



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



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NOTICE: RECOMMENDED THERAPEUTIC ALTERNATIVES FOR LORAZEPAM INJECTION

The Adult and Paediatric Hospital Level Standard Treatment Guidelines (STGs) and Essential Medicines List (EML) recommends the use of lorazepam 4mg/ml injection for various indications.

Lorazepam injection is currently not contracted under HP06-2024SVP, as no responsive bids were received. The product is marketed by a sole supplier in South Africa, which has indicated an indefinite stock out. The product is therefore not available for procurement through either the national contract or quotation process. The National Department of Health (NDoH) is currently assessing the impact of having no access to lorazepam injection in the long-term as an EML item, while also taking measures to optimise the availability of alternative therapies listed in the STGs and EML. During this period, alternative oral and injectable benzodiazepines are available for various indications as listed in the STGs and EML. Please refer to the relevant sections of the Adult and Paediatric Hospital Level STGs and EML for comprehensive guidance on the management of various indications for which alternatives to lorazepam injection are recommended.

The following indications are however specifically highlighted for your attention:

Adult Hospital Level STGs and EML

Indication: Hospital Level (ADULTS)	Therapeutic alternatives to lorazepam 4mg/ml injection
6.4.2 ECLAMPسيا	For agitated and restless women with eclampsia: • Lorazepam, IV/IM, 4 mg. ◦ May be repeated after 10-15 minutes. ◦ Maximum dose: 8 mg. OR • Clonazepam, IV, 2 mg. ◦ May be repeated after 5 minutes. ◦ Maximum dose: 4 mg. OR If above not available: • Diazepam, IV, 10–20 mg, not faster than 2 mg/minute.
14.5.1 EPILEPTIC SEIZURES AND STATUS EPILEPTICUS IN ADOLESCENTS (13 – 18 YEARS) AND ADULTS	EARLY STATUS EPILEPTICUS (5 – 10 minutes) LEVEL 1 INTERVENTION: (Benzodiazepines) MEDICINE TREATMENT If IV access: • Lorazepam, IV, 4 mg, administered not faster than 2 mg/minute. OR • Midazolam, IV, 10 mg. OR • Diazepam, IV, 10 mg administered over at least 5 minutes (not faster than 2mg/min). OR • Clonazepam, IV, 1 mg.

