



Community Drug and Alcohol Team Standards and Guidance for the induction of Buprenorphine (Buvidal) prolonged release solution for injection prescribing

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Considerations for Opioid Substitution Treatment in Community settings

Introduction

Buprenorphine prolonged-release injection (Buvidal, Camurus) is an opioid partial agonist/antagonist. It is administered as a weekly or monthly subcutaneous injection and must be given by a Community Drug and Alcohol Team (CDAT) Prescriber or suitably trained nurse. It has a marketing authorisation for treating opioid dependence in adults within a framework of medical, social and psychological treatment.

Buvidal is a prolonged-release solution for injection and is prepared within a pre-filled syringe. Buvidal may be an option for people who have difficulties adhering to daily supervised opioid substitution medication, such as for people who are working or in education.

Buprenorphine prolonged-release injection may have a place in treating opioid dependence in where the risk of diversion and time needed for supervised consumption currently leads to challenges in supplying supervised medicines safely.

Licensing Status

Buvidal is licensed for use in the treatment of opiate dependency

Formulary Status:

** Specialist (substance Misuse) consultant initiated – Hospital only **

Criteria for Prescribing

At present Buvidal should be considered as a treatment option for service users where there has been an established period of stabilisation on Opioid Substitution Treatment.

Prior to prescribing Buvidal – the consultant should ensure the following:

- A Specialist Drug Assessment has been completed
- Evidence of Opiate Dependence Syndrome
- The service user has been provided with comprehensive information concerning the potential benefits and risks of Buvidal treatment
- That informed consent of the service user has been gained and written recorded acceptance to engage in this treatment with full knowledge of the risks involved
- Baseline liver function tests are recommended prior to commencing treatment

Induction

- To avoid precipitating symptoms of withdrawal, treatment with Buvidal should be started when objective and clear signs of mild to moderate withdrawal are evident. Consideration should be given to the types of opioid used (that is long- or short-acting opioid), time since last opioid use and the degree of opioid dependence.
- For patients using heroin or short-acting opioids, the initial dose of Buvidal must not be administered until at least 6 hours after the patient last used opioids.
- For patients receiving methadone, the methadone dose should be reduced to a maximum of 30 mg/day before starting treatment with Buvidal which should not be administered until at least 24 hours after the patient last received a methadone dose. Buvidal may trigger withdrawal symptoms in methadone-dependent patients.



Transferring from sublingual Buprenorphine products to Buvidal

Patients treated with sublingual Buprenorphine may be switched directly to weekly or monthly Buvidal, starting on the day after the last daily Buprenorphine sublingual treatment dose in accordance with the dosing recommendations in Table 1. Closer monitoring of patients is recommended during the dosing period after the switch.

Table 1: Conventional sublingual Buprenorphine daily treatment doses and recommended corresponding doses of weekly and monthly Buvidal

Dose of daily sublingual Buprenorphine	Dose of weekly Buvidal	Dose of monthly Buvidal
2-6 mg	8 mg	
8-10 mg	16mgs	64mgs
12-16 mg	24mgs	96mgs
18-24 mg	32mgs	128mgs

Treatment and dose adjustments

Buprenorphine prolonged-release injection is recommended up to a weekly maximum dose of 32 mg or monthly maximum dose of 128 mg, which is approximately equivalent to 18 mg to 24 mg daily of sublingual Buprenorphine. Therefore it may not be suitable for people with opioid substitution requirements greater than this.

A maximum of 1 additional 8-mg dose can be given between regular weekly or monthly injections if needed, based on an individual person's temporary needs.

Buvidal can be administered weekly or monthly.

Doses may be increased or decreased and patients can be switched between weekly and monthly products according to individual patient's needs and treating physician's clinical judgment as per recommendations in Table 2. Following transfer, service users may need closer monitoring.

Table 2: Recommended dose conversion when switching from weekly to monthly dosing or from monthly to weekly dosing

Weekly dose of Buvidal	Monthly dose of Buvidal
16mgs	64mgs
24mgs	96mgs
32mgs	128mgs

Supplemental dosing

- A maximum of one supplemental Buvidal 8 mg dose may be administered at an unscheduled visit between regular weekly and monthly doses, based on individual service users temporary needs.
- The maximum dose per week for service users who are on weekly Buvidal treatment is 32 mg with an additional 8 mg dose.



- The maximum dose per month for patients who are on monthly Buvidal treatment is 128 mg with an additional 8 mg dose.

