

## Data Sheet

### Xylestesin™-A

Anhydrous lignocaine hydrochloride 20mg  
(R)-adrenaline hydrochloride 0.015mg (equivalent to 0.0125mg base)  
Solution for injection  
(local anaesthetic for dentistry)

### Composition

1 ml solution for injection contains:

Active ingredients:

Anhydrous lignocaine hydrochloride 20 mg  
(R)-adrenaline hydrochloride 0.015 mg  
(equivalent to 0.0125 mg base)

Other ingredients:

Anhydrous sodium sulphite 0.6 mg  
(equivalent to 0.31 mg SO<sub>2</sub>)  
Sodium chloride  
Water for injections

### Pharmaceutical Form and Content

Solution for injection in 1.7 ml cartridges  
Local anaesthetic of the anilide series with vasoconstrictive component for administration in dentistry

### Therapeutic Indications

Infiltration anaesthesia and nerve-block in dentistry.

### Contraindications

Due to the local anaesthetic ingredient lignocaine, XYLESTESIN-A cannot be used in the event of

- known allergy or hypersensitivity to local anaesthetics of the amide type
- severe impairment of the nervous impulses and conduction system of the heart (e.g. grade II and III AV block, pronounced bradycardia)
- acutely decompensated cardiac insufficiency (acute failure of cardiac output)
- severe hypotension (very low blood pressure)

Due to the content of adrenaline as a vasoconstrictor admixture, XYLESTESIN-A also cannot be used in the event of

- paroxysmal tachycardia or high-frequency continuous arrhythmia
- pronounced coronary insufficiency
- severe hypertension (high blood pressure)
- thyrotoxicosis (hyperactivity of the thyroid)
- narrow-angle glaucoma

- decompensated diabetic metabolic condition
- phaeochromocytoma
- concurrent treatment, or treatment during the past 14 days, with tricyclic antidepressants or monoamine oxidase (MAO) inhibitors

XYLESTESIN-A must be used with particular caution in the event of

- severe impairment to the renal or hepatic function
- angina pectoris (tightness in the chest)
- arteriosclerosis (vascular sclerosis)
- injection into an inflamed (infected) area
- considerable impaired blood coagulation

## Warning

XYLESTESIN-A must not be used in persons who are allergic or hypersensitive to sulphite, as well as in persons with severe bronchial asthma.

In these persons, XYLESTESIN-A can provoke acute allergic reactions with anaphylactic symptoms (e.g. bronchospasm).

## Administration During Pregnancy and Lactation

No sufficient studies of the use of XYLESTESIN-A during pregnancy are available for evaluating the safety of its application. Above all during the early stages of pregnancy XYLESTESIN-A should be used only after careful consideration of the benefit-risk ratio. A relevant transfer of the active ingredients to the breast milk is not to be anticipated, as they are rapidly decomposed and eliminated.

## Special Warnings and Precautions for Use

Erroneous intravascular application must be avoided (see section: Posology and method of administration).

In sensitive patients, the injection of XYLESTESIN-A may be followed by a temporary impairment of reactions, e.g. in traffic. The physician must decide from case to case whether the patient should be allowed to operate a motor vehicle or machinery.

## Interactions

The sympathomimetic effect of adrenaline can be intensified by the simultaneous intake of MAO inhibitors or tricyclic antidepressants.

Adrenaline can inhibit insulin release in the pancreas and thus diminish the effect of oral antidiabetics. The concomitant administration of non-cardioselective beta-blockers can lead to an increase in blood pressure due to the adrenaline in XYLESTESIN-A. Certain inhalational narcotics, such as halothane, can sensitise the heart to catecholamines and therefore induce arrhythmias following administration of XYLESTESIN-A.

It should be taken into consideration that during treatment with blood clotting inhibitors (e.g. heparin or acetylsalicylic acid), an inadvertent vasopuncture when administering the local anaesthetic can lead to serious bleeding, and that in general the haemorrhagic tendency is increased.

## Posology and Method of Administration

The Following Dosage Guidelines Apply:

The smallest possible volume of solution which will lead to effective anaesthesia should be used.

The dosage should be individually determined from case to case depending on the method used and special characteristics of the particular case.

As a rule, doses of 1-4 ml are sufficient for young persons over 15 years of age and adults.

In children weighing about 20-30 kg, doses of 0.25-1 ml are sufficient; and in children weighing 30-45 kg, 0.5-2 ml.

