1. Name of medicinal product

SOCKETOL Paste (for introduction into the alveole)

2. Qualitative and quantitative composition

Active substances
1 g of paste contains 150 mg lidocaine hydrochloride 1 H2O, 100 mg phenoxethanol (Ph. Eur.), 5 mg thymol and 30 mg Peru balsam

Full list of excipients, see section 6.1

3. Pharmaceutical form

light brown paste in syringe for dental application

4. Clinical particulars

4.1 Therapeutic indications

Agent for the treatment of tooth extraction wounds.

Painkilling, antiseptic agent for application in tooth sockets.

4.2 Posology and method of administration

The required amount depends on the size of the socket, which should be filled no more than halfway up with SOCKETOL. On average, 200 - 300 mg paste is required; this is equivalent to 30 - 45 mg lidocaine hydrochloride. Teeth with several roots may require up to 500 mg paste, equivalent to 75 mg lidocaine hydrochloride.

These are doses well below the recommended maximum dose of 200 - 300 mg lidocaine hydrochloride for nerve blocks or infiltration anaesthesia. Therefore, intoxication due to the local anaesthetic can largely be ruled out.

After thoroughly cleaning and rinsing the extraction wound with hydrogen peroxide, fill the socket no more than halfway up with SOCKETOL and press the edges of the socket together.

Depending on the level of pain, the paste plug can be reinserted in the socket on several consecutive days.

4.3 Contraindications

SOCKETOL may not be used:

In patients who are allergic or hypersensitive to Peru balsam, cinnamon or any of the other ingredients in the medicinal product. This also applies for patients who are hypersensitive to cinnamon (cross-reacting allergy).

In patients who are allergic to local anaesthetics of the acid amide type or by patients who report adverse events (particularly symptoms of intoxication) associated with a previous local anaesthetic.

4.4 Special warnings and precautions for use

SOCKETOL should be used only with special care in patients with severe defects affecting the impulse-formation and impulse-conduction systems of the heart, acute congestive heart failure or severe kidney or liver disease.

Lidocaine is metabolised in the liver and should therefore be used with greater care by patients with severe liver failure.

Wool fat may cause localised skin reactions (e.g. contact dermatitis).

4.5 Interactions with other medicinal products and other forms of interactions

In some circumstances, SOCKETOL may enhance the effect of local anaesthetics and antiarrhythmic agents.

4.6 Pregnancy and lactation

What to consider during pregnancy?

It is not known whether the use of SOCKETOL has negative effects on pregnancy and breastfeeding.

Lidocaine should not be used during pregnancy unless the treating physician considers it strictly necessary, because no controlled studies have been carried out in pregnant women. To date, there is no evidence that the use of lidocaine during pregnancy causes congenital malformations.

After injection into the body, lidocaine crosses the placenta. There have been no studies of transfer following application onto skin or mucous membranes.

What to consider during breastfeeding?

After injection into the body, lidocaine crosses into breast milk in small amounts. There have been no studies of transfer following application onto skin or mucous membranes, but a risk to the baby is unlikely.

4.7 Effects on ability to drive and use machines

There have been no studies on the effects on the ability to drive and use machines

4.8 Undesirable effects

In the assessment of adverse events following frequencies are used:

Very common (≥ 10%), common (≥ 1% - <10%), uncommon (≥ 0.1% - <1%), rare (≥ 0.01% - <0.1%), very rare (<0.01%, or unknown).

Due to lidocaine, Peru balsam and eucalyptus oil contained in the paste, allergic reactions may occur in rare cases. Peru balsam may cause skin reactions. Patients are asked to inform their dentist if they notice any symptoms, especially those not listed in this package leaflet.

4.9 Overdose and other dosage mistakes

Due to the dosage and slow release of the active substances from the paste, no systemic intoxication reactions are to be expected. In the event of signs of a lidocaine overdose, such as agitation and tremor, the paste plug should be removed from the socket and the patient should be monitored until the symptoms subside.

