

Direct Healthcare Professional Communication on the association of Xylocaine 10mg Spray with Cross Infection

Summary

Xylocaine 10mg Spray is supplied with a single use nozzle for the administration of Xylocaine Spray. A multi-pack of 50 individual nozzles are also available separately. If the nozzles are shared among patients, or reused by individual patients, there is a potential risk of cross contamination. Due to this risk, the Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labelling have been updated with important information on the use of the nozzle.

Aspen Pharma Trading Limited (APTL) in agreement with the Medicines and Healthcare Regulatory Authority (MHRA), United Kingdom, would like to inform you of the following:

Xylocaine pump spray is intended for use on mucous membranes and provides efficient surface anaesthesia, which lasts for approximately 10-15 minutes. In order to administer the product effectively, a nozzle is supplied with the spray in order to administer in nasal cavity or other areas. As a result, there is a risk of cross contamination between patients or for a single patient if the nozzle is shared or re-used.

Therefore, the following important changes have implemented into the product information to outline clear instructions on the recommended use and handling of the nozzle:

- Introduction of the wording “non-sterile” into the Xylocaine Spray product information (SmPC, PIL and labelling)
- Introduction of wording stating that the product is not recommended for procedures that require aseptic technique
- Introduction of wording into the SmPC on the need to adhere to national/local procedures to prevent contamination
- Strengthening of the information present in the product information on the single patient use nature of the nozzles in the current product information
- Update to the wording of current indications in line with current medical terminology
- Product Information Leaflet updated to bring it in line with current clinical practice

Please refer to **Annex I** for a detailed outline of these changes and communicate to your patients as necessary. These changes have been applied to the finished product (supplied with one nozzle) and similar changes will be applied to the bulk pack of 50 nozzles available in the United Kingdom. Where the product is used in line with recommendations on the product information, there is no expected change to the benefit risk profile.

Reporting side effects

Spontaneous reports are extremely important for the rapid identification of adverse effects. Health care professionals are requested to report all suspected adverse events to the MHRA via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Contact information

If you have more information or questions, please contact Aspen Medical Information directly via e-mail: aspenmedinfo@professionalinformation.co.uk or via phone: 0800 008 7392.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'KS', is positioned above the printed name.

Karolina Szkudlarek MSc.
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Aspen Pharma Trading Limited

Annex I - Text of the revised Product Information (with changes made visible)

Changes to the SmPC

1.3. PHARMACEUTICAL FORM

Non-sterile solution for topical application supplied in a ~~Topical anaesthetic~~ pump spray, with nozzles for single use in an individual patient.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

General

This product is **non-sterile** and therefore not recommended for use prior to procedures that require aseptic techniques.

For the prevention of pain associated with the following procedures:

Otorhinolaryngology

Anaesthesia prior to ~~—Puncture of the maxillary sinus and minor surgical non-invasive~~ procedures in the nasal cavity, pharynx and epipharynx including rhinoscopy and laryngoscopy.

~~•~~

~~— Paracentesis.~~

Obstetrics

During the final stages of delivery and before episiotomy and perineal suturing ~~a~~ supplementary pain control for procedures not requiring aseptic technique.

~~Introduction~~ Insertion of instruments and catheters into the respiratory and digestive tract

Provides surface anaesthesia for the oropharyngeal and tracheal areas to reduce reflex activity, attenuate haemodynamic response and to facilitate insertion of the catheter~~tube~~ or the passage of instruments during endotracheal intubation, laryngoscopy, bronchoscopy, ~~and~~ oesophagoscopy and gastroscopy.

Dental practice

Before minor dental procedures where local anaesthesia is desired. ~~injections, dental impressions, X-ray photography, removal of calculus.~~

Method of administration

Xylocaine spray is administered using the supplied ~~n~~ nozzle. Nozzles are supplied in the finished product packaging and also available separately in boxes of 50. Nozzles are **non-sterile single patient single use only.** Appropriate measures should be undertaken to avoid cross contamination (see Section 6.6).

1.14.2 Posology and method of administration

As with any local anaesthetic, reactions and complications are best averted by employing the minimal effective dosage. Debilitated or elderly patients and children should be given doses commensurate with their age and physical condition.

Xylocaine Spray should not be used on cuffs of endotracheal tubes (ETT) made of plastic (see also section 4.4).

Each activation of the metered dose valve delivers 10 mg lidocaine base. It is unnecessary to dry the site prior to application. No more than 20 spray applications should be used in any adult to produce the desired anaesthetic effect.

The number of sprays depend on the extent of the area to be anaesthetised.

- ~~_____~~ Dental practice
1–5 applications to the mucous membranes.

- ~~_____~~ Otorhinolaryngology
~~—3—~~ 3 applications for puncture of the maxillary sinus.

- ~~—~~ Obstetrics ~~_____~~ During delivery
~~—~~ _____
_____ Up to 20 applications (200 mg lidocaine base).

~~_____~~
- Introduction-Insertion of instruments and catheters into the respiratory and digestive tract
1.2 ~~_____~~ Up to 20 applications (200 mg lidocaine base) for procedures in pharynx, larynx, and trachea.

6.6 Special precautions for disposal and other handling

The spray nozzle is bent to ensure correct spray function. Do not try to alter the shape as this could affect its performance.

The nozzle must not be shortened, as it will affect the spray function.

Nozzles are non-sterile single patient single use and national/local procedures should be adhered to in order to prevent cross contamination. The nozzles should be handled using gloves and the box of 50 should be kept closed between procedures. Nozzles should not be reused and should be discarded immediately after use.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Changes to the PIL

1. What Xylocaine Spray is and what it is used for

The name of your medicine is 'Xylocaine 10 mg Spray'. It is referred to as 'Xylocaine Spray' in the rest of this leaflet.

Xylocaine Spray contains a medicine called lidocaine. This belongs to a group of medicines called local anaesthetics.

Xylocaine Spray is a non-sterile solution used to numb (anaesthetise) parts of the body to reduce pain and reflex gagging happening during:

- During Medical examinations of the nose, throat, stomach or lungs requiring the insertion of viewing instruments
- Minor procedures involving the and operations of the nose and throat.
- After Childbirth, and after the birth if stitches are needed.
- During Treatment at the dentist.

3. How to use Xylocaine Spray ~~is given to you~~

- Xylocaine Spray will usually be given to you by a doctor or dentist. The dose that your doctor or dentist gives you will depend on the type of pain relief that you need. It will also depend on your age and physical condition.
- If you are given Xylocaine Spray to take home, you must use the dose recommended by your doctor or dentist. Always use Xylocaine Spray exactly as your doctor or dentist has told you. You should check with them if you are not sure.
- Xylocaine spray is given using the nNozzle supplied in the pack. Extra nozzles are also available separately in boxes of 50. Nozzles are single use only. The nozzles should not be re-used and should be disposed of immediately after use.
- Appropriate measures should be undertaken to avoid cross contamination in a healthcare setting including undertaking hand hygiene prior to use, use of disposable gloves during administration, keeping the box of 50 nozzles closed between procedures and ensuring disposal of each nozzle after use.