



## **Medicine Supply Alert Notice**

### **Xylocaine® (lidocaine) 10mg spray**

21<sup>st</sup> January 2025

**Priority: Level Tier 2**

**Valid until: 21 February 2025**

#### **Issue**

- Xylocaine® (lidocaine) 10mg spray is out of stock until mid-February 2025.
- Lidocaine 5% / Phenylephrine 0.5% spray remains available and can support an increase in demand.
- Lidocaine 150mg/g / Cetrимide 1.5mg/g (Xylonor®) oromucosal spray remains available but cannot support an increase in demand.
- Lidocaine 50mg/g / Cetrимide 1.5mg/g (Xylonor Gel) remains available and can support an increase in demand.
- Unlicensed supplies may be sourced, lead times vary.

#### **Advice and Actions**

Secondary care pharmacy procurement teams and clinical teams should work together to:

- review local stock holdings and prioritise existing stock for use in areas most in need of this product (i.e. upper gastrointestinal (GI) endoscopy/procedures); and
- consider appropriateness of preserving existing stock in endoscopy by limiting the number of sprays administered to patients and reviewing whether it is still required in patients who have received IV sedation.

Where there is insufficient stock to last until the resupply date:

- review all associated clinical guidelines and ensure appropriate alternatives are available, clinicians in endoscopy units and rhinologists should be consulted about suitability of an alternative product or alternative anaesthetic technique. Areas outside of endoscopy should consult formulary for selection of an alternative local anaesthetic product;
- ensure specialist clinicians are involved in the revision of clinical guidance to ensure risks associated with off-label use of alternative products and change in dosing are appropriately addressed;
- consider prescribing lidocaine 5% / phenylephrine 0.5% nasal spray for licensed indications and for off-label use, where appropriate, ensuring that phenylephrine is safe to use in the patient, and there is no intolerance to any of the excipient (see supporting information);
- consider use of Xylonor gel for use in the dental setting, if appropriate (see supporting information);
- consider prescribing unlicensed products only where licensed alternatives are not appropriate. Prescribers should work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see supporting information below); and
- agree a plan for communicating this supply issue to relevant teams within the organisation.



## Additional Information

	<b>Xylocaine® (lidocaine) 10mg spray</b>	<b>Lidocaine 5%/Phenylephrine* 0.5% spray</b>
<b>Presentation</b>	<p>50ml glass spray bottle (provides approx. 500 spray doses) with a metering spray pump.</p> <p>Package includes a single use plastic spray nozzle. Additional short spray nozzles are available separately in boxes of 50.</p> <p>Nozzles are for single patient, single use only.</p>	<p>Single use cutaneous solution for application to mucous membranes in nasal and pharyngeal areas.</p> <p>Pump spray dispenser supplied with product.</p> <p>Use once and discard any remaining topical solution at end of session. Each bottle of topical solution is to be used for one patient only.</p>
<b>Constituents</b>	Each depression of metered spray pump delivers 10 mg lidocaine base.	Each spray is equivalent to 6.5mg of lidocaine and 0.65mg phenylephrine.
<b>Licensed indications</b>	<p>Prevention of pain associated with following procedures:</p> <ul style="list-style-type: none"> <li>•<b>Otorhinolaryngology</b>: anaesthesia prior to minor non-invasive procedures in nasal cavity, pharynx and epipharynx including rhinoscopy and laryngoscopy.</li> <li>•<b>Obstetrics</b>: as supplementary pain control for procedures not requiring aseptic technique.</li> <li>•<b>Insertion of instruments and catheters into respiratory and digestive tract</b>: provides surface anaesthesia for oropharyngeal and tracheal areas to reduce reflex activity, attenuate haemodynamic response and to facilitate insertion of catheter or passage of instruments during endotracheal intubation, laryngoscopy, bronchoscopy, oesophagoscopy and gastroscopy.</li> <li>•<b>Dental practice</b>: before minor dental procedures where local anaesthesia is desired.</li> </ul>	<ul style="list-style-type: none"> <li>•Preparation of nasal mucosa for surgery or endoscopy</li> <li>•Aid in removal of foreign bodies from nose</li> <li>•Analgesia of pharynx prior to indirect or direct laryngoscopy</li> </ul>
<b>Paediatric use</b>	No age restrictions in SPC; children should be given doses commensurate with their age and weight.	Not recommended in children below 12 years of age
<b>Dose</b>	<p>No more than 20 spray applications should be used in any adult to produce desired anaesthetic effect.</p> <p>The number of sprays depends on the extent of the area to be anaesthetised.</p> <p><b>Dental practice</b>: 1– 5 applications to mucous membranes.</p>	<p>Adults, and Children over 12 years:</p> <p>Up to a maximum of 8 sprays in total.</p> <p>Prime pump dispenser by activating pump 3 times.</p>



