SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

< Invented name > 20 mg/g gingival/oromucosal gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g gel contains 20 mg lidocaine hydrochloride (as lidocaine hydrochloride 1 H_2O).

Excipient with known effect:
Benzalkonium chloride 1 mg / g.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gingival/oromucosal gel
White ointment-like gel.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Short-term, symptomatic treatment of pain on the oral mucosa, on the gingiva and lips. < Invented name > is indicated for adults, adolescents and children from 6 years of age.

4.2 Posology and method of administration

Posology
For adults and adolescents, a pea sized piece of gel (approx. 0.2 g gel (4 mg lidocaine hydrochloride)) is applied 4-8 times a day. The daily dose should not exceed 40 mg lidocaine.

Paediatric population
For children from 6 years the dosing should be up to 4 times daily a pea sized piece of gel (approx. 0.2 g gel (4 mg lidocaine hydrochloride).

The safety and efficacy of <invented name> in children younger than 6 years have not yet been established.

Currently available data are described in section 5.1 but no recommendation on a posology can be made.

If the patient's disorders persist for more than 2 days and the underlying cause is not known, the patient should consult a dentist or doctor.

Method of administration
Gingival/oromucosal use.
< Invented name > should be applied onto the painful areas and rubbed in gently.

When wearing new dental plates or braces, a thin layer of < Invented name > should be applied to the affected areas.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Hypersensitivity to local anaesthetics of the amide type.

4.4 Special warnings and precautions for use

Although the resorbed quantity of lidocaine is clearly lower after local application of the gel than after infiltration anaesthesia or nerve block anaesthesia, systemic effects cannot be completely excluded if resorption conditions are very unfavourable (strongly traumatised mucosa). Therefore extensive use should be avoided in patients with serious underlying conditions; in particular impairment of cardiac conduction, non-compensated cardiac insufficiency or severe liver or kidney disease.

Caution when intaking hot drinks or food within 45 minutes after application, to prevent choking, tongue bite or burns.

< Invented name > contains benzalkonium chloride. Irritant, may cause skin reactions.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Relevant clinical interactions are highly unlikely due to the local application and the amount of the gel to be applied. However, the analgesic effect of other local anaesthetics could be increased. Interactions known for lidocaine (antiarrhythmics, beta blockers) are not relevant for the oromucosal application of < Invented name>.

4.6 Fertility, pregnancy and lactation

There are no adequate data of pregnant women treated with <invented name>.
Lidocaine may cross the placenta barrier and may be absorbed in foetal tissue. The risk to humans is not known.
<Invented name> should not be used during pregnancy unless clearly necessary.

Lidocaine is excreted in breast milk in small quantities.
At therapeutic doses of <invented name> no effects on breastfed infants are anticipated.

4.7 Effects on ability to drive and use machines

< Invented name > has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile
The most serious adverse reaction during treatment is an anaphylactic reaction up to anaphylactic shock.

Tabulated list of adverse reactions

Reported adverse reactions are listed below, by MedDRA body system organ class and by frequency. Frequencies are defined as: very common (≥ 1/10); common (≥ 1/100 to <1/10); uncommon (≥ 1/1,000 to <1/100); rare (≥ 1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).

System Organ Class	**Adverse reaction**
Immune system disorders	*Very rare:* anaphylactic shock, anaphylactic reaction, hypersensitivity
Nervous system disorders	*Very rare:* burning sensation mucosal, hypoaesthesia, dysgeusia
Skin and subcutaneous tissue disorders	*Very rare*: pruritus, urticaria (localised), dermatitis contact, rash
General disorders and administration site conditions	*Very rare:* local swelling, local reaction, application site erythema, application site pain

Locally administrated lidocaine can cause allergic reactions and, when absorbed, systemic reactions. Occurring and intensity of systemic reactions depend on lidocaine serum concentration (influence of application site and dose), patient's condition, hepatic function, age, body weight, and co-morbidities – heart diseases and hyperthyroidism.

Description of selected adverse reactions
Due to the rare, mostly transient and mild adverse reactions, a special description of selected adverse reactions is not necessary.

Paediatric population
There is no specific information on differences in adverse reactions in children.

Other special population(s)
There is no specific information on differences in adverse reactions in other special populations.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit / risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Until now no cases of intoxication due to overdose, accidental intake or mistakes with < Invented name > are known. In case of overdose, patients should be managed by symptomatic treatment.

