



# Buvidal Management at Homeless Health Centre SOP

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# Buvidal Management at HHS - SOP

## Introduction

Buvidal is an injectable solution of Buprenorphine used within a psychosocial framework for the treatment of opioid addiction.

Buvidal can be offered as a weekly or monthly injection allowing for less impact on the patient's activities of daily life.

## Objectives

To provide all practitioners working within the Homeless Health Service (HHS) with guidance on the prescribing, administration, storage, and disposal of Buvidal®.

Maximise safety to patient, increase efficacy, reduce professional risk, maximise time and cost efficiency for practice and partners.

## The Standard Operating Procedure

### Referrals

Referrals are accepted as self-referrals and from other Health & social care professionals both from internal and external agencies. Whilst anyone can make a referral, the decision to accept the referral lies with the Buvidal® Clinical Nurse Specialist and Opioid Substitution Treatment (OST) lead. Complex cases may be discussed by the HHS as a team, with additional input from external experts e.g., Addiction's consultant, Consultant psychiatrist, Buvidal® Clinical Nurse specialist (CNS).

Should more patient referrals be accepted than the 20 places available, following a discussion with Buvidal® Lead, they can be added to the waiting list if a space becomes available. As a standard, this will be on a first come first served basis, however exceptions can be made for patients presenting with a severe risk to health or for patients transferring from another locality who are already on treatment.

<Y:\Buvidal resource folder\Buvidal Waiting list- Confidential\Buvidal waiting list.docx>

### Assessment

Patient assessment must be undertaken by the Buvidal® Specialist Nurse or other qualified and trained practitioners and takes the form of a pre-consultation. The timing of the assessment is less important than the opportunity to discuss treatment aims & requirements, potential intended and non-intended side effects, expectations from patient and practitioner. This can be done up to the day before induction.

The patient is required to sign a consent form which can be found here:

<Y:\Buvidal resource folder\Buvidal academic papers & consents\Buvidal pre-initiation consent.rtf>

### Contraindications

Hypersensitivity to the active substance or to any of the excipients.

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## Special precautions during treatment

Hepatic impairment - Baseline liver function tests and documentation of viral hepatitis status are recommended prior to starting therapy. Patients who are positive for viral hepatitis, on certain concomitant medicinal products and/or who have existing liver dysfunction are at greater risk of liver injury. Regular monitoring of the liver function is recommended.

Severe respiratory insufficiency

Lack of capacity to consent to treatment

Delirium tremens

Concomitant administration of Buvidal® and other serotonergic agents may cause serotonin syndrome, a potentially life-threatening condition. If concomitant treatment with other serotonergic agents is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases.

Symptoms of serotonin syndrome may include mental-status changes, autonomic instability, neuromuscular abnormalities, and/or gastrointestinal symptoms. If serotonin syndrome is suspected, a dose reduction or discontinuation of therapy should be considered depending on the severity of the symptoms.

## Prescription

Following assessment by the Buvidal® lead or competent deputy, a green FP10 prescription should be generated by the practitioner. New patients for initiation should be discussed with the prescriber including potential safety concerns. (Dr Taylor reserves the right to do an electronic EPS script when necessary due to time constraints (not having time or staff to run down to Stokes Croft Pharmacy with the green paper FP10).

Prescriptions should be signed by named HHS GPs. Locums and new GPs should not sign Buvidal® prescriptions except in exceptional circumstances and following a thorough discussion of the clinical guidance and the SOP with the Specialist Nurse/ Lead nurse. Prescriptions will follow legal requirements for CD prescriptions as per BNF/MEP guidance

<https://bnf.nice.org.uk/guidance/controlled-drugs-and-drug-dependence.html>

Buvidal® Prescriptions should not usually be prescribed by EPS, they should be printed, signed and hand delivered to Stokes Croft Pharmacy 40-48 Stokes Croft, St Paul's, Bristol BS1 3QD – Telephone: 0117 942 6941.

**Prescriptions should not be sent to any other pharmacy.**

Prescriptions should be sent at least 24 working hours prior to agreed appointment time. Practitioners can call stokes croft Pharmacy to confirm if the prescription is ready. **Buvidal® should be collected by HHS staff only.**

To prevent costly wastages of Buvidal® it should be collected when the patient has arrived for their appointment.

Detailed dosing and prescribing guidance can be found here.

<Y:\Buvidal resource folder\Buvidal national guidance\SMMGP - Clinical Guidelines for Buvidal.pdf>

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## Initiation

Initiation to Buvidal® should ideally be undertaken by the Buvidal® clinical lead or overseen by the OST Lead in their absence.

Initiation can be managed in several ways depending on the patient's individual circumstances:

**A) The patient has not used short acting opiates in at least 6 hours or the patient has not used long-acting opiate in >24 hours.**

Prior to initiation patients should have signs of opiate withdrawal and an objective scale such as Clinical Opiate Withdrawal Score (COWS) can be used or the practitioner can use their professional judgement if they are sufficiently competent and experienced in substance misuse.

**B) The patient is on methadone and requires a transition.**

This should be carefully planned with the patient and the Buvidal®/OST lead. If wishing to make a direct switch, patients should be reduced to 30ml daily and should wait at least 24 hours from last dose before initiation. The patient should be counselled on the risks of precipitated withdrawal and the dose should not be administered if the patient does not appear to be in withdrawal.

**C) The Patient is already on Buprenorphine (BPN).**

They may be transferred directly to weekly or monthly Buvidal®, starting on the day after the last daily Sublingual BPN dose, in accordance with dose conversion table.

