. zinc oxide eugenol until final treatment. Furthermore, **LEDERMIX®** Paste can be used generally as medicinal temporary filling for every kind and method of root canal treatment“.

Deep caries, with or without symptoms of pulpitis

Wicht et al. (12) provided evidence in 2003, that **LEDERMIX®** Paste was extremely effective against cariogenic micro-organisms, even more effective than chlorhexidine.

The antibiotic contained as active substance is utilised in a way that excavation is carried out as far as possible, however the area of the pulpa near the hard tissue is saved according to a minimal invasive procedure.

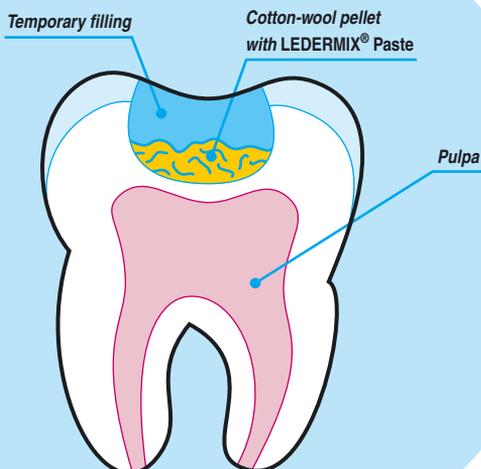
Due to the anti-inflammatory effect the corticoid is able to cause quick relief from pain. Experience has shown that pain relief is experienced shortly after treatment.

When applying a preparation which blocks pain so effectively a regular check-up of vitality is mandatory. Pain as symptom of devitalisation hardly occurs, objective controls should therefore be undertaken as recall (4).

Method of application

After removing the carious material or after maximum possible excavation (without opening the pulpa) resp., **LEDERMIX®** Paste is applied to the cavity using a cotton-wool pellet. The cavity is then closed by a provisional cap.

It is discussed that corticoids as contained in **LEDERMIX®** Paste may impair the development of tertiary dentin. For this reason **LEDERMIX®** Paste should be removed again for revision within one week, after the acute pain symptoms have subsided. When teeth are directly capped this is not reasonable; depending on the extent of the defect or the age of the patient longer periods of observation may be necessary.



Infected pulp necrosis

In all stages of a pulpitis up to the primary infected necrosis (gangrene) the use of **LEDERMIX**[®] Paste is reasonable. Quick relief can be achieved using **LEDERMIX**[®] in these cases, too. An immediately necessary pulp extirpation can be delayed a little with application of **LEDERMIX**[®].

Long-term results of use of **LEDERMIX**[®] Paste in all stages of pulpitis provided evidence that even the vitality of the pulpa could be maintained in many cases (4). It is often very difficult for the expert, to recognise without opening the pulp cavity whether vital tissue is still available or whether tissue necrosis has already developed.

The good efficacy of **LEDERMIX**[®] Paste has led to this preparation being extensively used in Switzerland (3). If no success (relief from pain) is experienced after application of **LEDERMIX**[®] Paste to the closed pulp cavity, or devitalisation has to be registered, the trepanation of the pulp cavity is

The advantage is:

LEDERMIX[®] ***provides quick relief from pain; calcium hydroxide enhances the regeneration of the alveolar bone. The antiproliferative effect of the corticoid is abolished immediately upon replacement by calcium hydroxide.***

indicated and, in the scope of the necessary root canal treatment, **LEDERMIX**[®] has to be applied in the opened pulp cavity.

Method of application

Analogue to the reduced regeneration ability of the pulp tissue (tertiary dentin) the corticoid also has the effect of impairing regeneration of the apical bone. It is therefore recommended that **LEDERMIX**[®] is replaced by a calcium hydroxide preparation after relief from pain (1 to 7 days) (6).

After the acute pain treatment, the root canal undergoes final preparation; possibly a second temporary filling is applied. The following should apply as benchmark for the preparation; prepare approx. 2-3 ISO sizes further as soon as first clamping can be found in the apical region. Usually relief of pain is experienced within a few hours. If the percussion test is negative, earliest after one week, **LEDERMIX**[®] Paste is rinsed out with physiological sodium chloride solution and standard treatment of the tooth can be continued. If the percussion test is positive, a second application of **LEDERMIX**[®] is possible.