Increased plasma levels of XYLESTESIN-A can occur in older patients due to diminished metabolic processes and lower distribution volume. The risk of accumulation of XYLESTESIN-A increases in particular due to repeated application (e.g. post-injection). A similar effect can ensue from the reduced general condition of the patient, as well as severely impaired hepatic and renal function. A lower dosage range is thus recommended in all such cases (minimum quantity for sufficient anaesthetic depth). The XYLESTESIN-A dose is to be likewise reduced in patients with certain pre-existing diseases (angina pectoris, arteriosclerosis) or a local anaesthetic which does not contain a vasoconstrictor should be used. The maximum dose of the active ingredient lignocaine with vasoconstrictor admixture is 500 mg (7 mg/kg body weight). However, due to the addition of adrenaline 1:80,000, the maximum administered quantity of 20 ml solution for injection (equivalent to 0.25 mg adrenaline) must not be exceeded. No more than 5 mg lignocaine per kg body weight should be injected in children.

For injection (local anaesthetic in dentistry)

To avoid intravascular injection, aspiration control in two planes (rotation of the needle by 180°) must always be carefully undertaken, although a negative aspiration result does not safely rule out an unintentional and unnoticed intravascular injection.

The injection rate should not exceed 0.5 ml in 15 seconds, i.e. 1 cartridge per minute.

Opened cartridges must not be used in other patients.

Residues must be discarded.

## Therapy of Overdose

### General Basic Measures:

Diagnostics (respiration, circulation, consciousness), maintenance/restoration of the vital functions of respiration and circulation, oxygen administration, intravenous access.

### Special Measures:

- Hypertension: Elevation of the upper body, if necessary sublingual nifedipine
- Convulsions: Protect patients from concomitant injuries, if necessary diazepam i.v.
- Hypotension: Horizontal position, if necessary intravascular infusion of an electrolyte solution, vasopressors (e.g. etilefrine i.v.)
- Bradycardia: Atropine i.v.

- Anaphylactic shock: Contact emergency physician, in the meantime shock positioning, generous infusion of an electrolyte solution, if necessary adrenaline i.v., cortisone i.v.
- Cardiac shock: Elevation of the upper body, contact emergency physician
- Cardiovascular arrest: Immediate cardiopulmonary resuscitation, contact emergency physician

## Undesirable Effects

### Precautionary Note

If you notice side effects, especially those that are not described in the following paragraphs, please report this to your dentist or physician.

Undesirable effects can arise from overdose, particularly as a result of inadvertent intravascular injection or abnormal absorption conditions, e.g. in the inflamed or severely vascularised tissue, and manifest themselves as central nervous and/or vascular symptoms.

The measures which should be taken in the event of the occurrence of the following symptoms are described in the section "Therapy of overdose".

### **Due to the local anaesthetic ingredient lignocaine, the following side effects can occur from the use of XYLESTESIN-A:**

- Milder central nervous symptoms involve metallic taste, tinnitus, dizziness, nausea, vomiting, restlessness, anxiety, initial increase in respiratory rate.
- More severe symptoms are drowsiness, confusion, tremor, muscle twitching, tonic-clonic spasms, coma and respiratory paralysis.
- Severe cardiovascular episodes are seen in the form of a drop in blood pressure, asystole, bradycardia, cardiovascular arrest.
- Allergic reactions to lignocaine are extremely rare.

### **Undesirable effects which can occur due to the admixture of adrenaline as vasoconstrictor:**

- Symptoms such as heat sensation, sweating, heart racing, headache, blood pressure increase, anginal disorders, tachycardias, tachy-arrhythmias, and cardiovascular arrest cannot be ruled out.
- A disguising of the clinical picture can result from the simultaneous occurrence of various complications and side effects.

## Special Precautions

Due to the content of anhydrous sodium sulphite, allergic reactions or hypersensitivity reactions can ensue in isolated cases, particularly in bronchial asthmatics, which are manifested as vomiting, diarrhoea, wheezing, acute asthma attack, disturbance of consciousness or shock.

## Storage Information

Do not use the preparation after the expiry date.  
Store protected from light and not above 25 °C.

## **Medicine Classification**

Prescription Medicine

## **Package Size**

50 cartridges of 1.7 ml each

## **Further Information**

Keep out of the reach of children.

## **Name and Address**

### **Sponsor**

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### **Manufacturer**

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