5. Pharmacological properties

5.1 Pharmacodynamic properties

The cause of post-extraction pain can be regarded as the infectious breakdown of the blood clot that forms initially or as a dry socket. The irritation of exposed nerve endings can lead to unbearable pain. The aim of treatment is to eradicate the infection and alleviate the pain.
SOCKETOL contains a paste base, which adheres well in the moist environment of the tooth socket and doubles in volume when it absorbs moisture. This means that the socket is well filled with the paste, and the paste can slowly release the active substances in the infected, painful socket.

SOCKETOL contains phenoxethanol and thymol, active substances that counteract pathogenic micro-organisms and, together, are effective against aerobic and anaerobic organisms as well as Gram-negative and Gram-positive pathogens and fungal infections. SOCKETOL contains lidocaine hydrochloride for the eradication or alleviation of unbearable pain. The local anaesthetic starts to take effect a few minutes after administration. As the paste releases the active substances relatively slowly, pain relief is relatively prolonged.

SOCKETOL contains Peru balsam, which, besides its antibacterial effect, also encourages granulation and therefore has a positive influence on wound healing.

5.2 Pharmacokinetic properties
Lidocaine absorption by the intact mucosa was 15 - 35%. After oral administration, systemic bioavailability is low due to the extensive first-pass effect. Lidocaine is up to 64% bound to plasma proteins. Lidocaine crosses the placenta by passive diffusion. The foetal to maternal concentration ratio in plasma was 1.4 following epidural anaesthesia. Phenoxethanol is absorbed orally and through the skin, and is completely excreted in the urine within 24 hours.

5.3 Preclinical safety data
Toxicological properties
No systematic toxicology studies have been conducted with SOCKETOL. In animal studies with phenoxethanol, skin irritation was found to be marginal or non-existent. In standard animal experiments, pure thymol caused severe skin and eye irritation. No results from animal experiments using low doses are available. Local toxicity studies with lidocaine in various animal species have produced no evidence of irreversible tissue damage. Numerous acute toxicity studies with lidocaine have been conducted in a variety of animal species. Pronounced CNS effects were observed in the dose range of approximately 5 mg/kg following intravenous administration and 30 – 50 mg/kg following subcutaneous administration. Fatalities occurred at higher doses, mainly as a result of seizures.

Mutagenic and tumorigenic potential
Mutagenicity studies with lidocaine have produced negative results. However, there is evidence that one metabolite, 2,6-xylidine, which is formed from lidocaine in rats as well as in humans, may have mutagenic effects. This evidence comes from in vitro tests, in which this metabolite was used in very high, almost toxic concentrations. Furthermore, 2,6-xylidine showed tumorigenic potential in a carcinogenicity study in rats, involving transplacental exposure and post-partum treatment of the animals for 2 years. In this highly sensitive test system, malignant and benign tumours were observed, primarily in the nasal cavity (ethmoturbinalia), with very high doses. As the significance of these findings for humans cannot be entirely dismissed, SOCKETOL should not be administered in high doses for prolonged periods.
To date, genetic toxicity tests with thymol and phenoxethanol have produced negative results. Animal-experimental studies with lidocaine have produced no evidence of teratogenic potential or of adverse effects on physical development following in utero exposure. Possible effects on the behaviour of prenatally exposed offspring have not been adequately studied in animal experiments.

6 Pharmaceutical particulars
6.1 List of excipients
Ovis aries wool fat, hymetellose, dimeticone (visc. =100 cSt.) and eucalyptus oil, refined

6.2 Incompatibilities
Since no studies on compatibility have been conducted, this medicinal product must not be mixed with other drugs.

6.3 Shelf life
SOCKETOL has a shelf life of 3 years in the unopened container; once opened, it should be used up within 6 months. Do not use the product after the expiry date, which is stated on the carton and label.

6.4 Special precautions for storage
Do not store above 25 °C

6.5 Nature and contents of container
Applicator syringe containing 5 g paste

6.6 Special precautions for disposal
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines, if you no longer need it. These measures are helping to protect the environment. Any unused product or waste material should be disposed of in accordance with local requirements

7. Marketing authorisation holder
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8. Marketing authorisation number
6031087.00.00

9. Date of renewal of the authorisation
19.07.2005

10. Date of revision of the text
March 2011

11. Deferred sales
For sale in pharmacies ("Only for dental use")