Package leaflet and summary of product characteristics

SOCKETOL

Paste (for introduction into the alveole)

Package leaflet and summary of product characteristics: Information for the user

SOCKETOL paste

Active substances lidocaine hydrochloride 1 H_2O, phenoxyethanol (Ph. Eur.), thymol and Peru balsam

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. WHAT SOCKETOL IS AND WHAT IT IS USED FOR

Agent for the treatment of tooth extraction wounds
Painkilling, antiseptic agent for application in tooth sockets

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SOCKETOL

SOCKETOL may not be used:
- If the patient is allergic to any of the active ingredients, Peru balsam, or to any excipients of this medicinal product referred to in Section 6. This also applies to patients who are hypersensitive to cinnamon (cross-reacting allergy).
- Allergy to local anaesthetics of the acid amide type or in patients who report about adverse events (particularly symptoms of intoxication) associated with a previous local anaesthesia.

Warnings and precautions
- 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).

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Please note that this information may also apply to recently administered medicines.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
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.

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

3. HOW TO TAKE SOCKETOL

Apply this drug according to the following dosage recommendations. The product should be used only by dental care professionals in accordance with the following recommended dosages.
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. For this purpose, please screw off the closing cap of the applicator syringe and screw one of the enclosed shortly before unpacked applicator cannulas from the individual packaging onto the applicator syringe to apply the required amount of SOCKETOL. For each application a new applicator cannula is to be used.
Depending on the level of pain, the paste plug can be reinserted in the socket on several consecutive days.

If you take more SOCKETOL than you should
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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Due to lidocaine, Peru balsam and eucalyptus oil contained in the paste, allergic reactions may occur in rare cases. Peru balsam and wool fat may cause skin reactions.

In the assessment of adverse events following frequencies are used:
Very common: may affect more than 1 in 10 people
Common: may affect up to 1 in 10 people
Uncommon: may affect up to 1 in 100 people
Rare: may affect up to 1 in 1,000 people
Very rare: may affect up to 1 in 10,000 people
Not known: frequency cannot be estimated from the available data

Reporting of suspected adverse reactions
Reporting of suspected adverse reactions after marketing authorisation is of great importance. It allows continuous monitoring of the risk-benefit ratio of medicinal product. Health professionals are encouraged to report any suspect case of an adverse reaction to the Federal Institute for Drugs and Medical Devices, Department of Pharmacovigilance, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, website: www.bfarm.de

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the Federal Institute for Drugs and Medical Devices, Department of Pharmacovigilance, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, website: www.bfarm.de.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE SOCKETOL
Keep this medicine out of the sight and reach of children
Do not store above 25 °C

Do not use SOCKETOL after the expiry date, which is printed on the label and on the package.
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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What SOCKETOL contains
- The active substances are lidocaine hydrochloride 1 H_2O, phenoxyethanol (Ph. Eur.), thymol and Peru balsam
- 1 g of paste contains 150 mg lidocaine hydrochloride 1 H_2O, 100 mg phenoxyethanol (Ph. Eur.), 5 mg thymol and 30 mg Peru balsam
- The other ingredients are Ovis aries wool fat, hymetellose, dimeticone (visc. =100 cSt.) and eucalyptus oil, refined

What SOCKETOL looks like and contents of the pack
Light brown paste in an applicator syringe for dental application
SOCKETOL paste is available in packages with 1 x 5 g paste and 10 luer lock cannulas (medical device, CE) or 3 g (2 x 1.5 g) paste and 6 luer lock cannulas (medical device, CE).

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Other sources of information
Pharmacological and toxicological properties and pharmacokinetic and bioavailability-speed

7. PHARMACOLOGICAL PROPERTIS

7.1 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 phenoxyethanol 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.

7.2 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. Phenoxyethanol is absorbed orally and through the skin, and is completely excreted in the urine within 24 hours.

7.3 Preclinical safety data
Toxicological properties
No systematic toxicology studies have been conducted with SOCKETOL.
In animal studies with phenoxyethanol, 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 toxicology tests with thymol and phenoxyethanol 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.

8. PHARMACEUTICAL PARTICULARS

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

8.2 Shelf life
SOCKETOL has a shelf life of 3 years in the unopened container; once opened, it should be used up within 6 months.

9. MARKETING AUTHORISATION NUMBER
6031087.00.00

10. DATE OF FIRST AUTHORIZATION / RENEWAL OF AUTHORIZATION
19. July 2005

11. DEFERRED SALES
For sale in pharmacies ("Only for dental use")

Package with 5 g paste Art.-No. 0032117
Package with 3 g paste (2 x 1.5 g) Art.-No. 0032130