The patency of the root canal (of the root canals respectively) is controlled up to the physiological apex (approx. 1 mm coronal to the apex visible on the X-ray). **LEDERMIX**[®] Paste is applied using a root canal instrument: the root canal walls should be completely covered. The efficacy is as quicker and lasting as better **LEDERMIX**[®] Paste is applied into the canal.

Indications

Medicinal temporary filling in the scope of endodontic treatment

Ehrmann (7.8) reported that **LEDERMIX®** Paste acted particularly quickly and effectively in apical processes which often cannot be handled by conventional possibilities (Ehrmann speaks of „Peri-Cementitis“). Even in the case of the described, particularly painful symptoms of an obviously periapical process, **LEDERMIX®** Paste could be used particularly effectively. The impairment of bone regeneration due to the antiproliferative effect of the corticoid contained in **LEDERMIX®** does not represent a real problem - by replacing the temporary filling after relief from pain, the antiproliferative effect is stopped and the stimulation of regeneration, e.g. by calcium hydroxide, can unfold and act immediately (6).

Method of application see „Pulp necrosis“

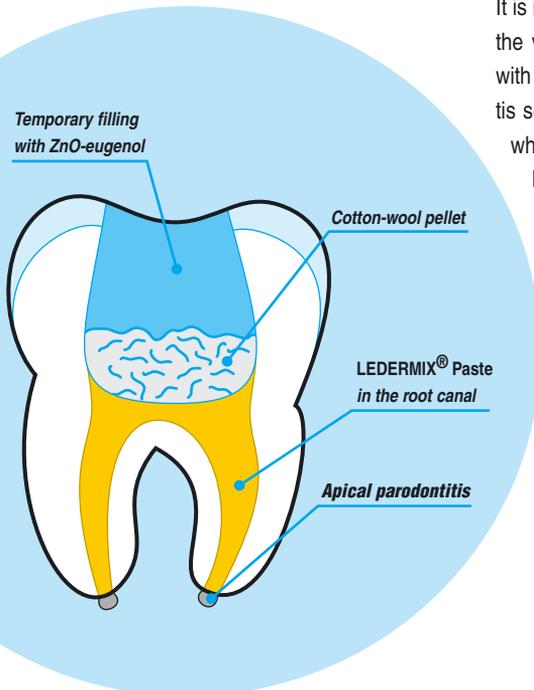
Pain after preparation measures

Post-traumatic irritations are often experienced in the scope of prosthetic measures and long-lasting post-operative pain often occurs after a filling therapy with the modern plastic materials. Here again, the use of **LEDERMIX®** Paste can be very helpful when combating the symptoms of pain. The alternative of a direct revision of the filling often causes further persistent pains which can end in a vital extirpation.

A possible irreversible damage to the pulpa may be avoided by the use of **LEDERMIX®** Paste (4).

Method of application

It is recommended for reasons of safety to check the vitality every 6 months in the case of teeth with pulpitis. It cannot be excluded that the pulpitis sensations came from an irreversible pulpitis which led to the chronic inflammation and finally to devitality. Evidence was provided by an examination by Hagedorn et al. (4) that at great percentage the vitality of the teeth could also be permanently retained by the use of **LEDERMIX®** Paste.



Tips for practical implementation

When using the well-established **LEDERMIX®** Paste unexpected handling difficulties may be experienced, as it is occasionally the case with almost all preparations being used in odontology. The most frequently asked questions are therefore to be handled in more detail here.

» *I have not used **LEDERMIX®** Paste so far; what is the best way to apply the paste to the root canal?*

We recommend you work exclusively with the lentulo which is particularly useful to cover the canal walls up to the apex with the preparation.

» *The colour of **LEDERMIX®** Paste is often different; what does it mean?*

Colour variations are possible in **LEDERMIX®** Paste due to the manufacture of the natural substance Demeclocycline and has no influence, either on the shelf-life or the efficacy of the paste. Additional colourings have not been admixed.

» *The consistency of **LEDERMIX®** Paste is often different; what does it mean?*

It may be said on principle that **LEDERMIX®** Paste has no consistent viscosity, rather the viscosity is influenced by the duration and temperature of storage and by handling (frequent opening of the tube).

