kreussler PHARMA

# DYNEXAN Mundgel®

## 1 Name of medicinal product

DYNEXAN Mundgel®

2 % gel

Active substance: Lidocaine hydrochloride

## 2 Qualitative and quantitative composition

DYNEXAN Mundgel is a topical local anaesthetic based on lidocaine hydrochloride and contains the following amount of active ingredient:

***Type and quantity of active substance***

1 g gel contains 20 mg lidocaine hydrochloride.

***Excipients***

See chapter 6.1

## 3 Pharmaceutical form

Oromucosal gel

## 4 Clinical Particulars

### 4.1 Therapeutic Indications

For temporary, symptomatic treatment of pain on the oral mucosa, gingiva and lips.

### 4.2 Posology and method of administration

***Dosage with single and daily doses***

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

For children, toddlers and infants the dosing should be individually adapted to age and weight (maximal 4 times daily a pea sized piece).

***Method and duration of administration***

DYNEXAN Mundgel should be applied and rubbed gently into the painful areas.

When wearing new dental plates or braces, a thin layer of DYNEXAN Mundgel should be applied to the affected areas.

When the dentist applies DYNEXAN Mundgel from cylindric ampoules he uses a special cannula to apply the gel into alveolae and gingival pockets.

If the disorders persist for more than a week or unclear disorders occur, a dentist or doctor should be consulted.

### 4.3 Contraindications

DYNEXAN Mundgel must not be used in case of hypersensitivity to one of the ingredients or to another local anaesthetic belonging to the amide type.

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, DYNEXAN Mundgel is only allowed to be applied under special caution in patients suffering from severe disorders of the conduction system of the heart or acute decompensated cardiac insufficiency and severe kidney or liver diseases.

### 4.4 Special warnings and precautions for use

This medicinal product contains 1 mg benzalkonium chloride. Benzalkonium chloride may cause local irritations.

### 4.5 Interactions with other medicinal products and other forms of interaction

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

### 4.6 Fertility, pregnancy, and lactation

There are no adequate data of pregnant women treated with DYNEXAN Mundgel.

Lidocaine is able to cross the placental barrier and may be absorbed by foetal tissue. The potential risk for humans is not known. Lidocaine is excreted in breast milk in small quantities.

DYNEXAN Mundgel should not be used during pregnancy and lactation unless clearly necessary.

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

No negative influence of DYNEXAN Mundgel to drive vehicles and operate machinery is known.

### 4.8 Undesirable effects

Frequency information is based on the following categories:

Very common (≥ 1/10)
Common (≥ 1/100 to < 1/10)
Uncommon (≥ 1/1,000 to < 1/100)
Rare (≥ 1/10,000 to < 1,000)
Very rare (<1/10,000)
Not known (frequency cannot be estimated from the available data).

***Very rare***

- Local allergic and non-allergic reactions, e.g.
  - Burning sensation
  - Swelling
  - Erythema
  - Pruritus
  - Urticaria
  - Contact dermatitis
  - Exanthema
  - Pain
- Changes in taste
- Anaesthesia
- Anaphylactic reactions and anaphylactic shock reactions with accompanying symptoms.

***Reporting of suspected adverse reactions***

Reporting suspected adverse reactions after authorisation is of great importance. It allows continued monitoring of the benefit / risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger Allee 3, D-53175 Bonn, Website: www.bfarm.de.

### 4.9 Overdose

***Symptoms of intoxication***

Until now no cases of intoxication with DYNEXAN Mundgel are known.

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 (5 to 10 mg i.v.), if the vagotone is increased (bradycardia) atropine (0.5 to 1 mg i.v.), if needed administration of oxygen, i.v.-volume substitution and reanimation.

## 5 Pharmacological properties

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: anaesthetics, local; amides

ATC code: N01BB02

Lidocaine reversibly inhibits the opening of sodium-ion channels and thus the development of an action potential. The active substance binds on a specific receptor of the sodium-ion 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 quicker than thick motoric nerve fibres. Perceptions are switched off in the following order: Pain, cold / warmth, touch, and pressure.

### 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.

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

Due to the delayed release of lidocaine from the gel base and its rapid metabolism, systemic or toxic effects are unlikely after application of DYNEXAN Mundgel.

***Acute toxicity***

The acute toxicity of lidocaine was tested in various species in different administration forms (see table).

| Species | Intra venous (mg/kg) | Oral (mg/kg) | Subcutaneous (mg/kg) |
|---|---|---|---|
| Mouse | 15 | 220 | 163 |
| Rat | 21 | -- | 570 |
| Rabbit | 25.6 | -- | -- |
| Guinea pig | 24.5 | -- | -- |

First toxic effects on the CNS were seen after intravenous dosages of 3-5 mg/kg and subcutaneous dosages of 30-50 mg/kg.

The limit dose below the use of lidocaine is considered to be safe is 4 mg/kg body weight (intramuscular injection).

***Chronic toxicity***

Investigations were performed in rats and dogs with 6 months duration. The studies in rats did not reveal any pathological changes caused by lidocaine. The studies in dogs indicated fatty changes in the liver at subcutaneous dosages of 30 mg/kg and oral dosages of 50-60 mg/kg.

***Reproduction toxicity***

In studies aiming at the embryonic and foetal development in which rats or rabbits were treated with lidocaine during the period of organogenesis, no teratogenic effects were found. Embryotoxicity was observed at maternal toxic doses in rabbits. In rat dams that were treated with maternally toxic doses of lidocaine during pregnancy and lactation, influencing the length of pregnancy, the survival rate of the offspring was diminished.

***Genotoxicity and carcinogenic potential***

Investigations with regard to lidocaine genotoxicity were negative. However, *in vitro* genotoxicity studies with the metabolite 2,6-xylidine showed a genotoxic potential.

In a carcinogenicity study in rats, tumors have been observed in the nasal cavity, the subskin and the liver. 2,6-xylidinde was administered in utero and lifelong postnatal.

***Local tolerance***

As a result of a 4-week experimental study on the local tolerance of DYNEXAN Mundgel in the hamster using the cheek pouch technique only unspecific reactions were observed. There were no clinically relevant changes after application of DYNEXAN Mundgel.

***Sensitisation potential***

A study on the sensitising potential of DYNEXAN Mundgel in the guinea pig was performed using the technique of Magnusson and Kligman. Under these experimental conditions, the product showed only a slight sensitising capacity at 24 hours.

## 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, white soft vaseline, purified water.

### 6.2 Incompatibilities

Not applicable.

### 6.3. Shelf life

5 years.

After first opening, DYNEXAN Mundgel can be used for 3 months.

### 6.4. Special precautions for storage

Cylindrical ampoules: store protected from light and not above 25 °C.

### 6.5. Nature and contents of container

Pack with one tube containing 10 g or 30 g gel, respectively

Pack with 2 or 4 cylindrical ampoules, each 1.7 g gel.

### 6.6 Special precautions for disposal

Not applicable.

## 7 Marketing authorisation holder

Chemische Fabrik Kreussler & Co. GmbH
Rheingaustraße 87-93
D-65203 Wiesbaden
Tel.: 0611 / 9271-0
Fax: 0611 / 9271-111
www.kreussler.com
E-Mail: info@kreussler.com

## 8 Marketing authorisation number

6430574.00.00

## 9 Date of first authorisation / Renewal of the authorisation

25.02.2005

## 10 Date of revision of the text

January 2021

## 11 Classification for supply

Pharmacy only