Missed doses

To avoid missed doses:

- The weekly dose may be administered up to 2 days before or after the weekly time point,
- The monthly dose may be administered up to 1 week before or after the monthly time point.

If a dose is missed, the next dose should be administered as soon as practically possible.

Termination of prescribing

If Buvidal treatment is discontinued, its prolonged-release characteristics and any withdrawal symptoms experienced by the patient must be considered. If the service user is transferred to treatment with sublingual Buprenorphine, this should be done one week after the last weekly dose or one month after the last monthly dose of Buvidal according to the recommendations in Table 1.

Contraindications

Severe respiratory insufficiency

Severe hepatic impairment

Acute alcoholism or delirium tremens

Cautions

See British National Formulary (BNF) & www.medicines.org.uk/emc/ for any side effects precautionary notes including contraindications anti-biotic or anti-depressants).

Allergies and Sensitivities: Allergy status or sensitivities must be recorded clearly on the community prescription charts, ideally by the prescriber when first writing up the chart. The medical team is responsible for completing the allergy status box as soon as possible, but another health care clinical involved in the medicines management process may ascertain the status and sign instead of the prescriber.

Supply of Buvidal

Buvidal may be supplied from hospital pharmacies in one of 2 ways:

1. Supply via Prescriptions for Buvidal

Buvidal is to be initially prescribed by specialist CDAT consultants.

Other prescribers within CDAT (other doctors, independent prescribers) may provide ongoing prescriptions.

It dispensed on a named patient basis on a controlled drug outpatient prescription and a community administration chart. Ensure every outpatient prescription adheres to Controlled Drug prescription legal requirements.

For the Pharmacy to be able to dispense, both the community prescription and Buvidal Prescription an administration chart must be presented.

Function of the community medication prescription charts



- To provide a permanent record of the patients Buvidal administration
- To indicate the patients allergies & sensitivities
- To direct and record the administration of Buvidal to the patient
- To enable the pharmacy to dispense Buvidal

The Doctor/ Independent prescriber must ensure that the prescription must be:

- Clearly written in BLOCK CAPITALS, and indelibly written in black ink.
- Clearly identifies the patient for whom the medication is intended. The prescription must state the patients name, address and date of birth, NHS number in the prescribers own handwriting.
- Clearly states the drug (approved name), dose, and frequency, route of administration and date of prescribing.

Patients should be given a Buvidal patient information leaflet.

Alterations: Any change in medication must be written as a new entry

2. Supply via Controlled Drug Requisitions for Buvidal

Buvidal may alternatively be ordered and supplied via a Controlled Drug (CD) requisition book as a 'stock' CD.

This is possible if the CDAT premises have a CD cupboard with sufficient capacity and they run buprenorphine community titration / Buvidal clinics on site.

Each patient must have a current prescription on a Buvidal Prescription an administration chart, which must be presented to the pharmacy with the CD requisition book.

Dispensing Buvidal from a Hospital Pharmacy

Substance Misuse Nurse (NMC Registered) staff should contact pharmacy in advance (at least 24 hours), this is to ensure Pharmacy have ample time to ensure the medication is in stock.

As Buvidal is a CD, staff must ensure they have proof of identification when collecting it from the pharmacy.

For outpatient prescriptions, the Substance Misuse Nurse (NMC Registered) should take the community prescription **and** administration chart to the pharmacy department on the day the prescription is due and wait for the medication to be dispensed.

If the Substance Misuse service have a CD cupboard, the medication can be dispensed in advance of the intended date of administration.

If the Substance Misuse service do not have a CD cupboard, the medication **must** be dispensed on the day of administration.

Storage of Buvidal

Buvidal is a Schedule 3 Controlled Drug, therefore must be stored in a CD cupboard. Please refer to CID398 Policy for the Management of Controlled Drugs for further information.



If there is no CD cupboard available within the substance misuse unit, Buvidal must be administered to the patient immediately.

Method of administration

Buvidal is intended for subcutaneous administration only.

It should be injected slowly and completely into the subcutaneous tissue of different areas (buttock, thigh, abdomen, or upper arm), provided there is enough subcutaneous tissue.

Each area can have multiple injection sites. Injection sites should be rotated for both weekly and monthly injections.

A minimum of 8 weeks should be left before re-injecting a previously used injection site with the weekly dose.

There is no clinical data supporting reinjection of the monthly dose into the same site. This is unlikely to be a safety concern. The decision to reinject at the same site should also be guided by the attending CDAT Prescriber / Substance Misuse Nurse (NMC Registered) clinical judgment.