A temporary hardening of the **LEDERMIX®** Paste may be due to the thixotropic pharmaceutical form of **LEDERMIX®** Paste. To prevent the active pharmaceutical ingredients and excipient materials to demix in the course of storage, and to be able to guarantee that the quality remains consistent, a gelifier is added which begins to gelatinise when not agitated in storage. This „Gel Net“ liquefies again quickly as soon as pressure is exerted (e.g. when pressing the tube or mixing and distributing with the applicator) making it easy to apply the paste to the pulpa or the root canal, resp.

However, it should be noted that **LEDERMIX®** Paste becomes even more liquid by too intensive stirring with the applicator. When the required viscosity is available it is therefore recommended that the paste is no longer be treated with the applicator, but is used directly.

The efficacy of the paste is not impaired by the varying degree of consistency.

» *It is difficult to press the **LEDERMIX®** Paste out of the tube, what to do?*

It is important that **LEDERMIX®** Paste is stored at room temperature below 25 °C (approx. 18 - 23 °C) and not in the refrigerator. Furthermore, **LEDERMIX®** Paste is a thixotrope pharmaceutical form. To prevent the active pharmaceutical ingredients and excipients to demix , and to guarantee constant quality, a gelifier is added which starts to gelatinise when the product is not agitated. This „Gel Net“ liquefies again quickly as soon as pressure is exerted (e.g. when pressing the tube or mixing and distributing with the applicator) making it easy to apply the paste to the pulpa.

Tips for practical implementation

» *The **LEDERMIX**[®] Paste is too soft, what to do?*

The cause may be that the paste was stored too warm. Great heat (direct exposure to sun light) can have a damaging effect on the quality.

It is also possible that the tube was simply pressed too often and too intensively. For such a case we recommend that the paste is allowed to „rest“ and to wait for the thixotrope action (the hardening of the paste).

» *Why is it reasonable to use the tube roller?*

As a result of the thixotropic property of **LEDERMIX**[®] Paste, the content of the tube may become more plastic by pressing the tube while the small paste plug in the tube cannula remains hard. It is therefore principally recommended to use the enclosed tube roller to remove paste. Then the pressed out line of paste can, without much ado, be mixed to the very best, homogenous consistency as required by using the spatula.

You are on the safe side with the tube roller, and can empty the tube completely.

» *The closure of the **LEDERMIX**[®] Paste tube is too difficult to open, what to do?*

As a basic principle the tip of the tube should be cleaned before closing the tube to avoid sticking. A slight turning of the cap then suffices to open or close the tube.

» *Can I mix **LEDERMIX**[®] Paste with other preparations, e.g. calcium hydroxide?*

Any mixing changes the properties in a manner that cannot be foreseen; in an extreme case the action of **LEDERMIX**[®] Paste may be entirely abrogated. Therefore use **LEDERMIX**[®] Paste only in its pure form and change the temporary filling if necessary!

» *How long should **LEDERMIX**[®] Paste remain in the tooth?*

On principle it is reasonable to leave it until pain is relieved (pulpitic reaction) a tight recall is therefore necessary. As soon as pain has been relieved, **LEDERMIX**[®] Paste should be removed and exchanged by a conventional preparation. Then possible negative effects (corticoids act antiproliferatively) need hardly be feared. After being applied for several weeks without experiencing pain relief another therapy should be initiated (among others reparation of the tooth).

» *What should I use as cover after applying **LEDERMIX**[®] Paste to the pulp cap?*

LEDERMIX[®] Paste should be applied on a small area and then be covered by a cotton-wool pellet. It can then be covered with any cement that seems to be suitable. Frequently a temporary cement or filling material will suffice (application without pressure to the dental material), whereby care should be taken that no cement containing eugenol is used if composite restoration is planned.

» *What should I use to apply **LEDERMIX®** Paste?*

As a very slight amount suffices, use a small ball-like filling instrument or the tip of the inspection instrument. Should **LEDERMIX®** Paste have to be applied to the root canal, a lentulo is the best choice.

Further practical tips for users, other information and study results are available in the web under www.ledermix.de

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