SUMMARY OF PRODUCT CHARACTERISTICS

PRODUCT SUMMARY

1. NAME OF THE MEDICINAL PRODUCT

LEDERMIX FOR DENTAL USE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The LEDERMIX Combination Kit consists of a package containing four units:
LEDERMIX Dental Paste. Each gram contains: demeclocycline calcium
equivalent to Demeclocycline hydrochloride 30mg. Triamcinolone acetonide
10mg.

LEDERMIX Dental Cement. Each gram contains: demeclocycline
hydrochloride 20mg. Triamcinolone acetonide 6.7mg in combination with
zinc oxide and calcium hydroxide.

Hardener 'F' (fast setting time) 85% w/w Eugenol Ph. Eur. in rectified
turpentine oil.

Hardener 'S' (slow setting time) 85% w/w Eugenol Ph. Eur. and 10% w/w
polyethylene glycol 4000 USP in rectified turpentine oil.

3. PHARMACEUTICAL FORM

LEDERMIX is a dental treatment for topical application. It is supplied as a kit
containing LEDERMIX Dental Paste, LEDERMIX Dental Cement, Hardener
(fast setting time) and Hardener 'S' (slow setting time).

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Ledermix is a dental treatment which combines the antibiotic action of
demeclocycline with the anti-inflammatory action of triamcinolone acetonide.

Ledermix is indicated in pulpitis, periapical periodontitis, and hypersensitive dentine.

4.2. Posology and Method of Administration

Adults and children:
Pulpitis: In all instances of exposed pulp and in acute pulpitis (except total
purulent pulpitis). Ledermix paste is applied with a small cotton pledget to the
dentine adjacent to the pulp or to the exposed pulp. The cavity is then closed with a temporary dressing such as zinc oxide-eugenol.

Approximately three to six days later, the vitality of the tooth is determined, the cavity is reopened and the cotton pledge is removed. The dentine close to the pulp, or the wound in the pulp, is covered with Ledermix cement prepared in the following manner. To one drop of the hardener (no more), add sufficient Ledermix cement powder to obtain a homogenous mixture of cream-like consistency. This cement, which hardens rapidly, may be applied with an amalgam plugger or blunt probe.

In small cavities with small areas of pulp exposure, Ledermix cement suffices as a base. In larger cavities or more extensive pulp exposure, it is advisable to use Ledermix cement as a lining cement only and then to cover it with a structural layer of zinc phosphate or zinc oxide-eugenol cement before inserting the permanent restoration. In certain instances of hyperaemia and partial serious pulpitis with closed pulp cavity, the use of Ledermix paste may be eliminated with Ledermix cement mixed with the hardener) applied in the first treatment period. However, as a general rule, and particularly in acute pulpitis and in teeth where the pulp is exposed, the prepared Ledermix cement should not be applied without previous treatment with Ledermix paste. Pulp vitality should be monitored regularly.

Periapical periodontitis:
In primary acute periapical periodontitis and acute exacerbations of chronic periapical periodontitis, the canal may be prepared to the apex at the first sitting. After irrigation, the canal may be filled completely with Ledermix paste and sealed. This treatment can be repeated if necessary on the follow-up visit about one week later, or the canal may be irrigated to remove the paste and further treatment carried out according to one of the generally accepted methods. If an alveolar abscess is present, drainage should be effective before beginning treatment with Ledermix.

Hypersensitive dentine following cavity or crown preparations:
In instances of hypersensitive dentine following cavity or crown preparations, Ledermix cement plus hardener may be used as sublining for deep cavities. Pulp vitality should be monitored regularly.

Preparation of the cement:

Ledermix cement belongs to the class of zinc oxide-eugenol dental cements. The setting time of all such cements is greatly affected by temperature and humidity conditions and by the technique of the individual operator. Vigorous and prolonged mixing, or spreading the mix thinly over the slab leads to accelerated setting, whilst lowering the temperature of the mixing slab will prolong the setting time. Under any given set conditions, however, the operator may obtain a faster or slower setting of the paste using the appropriate hardener. In general it will be found that the time required for the mixture to set obtained by the use of Hardener 'S' will be approximately three to four times that obtained with hardener 'F'.

Under conditions of high temperature and humidity, care should be taken to blend
rapidly a small amount of Ledermix Cement powder (taking no more than 10 to 15 seconds) into one drop of Hardener with two to three strokes of the spatula. All of the resultant mix should then be taken up at once on the spatula blade.

4.3. Contra-Indications

Ledermix is contraindicated in instances of total purulent pulpitis or in patients hypersensitive to any of the active ingredients.

