Solcoseryl® Dental Adhesive Paste

For painful wounds of the oral mucosa, such as aphthae and denture sores

Composition

1 g of Solcoseryl Dental Adhesive Paste contains:

Active ingredients: Protein-free haemodialysate of calves' blood (Bos taurus), chemically and biologically standardised, 2.125 mg; polidocanol 600 (Laureth-9), 10 mg.

Excipients: Conserv.: methyl parahydroxybenzoate (E 218), 1.80 mg; propyl parahydroxybenzoate (E 216), 0.20 mg; gelatine, sodium carboxymethylcellulose, pectin, polyethylene, paraffin, Aromas: peppermint oil, menthol.

Properties and effects

Solcoseryl is a protein-free haemodialysate and contains a large number of low molecular weight constituents from cells and serum of calves' blood (dialysis/ultrafiltration, cut-off 5,000 Da), only some of which have been chemically and pharmacologically characterized.

It has been established in various cell and tissue cultures, in organs, in animals and in clinical investigations that Solcoseryl

- maintains or restores aerobic energy metabolism and oxidative phosphorylation and thus the provision of high-energy phosphates in cells with deficient supply,
- increases the oxygen utilization (in vitro) and the glucose transport in hypoxic and metabolically exhausted tissue and cells,
- improves the processes of repair and regeneration of tissue which is damaged and/or has deficient supply,
- prevents or reduces secondary degeneration and pathological changes in reversibly damaged cell systems,
- increases collagen synthesis in vitro models, and
- stimulates cell proliferation and migration in vitro.

Solcoseryl thus protects tissue endangered by hypoxia and/or substrate deficiency. It promotes the refunctionalization of reversibly damaged tissue and it speeds up and improves the quality of the healing of lesions. However, the clinical efficacy is a consequence of the synergism of all constituents of Solcoseryl.

Solcoseryl has shown no local and/or systemic toxicity after either a single administration or repeated dermal or intravenous administration in animal experiments even at a dosage 30–40 times the relevant human dose.

Intradermal sensitisation tests on guinea-pigs and subchronic and chronic toxicity studies have shown no skin-sensitising, contact-allergenic potential and no signs of immunotoxicological effects.

The surface anaesthetic polidocanol (hydroxypolyethoxydodecane) reversibly blocks penpheral nerves. The great wetting ability means that freedom from pain occurs 1–3 minutes after application. The effect lasts 1–5 hours corresponding to the duration of paste adhesion. It depends on the location of the lesion and the flow of saliva.

The paste base is composed of pectin, gelatine, carboxymethylcellulose sodium, liquid paraffin and polyethylene which, after swelling with saliva and wound discharge forms an adherent elastic protective film on the wound.

Pharmacokinetics

Absorption, distribution and elimination of the protein-free haemodialysate active ingredient cannot be analysed by conventional pharmacokinetic methods such as radioactive labelling etc. because protein-free haemodialysate has a variety of pharmacodynamic effects which are attributable to molecules with different physicochemical properties.

In the case of the topical forms, the effect is confined to the site of application, as has been shown by intraindividual comparison with multiple treatments.

There have been no investigations of the absorption of polidocanol on topical use. Compared with tetracaine and anaesthetics of related structure, the duration of action is longer because there is no hydrolysis. Studies on rats (2 ml/kg i.v.) showed 43% renal and 57% faecal excretion. The terminal elimination half-life was 1.7 hours.

No interaction between Solcoseryl and polidocanol was found in animal experiments.

Indications and usage

- Painful and inflammatory disorders of the oral mucosa, gums and lips: aphthae, herpes simplex labialis, gingivitis, periodontitis;
- denture sores;
- eruption difficulties with milk and wisdom teeth;
- as wound dressing after scaling, curetting, periodontal operations, extractions and insertion of immediate dentures, alveolitis.

Dosage and administration

Unless otherwise prescribed, apply a strip of paste about ½ cm long thinly onto the lesion 3–5 times a day. It is particularly advisable to do this before going to bed. Application should be repeated until the symptoms have disappeared. Do not massage in the paste.

For satisfactory adhesion it is advisable to dry the area before treatment. Solcoseryl Dental Adhesive Paste forms a protective film which adheres to the oral mucosa for a long time and prevents irritation when eating.

Restrictions on use

Contraindications

Solcoseryl Dental Adhesive Paste contains p-hydroxybenzoates (E 216 and E 218) as preservatives, and traces of the free acid (E 210). Solcoseryl Dental Adhesive Paste should not be used in cases of known hypersensitivity to one or more of the ingredients.

Precautions

The paste should not be packed into wound cavities which are subsequently tightly closed by an approximation suture as, for example, after extraction of molars and impacted wisdom teeth or apicectomies. Acute infections of the wound area should receive causal treatment before use of the product.

Pregnancy, lactation

Animal reproduction studies have revealed no risk for the foetus, but no controlled studies have been carried out on pregnant women. There are no objections to the use of Solcoseryl Dental Adhesive Paste during lactation.

Undesirable effects

Very rarely allergic reactions may occur. In such cases the therapy should be cancelled.

Interactions

No interactions with other agents have been reported.

Overdosage

Toxic effects from overdosage of the paste have not been reported.

Special remarks

Notes

The slightly granular/dry consistency of Solcoseryl Dental Adhesive Paste indicates optimal adhesive strength and is not a sign of a diminution in quality. Oil may occasionally separate out in the opening of the tube but likewise does not affect the quality of the product.

Stability

Store protected from heat (below 30°C) and do not use after the expiry (EXP) shown on the tube.

Packs

Tube containing 5 g o paste

This is a medicament

- a medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor

Medicine: keep out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

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