

This information was up to date at the time of release to the Heads of Midwifery.

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Updating arrangements for the formulary should be decided upon and implemented at a local level.

Xyloproct® Ointment	
Legal status (GSL, P or POM on exemption list, or PGD)	POM - midwife may supply as medicine is on midwives exemptions list
Patient group	Antenatal and postnatal women with haemorrhoids.
Clinical indication	Pain and inflammation associated with haemorrhoids – not first line.
Pharmacology (Onset and duration of action where appropriate)	<p>It contains a local anaesthetic which stabilises the neural membrane and preventing the initiation and conduction of nerve impulses and a corticosteroid which has anti-inflammatory and anti-pruritic action.</p> <p>The onset of action of lidocaine on mucous membranes is 3–5 minutes.</p>
Pharmaceutical form, strength, route of administration	<p>Ointment containing lidocaine 5% and hydrocortisone acetate 0.275% in a 20g tube.</p> <p>Other ingredients are: zinc oxide, aluminium acetate, stearyl alcohol, cetyl alcohol, water purified, and macrogol (3350 and 400).</p> <p>Topical administration or intra rectal using applicator.</p>
Dose, frequency and maximum number of doses or period of time for administration or supply	<p>Thoroughly cleanse and dry the affected area and apply morning and night, and after each evacuation.</p> <p>Maximum daily dose of 6 g which is approximately a third of the tube and maximum duration of treatment is three weeks.</p>
Contra-indications/exclusion criteria	<ul style="list-style-type: none"> ▪ known hypersensitivity to any component of the medicine and local anaesthetics of the amide type ▪ atrophic skin around the anus ▪ local untreated infections of bacterial, viral, pathogenic fungal or parasitic origin ▪ if on class III anti-arrhythmic drug (such as sotalol or amiodarone) ▪ acute porphyria
Cautions and action that will be taken if a caution applies	<ul style="list-style-type: none"> ▪ excessive dosage of lidocaine or short intervals between doses may result in high plasma levels of lidocaine and serious adverse effects ▪ when using the special applicator, care should be taken to avoid instillation of excessive amounts of Xyloproct® ointment into the rectum ▪ the possibility of malignancy should be excluded before use ▪ if irritation or rectal bleeding develops treatment should be discontinued ▪ check for and document any allergies ▪ check and document past medical and drug history and current medication to ascertain potential for overdose ▪ if a caution applies consult with a doctor ▪ document consultation in maternity record

Xyloproct® 5% / 0.275% Ointment

Medicine interactions and action that will be taken if a patient is taking a medicine that may interact	<ul style="list-style-type: none"> ▪ anti-arrhythmic drugs ▪ local anaesthetics or agents structurally related to local anaesthetics ▪ if there is a clinically significant drug interaction, consult with a doctor before administration or supply ▪ document consultation in maternity record ▪ refer to current BNF for latest information on interactions
Potential adverse reactions and side effects including actions to be taken if adverse medicine reaction is suspected	<ul style="list-style-type: none"> ▪ <i>contact sensitivity to lidocaine or hydrocortisone</i> ▪ <i>other allergic reactions (in the most severe instances anaphylactic shock)</i> ▪ <i>excessive use of hydrocortisone use may produce systemic corticosteroid effects or local effects such as skin atrophy</i> ▪ <i>on labour</i> Nil ▪ <i>on the neonate</i> Nil ▪ <i>on breast feeding</i> Nil ▪ <i>if a serious adverse reaction is suspected please report to the MHRA Yellow Card Scheme http://yellowcard.mhra.gov.uk/</i>
Overdose	<ul style="list-style-type: none"> ▪ systemic absorption of lidocaine may occur from the rectum, and large doses may result in CNS side effects ▪ on rare occasions convulsions have occurred in children ▪ immediate assessment/treatment is essential - refer to medical staff ▪ manage in accordance with established treatment guidelines or see BNF overdose section ▪ for further advice contact National Poisons Centre 0344 892 0111
Action if patient declines	<ul style="list-style-type: none"> ▪ refer to authorised prescriber or doctor ▪ document in maternity record
Additional advice and information	<ul style="list-style-type: none"> ▪ advise to contact midwife/GP if condition worsens or symptoms persist ▪ give the manufacturer's patient information leaflet to the woman ▪ patients should be instructed to strictly adhere to recommended dosage
Patient monitoring arrangements during and after treatment and follow-up required	<p>If no improvement refer to a doctor.</p>
Particular storage requirements	<p>Store between 2°C and 8°C. Can be stored up to 25°C for 2 months while in use. Discard remainder of tube after this period.</p>
References <ol style="list-style-type: none"> 1. Summary of Product Characteristics Xyloproct Oint ®. Text revision 1.2.2017. Accessed 23.12.2019. http://www.medicines.org.uk 2. http://www.bnf.org 	