

Information for pharmacists and prescribers

A new option for patients on Opioid Maintenance Treatment (OMT)

From June 2019, new depot formulations of buprenorphine are available in Australia for treatment of opioid dependence. Two new brands are registered for use in Australia; Buvidal[®] and Sublocade[®]. Buvidal[®] is now available on the Pharmaceutical Benefits Scheme (PBS) for some specialist prescribers.

There are important safety and funding restrictions that prescribers and pharmacists need to be aware of before supplying this product.

Key information

- 2 products approved by the Therapeutic Goods Administration (TGA) - Buvidal[®] and Sublocade[®].
- May be injected weekly or monthly subcutaneously depending on product and strength.
- Current TGA restrictions require that only prescribers in hospital and specialist drug rehabilitation clinics who have reviewed education materials may prescribe depot buprenorphine.
- These prescriber restrictions will be reviewed by the TGA in 2020.
- Buvidal[®] is available on the PBS from September 2019, for treatment of opiate dependence within a framework of medical, social and psychological support. The TGA restrictions also apply to PBS eligibility.
- The product sponsors may provide the products to approved clinics free of charge during initial Patient Familiarisation Programs.
- ACT Chief Health Officer (CHO) Approval by Drug is required to prescribe. Category 3A or 3B approvals do not authorise prescribing of buprenorphine depot preparations.
- **Depot preparations must NEVER be dispensed by a pharmacist directly to a patient, carer or patient's agent.**
- **Supply of these products MUST be directly from the dispensing point to the clinic administering the injections.**
- Incorrect or intravenous injection presents significant risk of serious harm or death as the depot forms a gel depot upon contact with body fluids. Occlusion, local tissue damage and thromboembolic events, including life threatening pulmonary emboli, may occur if administered intravenously.

November 2019

Pharmacists: what to do if you receive a script for Buvidal® or Sublocade®

Do not dispense the prescription unless your pharmacy has entered into an arrangement with the dosing point to supply the product directly to the clinic.

Depot preparations must NEVER be dispensed by a pharmacist directly to a patient, carer or patient's agent.

Supply of these products MUST be directly from the dispensing point to the clinic administering the injections.

Why is this important? Unlike daily dose methadone or buprenorphine, depot preparations should never be supplied directly to a patient or their carer as there is a risk of serious harm or death if administered intravenously.

Prescribers: what to do if you want to prescribe Buvidal® or Sublocade® for your patient

ACT Health will only approve requests from prescribers for CHO approval for buprenorphine depot products where they are from a hospital or specialist drug rehabilitation clinic.

If you are unsure about whether your practice is considered a specialist clinic, or you wish to find out where to refer your patients, please contact the Health Protection Service on 02 5124 9208 or hps@act.gov.au.

Product comparisons

	Buvidal	Sublocade
Sponsor	Camerus	Indivior
PBS approved	Yes- S100	Pending as of Nov 2019
Products	Weekly injections 8mg, 16mg, 24mg, 32mg Monthly injections 64mg, 96mg, 128mg	Monthly injections 300mg loading for 2 months 100mg monthly maintenance
Induction	Stabilisation on sublingual buprenorphine products for at least 7 days. Start with weekly injections before moving to monthly if preferred and appropriate. Dosage depends on previous levels of opioid use.	Current information suggests stabilisation on sublingual products will be required. Commence with 300mg injection monthly for 2 months, then 100mg monthly
Withdrawal management	8mg injection	Sublingual products
Dosing flexibility	Weekly injections can be given up to 2 days either side of the scheduled due date Monthly injections can be given up to a week either side of the scheduled due date	Monthly injections can be given up to a week either side of the scheduled due date
Storage	Room temperature, usual controlled medicines safe	Refrigerated secure storage, can be at room temperature for up to 7 days prior to administration

Accessibility

If you have difficulty reading a standard printed document and would like an alternative format, please phone 13 22 81.



If English is not your first language and you need the Translating and Interpreting Service (TIS), please call 13 14 50.

For further accessibility information, visit: www.health.act.gov.au/accessibility

www.health.act.gov.au | Phone: 132281 | Publication No XXXXX

Australian Capital Territory, Canberra Month Year