

**Prescribing Protocol SESLHDPR/652
Safe Use of Buprenorphine subcutaneous
depot injection (Buvidal®) for opioid dependence**



Depot Buprenorphine (Buvidal®) IS A HIGH RISK MEDICINE

USE WITH CAUTION AND ENSURE THE DIRECTIONS WITHIN THIS PROTOCOL ARE FOLLOWED CAREFULLY

Areas where Protocol/Guideline applicable	District
Areas where Protocol/Guideline not applicable	Paediatrics
Authorised Prescribers	<p>The current 'Opioid dependent persons admitted to hospital in NSW – management' policy directive allows medical practitioners to prescribe a drug of addiction (including depot buprenorphine), for up to 14 days, to a person who is inpatient, without the need to obtain authority.</p> <p>If a patient on Buvidal® is admitted to hospital, it is strongly recommended to contact the Drug & Alcohol Services and/or their community prescriber regarding ongoing treatment options.</p>
Indication for use	Treatment of opioid dependence
Important Safety Considerations	<p>The product must not be handled by patients.</p> <p>Buvidal® must only be administered subcutaneously. Do not administer intravenously or intramuscularly.</p> <p>The administered dose should be in a single injection and not divided. Pre-filled syringes are for <u>single use in one patient only</u>.</p> <p>Buvidal® is administered weekly or monthly and may not need to be administered during a brief inpatient hospital admission. However, it is important that its use is accurately documented and handed over at transfers of care to ensure that it is considered in the overall management of the patient.</p> <p>If a patient on Buvidal® is admitted into hospital, Drug & Alcohol Services and/or their community prescriber should be contacted in regards to ongoing treatment and overall management.</p>
Contraindications	<ul style="list-style-type: none"> • Hypersensitivity to buprenorphine or any of the product excipients listed in the TGA Product Information • Children <16 years • Severe respiratory insufficiency • Severe hepatic insufficiency (Child-Pugh C) • Opioid naïve patients
Precautions	<ul style="list-style-type: none"> • Patients with head injury, intracranial lesions or history of seizures – opioids may elevate cerebrospinal fluid, which may cause seizures • Hypotension, prostatic hypertrophy or urethral stenosis • Myxoedema, hypothyroidism or adrenal cortical insufficiency • Patients with biliary tract dysfunction • Severe renal impairment • Hepatitis and hepatic impairment • Patients above 65 years old • Patients 16-18 years of age • Pregnancy or lactation

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<p>Important Drug Interactions</p>	<p>No specific interaction studies have been performed with Buvidal® Use buprenorphine cautiously when co-administered with:</p> <ul style="list-style-type: none"> • Benzodiazepines • Gabapentinoids • Alcohol • Other central nervous system depressants • Opioid analgesics • Naltrexone • CYP3A4 inhibitors or inducers • Monoamine oxidase inhibitors
<p>Dosage</p>	<p>Doses to be titrated as clinically indicated:</p> <ul style="list-style-type: none"> • Weekly doses of 8mg, 16mg, 24mg or 32mg • Monthly doses of 64mg, 96mg, 128mg or 160mg <p>Refer to Clinical guidelines for use of depot buprenorphine (Buvidal® and Sublocade®) in the treatment of opioid dependence(2019) for further guidance.</p>
<p>Duration of therapy</p>	<p>Individualised</p>
<p>Patient education</p>	<p>Consumers should be educated regarding the risks of polysubstance use (including use of prescribed sedating medication) and cautioned regarding driving or operating machinery under such conditions.</p> <p>The provision of take home naloxone should be considered.</p> <p>Patients should be advised to report their use of depot buprenorphine to other healthcare practitioners providing care, where appropriate</p>
<p>Prescribing Requirements</p>	<p>Schedule 8 medication handling requirements apply according to PD2013_014 Medication Handling in NSW Public Health Facilities</p> <p>Drug & Alcohol services should be consulted if unsure.</p>
<p>Administration instructions</p>	<p>Doses must be administered by trained nurses or doctors.</p> <p>Buvidal® is given by subcutaneous injection only. Injection sites should be rotated and alternated between the buttock, thigh, abdomen, or upper arm.</p> <p>The product must not be handled by patients.</p> <p>The administered dose should be in a single injection and not divided. Pre-filled syringes are for <u>single use in one patient only</u>.</p> <p>Inspect visually for particulate matter and discolouration prior to administration, whenever solution and container permit. Do not use Buvidal® prefilled syringes exhibiting particulate matter or discolouration.</p> <p>Follow schedule 8 medications handling procedures according to PD2013_014 Medication Handling in NSW Public Health Facilities</p> <p>For further details refer to TGA product information.</p>
<p>Storage requirements</p>	<p>Schedule 8 handling requirements apply according to PD2013_014 Medication Handling in NSW Public Health Facilities</p> <p>Buvidal® should not be made available directly to patients.</p>
<p>Monitoring requirements</p>	<p>Regular review and monitoring as per NSW Clinical Guidelines: Treatment of Opioid Dependence (2018), including:</p> <ul style="list-style-type: none"> - Opioid dependence treatment outcomes, including client's substance use, health, social conditions, engagement with treatment and related risks (e.g. BBV, overdose, child protection, DV)

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	<ul style="list-style-type: none"> - Subjective and objective adverse drug reactions - Patient experience of treatment
Management of complications	Individualised, based on TGA product information and NSW Clinical Guidelines: Treatment of Opioid Dependence (2018) and Clinical guidelines for use of depot buprenorphine (Buvidal® and Sublocade®) in the treatment of opioid dependence (2019)
Basis of Protocol/Guideline (including sources of evidence, references)	<p>NSW Ministry of Health (2018). <i>NSW Clinical Guidelines: Treatment of Opioid Dependence – 2018</i>. NSW Ministry of Health, Sydney Australia. https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2018_019.pdf</p> <p>NSW Ministry of Health (2019). <i>Clinical guidelines for use of depot buprenorphine (Buvidal® and Sublocade®) in the treatment of opioid dependence</i>. NSW Ministry of Health, Sydney Australia. https://www.health.nsw.gov.au/aod/Publications/full-depot-bupe-interim-gl.pdf</p>
Groups consulted in development of this protocol	Prof Nicholas Lintzeris SESLHD Drug and Alcohol Services Pharmacists

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GOVERNANCE	
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Chairperson, QUM Committee	Ms Amy Murray
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