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	<u>If no IV access:</u> • Midazolam, 10 mg, IM or buccal, using the parenteral formulation, while continuing to establish IV access. <u>If no IV access and no midazolam is available:</u> • Clonazepam, IM, 1 mg. OR • Diazepam, rectal, 0.2 – 0.5 mg/kg as a single dose (maximum 20 mg/dose).
15.1 AGGRESSIVE DISRUPTIVE BEHAVIOUR IN ADULTS	MEDICINE TREATMENT The goal of rapid tranquillisation is to calm the patient so that risk to self or others is minimised and manage the underlying condition. CAUTION » Rapid tranquillisation may cause cardiovascular collapse, respiratory depression, acute dystonic reactions, and neuroleptic malignant syndrome. » Pregnant women, elderly, intellectually disabled, and those with comorbid medical conditions and/or substance use are at highest risk of serious adverse drug reactions. » Late pregnancy: neonatal sedation or extra-pyramidal side effects may occur. » Write out single prescriptions and review between each prescription. » Allow at least 30 – 60 minutes between prescriptions. » An emergency trolley, airway, bag, oxygen, and intravenous line must be available for use if needed. » Monitor vital signs closely during and after medicine administration. » Use the safest route of administration possible: The safest route of administration of benzodiazepines is oral followed by IM. IV route has the highest risk of respiratory depression and arrest. » Do not use depot antipsychotic injections (e.g., flupenthixol decanoate or zuclopenthixol decanoate injections) for rapid tranquillisation. Offer oral treatment: <u>If aggression is clearly caused by psychosis, or if pregnant, elderly/frail, or has significant risk for respiratory depression:</u> • Olanzapine, orodispersible tablet or IM, immediately: - o Aggression clearly due to psychosis or if pregnant: 5–10 mg. - o Elderly/frail, respiratory depression risk / medically unwell: 2.5–5 mg. - o Repeat after 30–60 minutes if needed. <u>If cause of aggression unclear, non-pregnant, non-elderly/frail, and without significant risk for respiratory depression:</u> • Benzodiazepines, e.g.: • Lorazepam, oral, 0.5–2 mg immediately. OR • Clonazepam, oral, 0.5–2 mg immediately. OR • Diazepam, oral, 5–10 mg immediately. OR • Midazolam, oral or buccal, 7.5–15 mg immediately. <u>If there is an inadequate response to oral benzodiazepine (after 30–60 minutes), or where oral treatment is refused:</u> • Olanzapine, orodispersible tablet/IM, 5–10 mg immediately. - o Repeat after 30–60 minutes if needed. Note: Repeated doses may result in excessive sedation <u>If there is an inadequate response to oral benzodiazepine with a history of intolerance to olanzapine (e.g. previous neuroleptic malignant syndrome):</u> • Lorazepam, IM, 0.5–2 mg immediately. OR • Midazolam, IM, 7.5–15 mg immediately. OR • Clonazepam, IM, 0.5–2 mg immediately. Note: » To avoid inappropriate repeat dosing, allow at least 30 minutes for the oral/IM medication to take effect. » Repeated IM doses of benzodiazepines may result in toxicity owing to accumulation. » Lorazepam IM has slower onset of sedation than midazolam IM (32 vs 18 minutes) and longer duration of sedation (217 vs 82 minutes). » Clonazepam oral or IM may be used if longer duration of sedation is required. Onset of action may be 30-60 minutes, with predicted maximum effect after 1-4 hours. There is an increased risk of accumulation due to its long half-life (18-50 hours). Allow at least 12 hours between repeat doses. <u>To continue tranquillisation under specialist supervision in psychiatric wards:</u> • Zuclopenthixol acetate, IM, 50–150 mg every 2–3 days (specialist/specialist consultation). - o Start with 50mg in neuroleptic-naïve patients. - o Maximum dose: 400 mg over a two-week period.

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15.8.1.1 ALCOHOL WITHDRAWAL DELIRIUM (DELIRIUM TREMENS)	<u>If alcohol use is suspected:</u> ADD - Thiamine, oral, 300 mg immediately and daily for 14 days. MEDICINE TREATMENT Administer medicine doses according to severity of symptoms. These patients may require high doses of benzodiazepines because of hepatic enzyme induction. • Benzodiazepines, e.g.: Diazepam, slow IV (max rate <5 mg/minute), 10 mg (Not IM). - Repeat dose after 5–10 minutes if required. - If this dose is not sufficient, use 10 mg every 5–10 minutes for another 1–3 doses to a maximum of 50mg. Where intravenous access is not possible: Clonazepam, IM, 2 mg as a single dose. - If no response, repeat dose after 60 minutes until patient is sedated. - Repeat dose regularly to maintain mild sedation. OR - Lorazepam, IM, 1–4 mg every 30–60 minutes until patient is sedated. - Repeat dose regularly to maintain mild sedation. <u>Once patient is sedated, i.e. light somnolence, maintain mild sedation with:</u> Diazepam, oral, 5–20 mg. - Repeat dose regularly to maintain mild sedation. CAUTION Benzodiazepines, especially diazepam IV, can cause respiratory depression. Monitor patients closely as benzodiazepines can exacerbate an abnormal mental state or mask important neurological signs of deterioration. Note: » Lorazepam IM has slower onset of sedation than midazolam IM (32 vs 18 minutes) and longer duration of sedation (217 vs 82 minutes). » Clonazepam oral or IM may be used if longer duration of sedation is required. Onset of action may be 30-60 minutes, time to maximum concentration is 1-4 hours. Long half-life (18-50 hours) increases risk of accumulation. Allow at least 12 hours between repeat doses. <u>When administering glucose-containing fluids:</u> - Thiamine, oral/IM, 300 mg daily. Note: » Neuroleptic medicines such as haloperidol are associated with a reduced seizure threshold and QTc prolongation. » It is preferable to increase the dose of benzodiazepines than to add haloperidol. However, <u>oral haloperidol may assist with managing hallucinations and agitation:</u> - Haloperidol, oral, 0.75–2.5 mg 12 hourly. - Maximum dose: 5mg per 24 hours. Do NOT use olanzapine, IM in the management of alcohol withdrawal. Olanzapine, IM may increase risk of respiratory depression if combined with parenteral benzodiazepines particularly if alcohol has been consumed.
19.10 ISONIAZID POISONING	MEDICINE TREATMENT <u>For seizures:</u> - Pyridoxine, crushed tablets orally or via NGT in unconscious patient(s). - Known amount: Pyridoxine dose is 1 g for every gram of isoniazid ingested (maximum of 5 g) - Unknown amount: Pyridoxine dose is 5 g for unknown amount ingested. <u>Benzodiazepines may be used as an interim measure to control seizures:</u> - Lorazepam, IV/IM, 4 mg, repeat once after 5–10 minutes, if necessary. OR Diazepam, IV, 10 mg, not faster than 2 mg/minute, repeat once after 5-10 minutes if necessary. OR Clonazepam, IV, 2 mg, repeat once after 5–10 minutes if necessary. OR Midazolam, IM/IV 10 mg, repeat once after 5–10 minutes if necessary. OR Midazolam buccal, 10 mg using the parenteral formulation. CAUTION Phenytoin should not be used to control seizures in INH poisoning, as it does not have GABA agonist properties. REFERRAL » Uncontrolled seizures.