	<p><b>Obstetrics:</b> Up to 20 applications</p> <p>Insertion of instruments and catheters into respiratory and digestive tract: Up to 20 applications for procedures in pharynx, larynx, and trachea.</p>	
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\*Refer to [SmPC](#) for cautions, contraindications, interactions relating to phenylephrine.

#### Lidocaine 5% / Phenylephrine 0.5% spray

In the otorhinolaryngology setting, this could be an alternative licensed treatment option. In the gastroenterology setting (off-label), specialists differ in their opinion on whether the presence of phenylephrine precludes use of this product in patients undergoing upper GI endoscopy. Whilst some may not be so concerned about this additional drug in the spray, another view is that though in laryngoscopy the vasoconstrictor effect is desirable, for upper GI endoscopy, phenylephrine is not indicated, and any potential side effects could increase risk of complications during the procedure.

#### Lidocaine 50mg/g / Cetrimide 1.5mg/g gel (Xylonor®)

This is intended for use by dentists and stomatologists only. It is licensed for use in adults, and in children aged 4-18 years for production of topical anaesthesia in buccal cavity, especially in following procedures: anaesthesia of mucous membrane before injection, lancing of abscesses, or scaling, surface anaesthesia for extraction of mobile, deciduous or permanent teeth, and prevention of gagging during impression taking.

#### Links to further information

- [SmPC – Lidocaine \(Xylocaine®\) spray](#)
- [SmPC – Lidocaine 5% / Phenylephrine 0.5% spray](#)
- [SmPC – Lidocaine 50mg/g / Cetrimide 1.5mg/g \(Xylonor®\) gel](#)

#### Guidance on ordering and prescribing unlicensed imports

The following specialist importers have confirmed they can source unlicensed lidocaine 10mg/dose spray sugar free (please note there may be other companies that can also source supplies):

- Mawdsleys

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Unlicensed imports do not undergo any central quality assessment or suitability evaluation. Therefore, any import must be locally assessed in line with local unlicensed medicines processes.

Please see the links below for further information:

- [The supply of unlicensed medicinal products](#), Medicines and Healthcare products Regulatory Agency (MHRA)
- [Professional Guidance for the Procurement and Supply of Specials](#), Royal Pharmaceutical Society
- [Prescribing unlicensed medicines](#), General Medical Council (GMC)



## Specialist Pharmacy Service (SPS) website

The UK Department of Health and Social Care (DHSC) in conjunction with SPS have launched an online Medicines Supply Tool, which provides up to date information about medicine supply issues. To access the online Medicines Supply Tool you need to register with the [SPS website](#). Registration for access to the website is available to UK healthcare professionals and organisations providing NHS healthcare. The tool is located under the Tools tab and then click on the Medicines Supply option.

We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool to stay up to date concerning medicines supply disruptions. Please be aware that while medicines supply issues will appear on the SPS website, some of the recommended actions may not always be appropriate / relevant within the Scottish context.

## Enquiries

Enquiries from Health Boards or healthcare professionals should be directed in the first instance to [PharmacyTeam@gov.scot](mailto:PharmacyTeam@gov.scot) (primary care) or [NSS.NHSSMedicineShortages@nhs.scot](mailto:NSS.NHSSMedicineShortages@nhs.scot) (secondary care).