Administered dose should be as a single injection and not divided. The dose must not be administered intravascularly (intravenously), intramuscularly or intradermally (into the skin).

Administration

- Care must be taken to avoid inadvertent injection of Buvidal. The dose must not be administered intravascularly (intravenously), intramuscularly or intradermally.
- Intravascular such as intravenous injection would present a risk of serious harm as Buvidal forms a solid mass upon contact with body fluids, which potentially could cause blood vessel injury, occlusion, or thromboembolic events.
- To minimise the risk of misuse, abuse and diversion, appropriate precautions should be taken when prescribing and dispensing Buprenorphine. Healthcare professionals should administer Buvidal directly to the patient. Take-home use or self-administration of the product by patients is not allowed. Any attempts to remove the depot should be monitored throughout treatment.

Disposal of used Buvidal

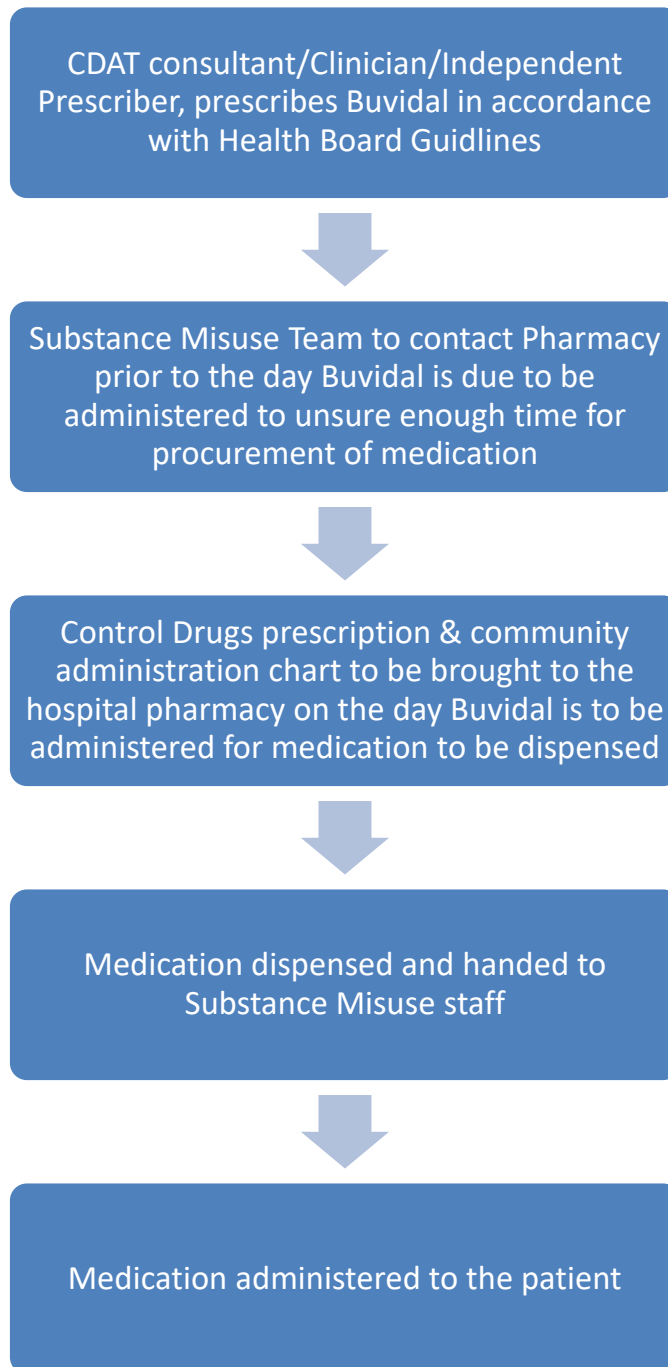
As Buvidal is a pre-filled syringe, the used syringe can be placed in a sharps bin for disposal

Pharmacy Department Contact Details

Cefn Coed Hospital
Tel No: 01792 516528

Neath and Port Talbot Hospital
Tel No: 01639 862169

Appendix 1 – Buvidal Procedure Flow Chart





Swansea Bay University Health Board

Authorisation Form for Publication onto COIN

PLEASE ENSURE THAT ALL QUESTIONS ARE ANSWERED – IF NOT APPLICABLE PLEASE PUT N/A

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