Summary of Product Characteristics/ SPC

## 1. NAME OF THE MEDICINAL PRODUCT

Kamistad®
20 mg lidocaine hydrochloride/185 mg chamomile flower extract per 1 g of oromucosal gel.

## 2. QUALITATIVE AMD QUANTITATIVE COMPOSITION

1 g of gel contains 20 mg lidocaine hydrochloride $1H_2O$ and 185 mg chamomile flower extract (1:4-5). Extractant: ethanol 50% (v/v) with 1.37% trometamol (adjusted to pH 7.3 with 98% formic acid).

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Gel

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Traditionally used as a mild-acting medicinal product in cases of mild inflammation of the gums and oral mucosa.

A doctor should be consulted if signs of inflammation do not improve within one week.

### 4.2 Posoiogy and method of administration

Adults and children over 12 years, of age
Apply ½ cm ribbon of gel approx., three times a day.

Children below the age of 12 years
As insufficient studies have been performed, Kamistad® should not be used in children below the age of 12 years.

**Method of administration and duration of use**
The gel is applied onto inflamed areas and rubbed gently in.

In principle, there are no time restrictions on the length of treatment.

### 4.3 Contraindications

- Hypersensitivity to the active substances, other amine-type local anaesthetics or to any of the excipients of the product.

**4.4 Special warnings and precautions for use**

As insufficient studies have been performed, Kamistad® should not be used in children below the age of 12 years.

Kamistad® should not be allowed to come into contact with the eyes or open wounds. The hands should be thoroughly washed after application of Kamistad®.

Benzalkonium chloride may cause skin irritation.

**4.5 Interaction with other medicinal products and other forms of interaction**

There are no known interactions with other agents within the dose range stated.

**4.6 Pregnancy and Lactation**

As insufficient studies have been performed, Kamistad® should not be used in pregnant women and during lactation.

**4.7 Effects on ability to drive and use machines**

To date, no effects on the ability to drive and use machines have been reported.

**4.8 Undesirable effects**

In this section, frequencies of undesirable effects are defined as follows: very common (>1/10); common (>1/100 to <1/10); uncommon (*И*/1,000 to <1/100); rare (> 1/10,000 to <1/1,000); very rare (<1/10,000 or not known).

*Skin and subcutaneous tissue disorders*

Uncommon: Transient mild stinging may occur following application of the gel.

*Immune system disorders*

Very rare: As this product contains lidocaine, cinnamon and chamomile, allergic reactions may occur (e.g. contact allergy). Such reactions may also occur in patients who are hypersensitive to members of the daisy family (e.g. mugwort) and Peruvian balsam (due to so-called cross reactions).

If dermal or mucosal hypersensitivity reactions occur, Kamistad® should be discontinued and a doctor consulted.

**4.9 Overdose**

To date, no cases of intoxication or overdosage with Kamistad® have been reported.

**5. PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: stomatological preparations
ATC code: A01AE51

*Lidocaine*

When compared with procaine, lidocaine is characterised by its longer duration of action and better tolerability.

Chamomile, or rather the liquid extract obtained from chamomile flowers, contains a complex of substances with various structures. Among these, the most therapeutically significant are sesquiterpenes, which represent the major component (up to 50%), with chamazulene and (-)a-bisabolol also playing a significant role.

### 5.2 Pharmacokinetic properties
Not applicable.

### 5.3 Preclinical safety data
There is evidence to suggest that 2.6 xylidine, a lidocaine metabolite occurring in the rat and possibly humans, might have mutagenic effects. This evidence is based on *in vitro* tests, in which this metabolite was used at very high, almost toxic concentrations. There are currently no indications to suggest that lidocaine (the parent substance) it is mutagenic.

In rat carcinogenicity study involving a highly sensitive test system (transplacental exposure and postpartum treatment with 2.6 xylidine over 2 years at very high doses), malign and benign tumours were observed particularly in the nasal cavity (ethmoid turbinates). It seems not wholly improbable that these findings may also be relevant for humans. High doses of Kamistad® (lidocaine) should therefore not be administered over prolonged periods.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients
Benzalkonium chloride solution 50%, ethanol 96%, formic acid, carbomers, sodium saccharin, trometamol, purified water, oil of cinnamon.

### 5.2 Incompatibilities
Not applicable.

### 6.3 Shelf life
5 years.
Shelf life once container is opened: 12 months.

### 6.4 Special precautions for storage
Do not store above +30°C.

### 6.5 Nature and contents of container
Aluminium tube with internal protective lacquer and PE seal. Original packs of 10 g gel.

### 6.6 Special precautions for disposal
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(S)

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

## 10. DATE OF REVISION OF THE TEXT

September 2007