4.4. Special Warnings and Special Precautions for Use

Precautions:
The suppression of the inflammatory process by the use of a corticosteroid may result in a temporary reduction of the resistance of the pulp to infection and a reduced healing capacity. Therefore, Ledermix paste should not be in contact with the exposed pulp for too long. If the application of this water-soluble preparation is uncontrolled, or if the temporary dressing fits loosely, the danger exists that the pulp may not survive. The tip of the Ledermix paste tube should always be kept clean and tightly closed after use. Store in a cool place.

The Ledermix cement vial must be kept tightly closed after use.

If severe reactions or idiosyncrasies are encountered, the restoration should be removed and appropriate measures instituted.

4.5. Interactions with other Medicinal Products and other Forms of Interaction

None known.

4.6. Pregnancy and Lactation

Not known.

4.7. Effects on Ability to Drive and Use Machines

Not applicable.

4.8. Undesirable Effects

Since Ledermix is only administered locally, and the various constituents are leached from the site of application in minute quantities over a long period of time, systemic side effects are extremely rare. However, a few cases of allergic reaction, including anaphylaxis, urticaria, rash and pruritus, have been reported. It has been suggested that in certain situations pulpal necrosis may occur. It is therefore advisable to monitor pulp vitality regularly and carry out endodontic treatment as appropriate.
4.9. Overdose

None known.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Demeclocycline hydrochloride has the antimicrobial activity and uses described for tetracycline hydrochloride. It is excreted more slowly and effective blood concentrations are maintained for a longer period.

The usual adult dosage is 600mg of demeclocycline hydrochloride daily by mouth in 2 or 4 divided doses preferably one hour before or 2 hours after meals; 900mg daily in divided doses may be given for mycoplasmal pneumonia. Children have been given 6 to 12mg per kg bodyweight daily in divided doses, but the effect of tetracyclines on teeth should be considered. Demeclocycline may be given to adults in the treatment of chronic hyponatraemia associated with the inappropriate secretion of antidiuretic hormone, when water restriction has proved ineffective. Initially, demeclocycline hydrochloride 0.9 to 1.2g is given daily in divided doses, reduced to maintenance doses of 0.6 to 0.9g daily.

An antimicrobial substance produced by the growth of certain strains of *Streptomyces aureofaciens* or by any other means. It occurs as a yellow, odourless, crystalline powder. The BP specifies not less than 900-Ig per mg, both calculated on the anhydrous basis.

Soluble 1 in 30 to 60 of water and 1 in 50 of methyl alcohol; slightly soluble in alcohol; practically insoluble in acetone, chloroform and ether; soluble in aqueous solutions of alkali hydroxides and carbonates.

5.2. Pharmacokinetic Properties

Peak plasma concentrations of about 24plg per ml have been reported 3 to 6 hours after an oral dose of 500mg of demeclocycline hydrochloride and persist for longer than after a similar dose of tetracycline, only falling to about 1 jig per ml after 24 hours. Its biological half-life is about 12 hours. The renal clearance of demeclocycline is about half that of tetracycline.

5.3. Pre-clinical Safety Data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients
Ledermix Cement:
Zinc oxide
Canada balsam neutral solidified
Resin
Calcium hydroxide

Ledermix Paste:
Calcium chloride
Zinc oxide
Sodium sulphite anhydrous (E221)
Trolamine
Macrogol 3000
Macrogol 400
Sodium calcium edentate
Colloidal anhydrous silica
Purified water

Hardener F:
Rectified turpentine oil

Hardener S:
Macrogol 4000
Rectified turpentine oil

6.2. Incompatibilities
None known.

6.3. Shelf-Life
24 months.

6.4. Special Precautions for Storage
LEDERMIX* should not be stored above 25°C. Store LEDERMIX* in the original pack. Do not refrigerate.

6.5. Nature and Content of Container

LEDER MIX Combination Kit:
2g LEDERMIX Dental Cement Powder.
5ml Hardener ‘F’ with separate glass dropper.
5ml Hardener ‘S’ with separate glass dropper.
3g LEDERMIX Dental Paste.

LEDERMIX Refill Kit No.2:
5g LEDERMLX Dental Paste

LEDERMIX Refill Kit No.3:
3g LEDERMIX Dental Cement Powder

*LEDERMIX Refill Kit No. 4:*
5ml Hardener 'F' with separate glass dropper.

*LEDERMIX Refill Kit No. 5:*
5ml Hardener 'S' with separate glass dropper.

6.6. **Instructions for Use, Handling and Disposal**
None.

**ADMINISTRATIVE DATA**

7. **MARKETING AUTHORISATION HOLDER**

Henry Schein UK Holdings Limited
Medcare House,
Centurion Close
Gillingham Business Park
Gillingham
Kent ME6 0SB
United Kingdom

8. **MARKETING AUTHORISATION NUMBER(S)**

PL 27880/002

9. **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

1 October 2001

10. **DATE OF (PARTIAL) REVISION OF THE TEXT**

March 2007