In case of a systemic adverse reaction the following emergency measures / counter agents are recommended: Keep the respiratory tract free, check blood pressure, pulse and pupil width, horizontal positioning of the patient with legs elevated in case of acute and threatening hypotension, administration of a beta-sympathomimetic (e.g. isoprenaline), in case of cramps diazepam, if the vagotone is increased (bradycardia) atropine, if needed administration of oxygen, i.v.-volume substitution and reanimation.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: anesthetics, local; amides
ATC code: N01BB02

Lidocaine reversibly inhibits the opening of sodium channels and thus the development of an action potential. The active substance binds on a specific receptor of the sodium channel, inhibiting the ion transport and the development of an action potential. The transmission of nerve impulses is suppressed locally.

Pain perception is suppressed. Thin unmyelinated nerve fibres are switched off more quickly than thick motoric nerve fibres. Perceptions are switched off in the following order: Pain, temperature, touch, and pressure.

Topically applied lidocaine efficaciously relieves pain of various etiology on mucous membranes of the mouth, like e.g., aphthous ulcers, gingivostomatitis herpetica, during teething and dental procedures.

Paediatric population
Children between 6 months and 8 years: In a randomized, placebo-controlled, double-blind study children were included in group I (4 – 8 years, average age 6.4 years, treated with <invented name> or placebo, main indication: aphthous ulcers (36%) (n=161)) or group II (6 months - < 4 years, average age 1.8 years, treated only with <invented name>, main indication: teething (n=64)) depending on age. Pain reduction from prior to administration to 10 or 30 minutes after application as measured by using the Wong-Baker FACES Pain Rating Scale was significantly higher after applying <invented name> in comparison to placebo in group I. In group II the individual pain rating shift showed a statistically significant lower pain after treatment. No adverse events related to the study medication were reported. The local tolerability was assessed as very good in over 97% of cases.

Children between 6 years and 15 years: In a randomized, placebo-controlled, double-blind study children between 6 years and 15 years with clamp placement, oral trauma or aphthous ulceration were included. Application of <invented name> led to a statistically significant higher reduction of pain intensity as measured using a 100 mm visual analog scale. No local or systemic adverse reactions were reported.

5.2 Pharmacokinetic properties

Lidocaine is well absorbed after application on the oral mucosa because of its special morphological conditions which are different from the normal skin (no stratum corneum, blood vessels nearer to the surface). It is absorbed within seconds to minutes and pain relief lasts for about 1 hour.

The plasma elimination half-life of lidocaine is 1.5-2 hours after absorption from the tissues. The distribution volume is 1.5 l / kg and the plasma protein binding is approximately 65 %.

Lidocaine undergoes extensive first pass-metabolism by the liver. 90-95 % is metabolised (N-dealkylation, ring hydroxylation, hydrolytic cleavage of acid amide linkage). About 5-10 % of the dose is excreted unchanged by the kidneys. The metabolic rate may be strongly decreased in case of impaired liver function.

5.3 Preclinical safety data

Reproduction Toxicology
In studies of embryonic/foetal development in which rats or rabbits were dosed during organ development, no teratogenic effects were observed. Embryotoxicity was seen in rabbits at a dose toxic to the mother. In rats, reduced postnatal survival was seen in the young of mothers treated during late pregnancy and lactation with doses which were toxic and influenced the length of the pregnancy.

Genotoxicity and carcinogenicity
Genotoxic studies of lidocaine were negative. 2,6-xylidine, a metabolite of lidocaine has, however, shown genotoxic potential in vitro. In a carcinogenicity study of rats exposed in utero, postnatally and throughout life to 2,6-xylidine, tumours were observed in the nasal cavity, the liver and subcutaneously. High doses of 2,6-xylidine were needed to induce tumours in animal studies. The clinical relevance of the tumour inducing effect of this lidocaine metabolite after intermittent use as a local anaesthetic is unknown.

Local Tolerance
The local tolerance of < Invented name > was tested in the hamster cheek pouch over 4 weeks. The observed reactions were unspecific. No clinically relevant changes were observed after application of < Invented name >.

Sensitizing Capacity
In guinea pigs < Invented name > showed only a slight sensitizing capacity under test conditions.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride,
Bitter-fennel fruit oil,
Glycerol,
Guar galactomannan,
Partly dementholised mint oil,
Liquid paraffin,
Peppermint oil,
Saccharin sodium,
Colloidal anhydrous silica,
Star anise oil,
Thymol,
Titanium dioxide (E171),
White soft vaseline,
Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.
Shelf life after first opening: 3 months.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Aluminium tubes with HDPE screw caps containing 10 g gel.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7. MARKETING AUTHORISATION HOLDER

<To be completed nationally>

8. MARKETING AUTHORISATION NUMBER(S)

<To be completed nationally>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<To be completed nationally>

10. DATE OF REVISION OF THE TEXT

< MM / YYYY >