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Paediatric Hospital Level STGs and EML

Indication: Hospital Level (PAEDIATRICS)	Therapeutic alternatives to lorazepam 4mg/ml injection
13.2.1 EPILEPTIC SEIZURES AND STATUS EPILEPTICUS IN CHILDREN < 13 YEARS OF AGE	MEDICINE TREATMENT (EARLY STATUS EPILEPTICUS 5-10 minutes after seizure onset) LEVEL 1 INTERVENTION: (benzodiazepines, up to 2 doses) <u>If vascular access is available:</u> • Lorazepam, IV or IO, 0.1 mg/kg over 60 seconds (max 4 mg/dose). OR • Midazolam, IV or IO, 0.25 mg/kg over 60 seconds, (max 10 mg/dose). OR • Diazepam, IV or IO, 0.25 mg/kg IV over 60 seconds (max 10 mg/dose). <u>If vascular access is not available:</u> • Lorazepam, IM or buccal, 0.1 mg/kg (max 4 mg/dose). OR • Midazolam, IM, 0.1 mg/kg, or buccal*, 0.5 mg/kg. OR • Diazepam, rectal**, 0.5 mg/kg (max 10 mg/dose). Expect a response within 1–5 minutes. If the seizure does not resolve within 5 minutes after first dose, give a repeat dose of benzodiazepine. CAUTION Benzodiazepines can cause respiratory depression. Monitor oxygen saturation and respiratory rate. If respiratory depression occurs, assist ventilation with bag-valve mask (1 breath every 3–5 seconds) and refer urgently/transfer to a high care setting. Note: * Midazolam, buccal, 0.5 mg/kg/dose. See Primary Health Care STGs and EML, Appendix IV: Standard paediatric dosing tables. o Use midazolam for injection 5 mg in 1 mL undiluted. o Draw up the required volume in a 5 mL syringe. o Remove needle then administer midazolam into the buccal cavity (between gum and cheeks). o Note: Buccal midazolam should not be used in infants < 6 months of age. **Diazepam, rectal, 0.5 mg/kg/dose as a single dose. See Primary Health Care STGs and EML, Appendix IV: Standard paediatric dosing tables. o Use diazepam for injection 10 mg in 2 mL undiluted. o Draw up the required volume in a 2 mL syringe. o Remove needle then connect syringe to an NGT and gently insert into the rectum (or insert the whole barrel of the lubricated syringe if no NGT available) and inject the contents. o Remove NGT / syringe and hold buttocks together to minimise leakage.
14.1 SEDATION OF AN ACUTELY DISTURBED CHILD OR ADOLESCENT	For children under the age of six years: Sedation with psychotropic agents should only be considered in extreme cases and only after consultation with a specialist. For children over the age of six years: • Lorazepam, oral - o 0.05–0.1 mg/kg/dose. - o Onset of action: 20–40 minutes. - o Always consider the use of oral lorazepam first. If not appropriate consult with a specialist.
14.13.3.2 ALCOHOL WITHDRAWAL DELIRIUM	MEDICATION TREATMENT Adult management can be applied to adolescents (for young children, management and dosing to be determined in conjunction with a specialist): • Thiamine, IV. - o Thiamine must be given prior to glucose to prevent Wernicke-Korsakoff syndrome. - o 500 mg 8 hourly, diluted in 100 ml normal saline infused over 30 minutes for 3 days. - o Followed by 250 mg 8 hourly. • Thiamine, oral. - o 100 mg daily once stable. Benzodiazepines: • Diazepam, slow IV, 10 mg (not IM due to erratic absorption). - o Repeat dose after 5–10 minutes if required. - o If this dose is not sufficient, use 10 mg every 5–10 minutes for another 1–2 doses. - o If patient is not yet sedated, continue with doses of 20 mg. - o Usual initial dose is 10–20 mg, but up to 60 mg is occasionally required. Where intravenous access is not possible:

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	• Clonazepam, IM, 1–2 mg as a single dose. ○ If no response, repeat dose after 60 minutes. ○ Maximum daily dose: 10 mg. OR • Lorazepam, IM, 1–4 mg every 30–60 minutes until the patient is sedated. ○ Repeat doses hourly to maintain mild sedation. ○ Maximum daily dose: 6 mg. Once patient is sedated, i.e. light somnolence, maintain mild sedation with: » Diazepam, oral, 5–20 mg 2–6 hourly. Severe agitation and restlessness: • Haloperidol, IV/IM, 0.5–5 mg. ○ Repeat after 4–8 hours as required to a maximum of 10 mg daily. ○ Once patient has responded and is able to take oral medication: Haloperidol, oral, 0.75–5 mg 6–8 hourly. Note: » Haloperidol may reduce the seizure threshold. Consider only for severe agitation and restlessness and give in combination with one of the sedative-hypnotic agents above.			
23.2 ANALGOSEDATION	During continuous mechanical ventilation			
		IV Bolus Dose	IV Infusion Dose	Comments
	Sedative			
	Midazolam	0.05–0.2 mg/kg	50–200 mcg/kg/hour	Significant vasodilator. Needs dose adjustment for renal failure.
	Lorazepam	0.05–0.1 mg/kg	0.05–0.15 mg/kg/hour	Maximum daily dose 2 mg/kg or 100 mg. Useful for anticipated longer term sedation, t½ 10–20 hours.
	Propofol	0.5–1 mg/kg	1.5–4 mg/kg/hour	For maximum of 48 hours continuously, significant vasodilator.
	Ketamine	1–2 mg/kg	5–40 mcg/kg/min	Currently recommended as an adjunctive sedative.

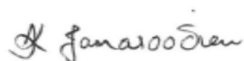
Procurement of Clonazepam, Diazepam and Midazolam Injections

NSN	Product	Supplier	Contract
180076401	Midazolam; 5mg/5ml; Injection; 5ml	Accord Healthcare (Pty) Ltd Adcock Ingram Critical Care (Pty) Ltd	HP06-2021SVP
180076404	Midazolam; 15mg/3ml; Injection; 3ml	Adcock Ingram Critical Care (Pty) Ltd Pharma-Q (Pty) Ltd	HP06-2021SVP
180075798	Diazepam; 10mg/2ml; Injection; 2ml	Pharma-Q (Pty) Ltd	HP06-2021SVP
222001090	Diazepam; 5mg; Tablet; 14 Tablet	Innovata Pharmaceuticals (Pty) Ltd	HP09-2023SD
180075726	Clonazepam; 1mg/ml; injection; 1 ml	Pharmaco Distribution (Pty) Ltd	HP06-2024SVP/01

Circular Implementation and Dissemination

Provinces and Healthcare facilities are requested to distribute and communicate this information in consultation with the Pharmaceutical and Therapeutics Committees and all other relevant stakeholders.

Kind regards



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