[Buvidal 8 mg prolonged-release solution for injection - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](#)

Planning & Preparation for Buvidal® initiation is a specialist practice and should be managed and supervised by the Clinical Nurse Specialist or other OST practitioners. However informal support and information may be provided by other members of staff.

Supplemental Buprenorphine dosing is available following a specialist review. If during the initiation period of one month the patient complains of discomfort or difficulties managing cravings, please contact Buvidal® CNS, HHS Clinical Lead or OST lead and arrange an urgent review.

## Maintenance

Buvidal® OST should be prescribed within a psychosocial framework and where possible maintenance doses should be administered alongside psychotherapeutic interventions by a practitioner trained and experienced in delivering them.

If a patient does not engage with Psycho/social elements of Buvidal® treatment either by missing multiple planned appointments with the specialist practitioner or lack of engagement at appointments, then their suitability for Buvidal® treatment may be reviewed.

Urine drug screening for cocaine, Tetrahydrocannabinol (THC), opiates and benzodiazepines should be offered to all patients at every appointment to assess for efficacy, treatment compliance and to inform data analysis.

The aim is for patients to be on a blocking dose of Buvidal, so that opiate cravings are minimised. It should be pointed out to patients that it is pointless taking extra opiates when blocked. If patients are not blocked and still craving, then a higher dose of Buvidal should be

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considered. A urine test for opiates and methadone should be carried out routinely at a patient's monthly review to help verify patient's statements about their drug use. If there is consistent "on top" use with positive urine tests, then a robust discussion with the patient about possibly stopping Buvidal should be undertaken.

All patients with a uterus should be asked for a urine sample for pregnancy testing. All patients with a uterus should be offered Long-acting reversible contraception (LARC) and supported to make an appointment to have this fitted with a staff member trained to do so at HHS or One25 or another appropriate service.

### Administration

**Buvidal must be administered by a health care professional.**

The administrator **MUST** be competent in the administration of subcutaneous injections and understand the special precautions for Buvidal®. They must also be trained to manage any adverse reaction or overdose. The prescriber **MUST** be on duty and available for advice at the time of the administration. All administrators should receive and have read a copy of the SOP.

The patient **MUST** confirm their identity which should be matched to the prescription on Emis and to the label on the product.

It is the administrator's responsibility to check that:

- The Buvidal® strength matches the prescription
- That the Buvidal® unit is only administered to the person it is prescribed for

The plunger should be attached by gently turning into the flange of the syringe until secure. Take care not to place the thumb on the plunger flange. Buvidal® should be injected slowly, into the subcutaneous tissue of the buttock, thigh, abdomen, or upper arm.

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.

A demonstration is available here <https://lisp.lwcdn.com/api/video/embed.jsp?id=eec6b012-7ee3-4b6c-b9f9-359d3f9ac587&pi=785b7fd1-761b-46d1-9e8c-fe5f8958ac14>

Empty units should be disposed of in a yellow lid sharps bin.

### Record-Keeping

Buvidal® needs to be signed into the premises using the blue Controlled Drug (CD) record book kept in the cupboard. The practitioner administering the Buvidal® needs to obtain a second signature from second clinician to witness removal from the drugs cupboard.

When returning Buvidal® to the pharmacy a signature from the receiving pharmacy staff member needs to be obtained and counter signed by the returning staff member in the CD book.

Buvidal® templates are available on Emis and should be made use of using subcategories induction or maintenance. Consultations should be coded as Buprenorphine maintenance therapy. Practitioners should complete as much of the templates as reasonably possible.

The lot number, expiry date and administration site **MUST** be recorded as a minimum.

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## The Yellow Card scheme

The MHRA runs the Yellow Card scheme, which collects and monitors information on suspected safety concerns involving a healthcare product. The scheme relies on voluntary reporting of problems to a healthcare product by the public (including patients, parents and carer givers) as well as from healthcare professionals.

Suspected adverse reaction should be reported to the MHRA and to the manufacturer at [safety@camurus.com](mailto:safety@camurus.com)

And

<https://yellowcard.mhra.gov.uk/>

## Recording of data to Theseus data base

All patients receiving injectable buprenorphine should consent to their data being added to the National Drugs Treatment Monitoring System (NDTMS).

A treatment episode should be opened on Theseus as soon as treatment has commenced. For patients who already have an open episode on Theseus for other OST treatment within HHS Complex Homeless Addicted Re-Engagement Team (CHART) service, a Buvidal “attribute” will be added to the Theseus episode.

The Buvidal nurse specialist and the OST lead will be responsible for the creation and management of treatment data on Theseus. The nurse specialist or practitioner responsible for the provision of psychosocial support will be responsible for the updating of the Treatment Outcome Profile every 90 days.

When a patient exits treatment whether planned or unplanned, the OST lead and the nurse specialist should be notified as soon as possible so that Theseus data is updated to reflect this exit.

## Storage

Buvidal® should be collected from Stokes croft pharmacy after the patient has arrived for treatment, if not used immediately for any reason, whilst on site it should be stored in the locked cabinet currently situated in the Doctors consultation room. The keys to this cupboard are kept in a lockable key cabinet accessible to clinicians, security and reception staff. Unused Buvidal® MUST not be stored at HHS overnight and MUST be returned to stokes croft pharmacy for destruction, this should be recorded in the control drugs book.

## Off-site administration

Clinicians must take reasonable precautions when transporting Buvidal® between sites. Buvidal® must not be stored off site and must stay in the custody of the clinician whilst in clinic where a suitable medicine cabinet is not available. In an emergency event it is acceptable for the Buvidal® to be stored in a locked cupboard behind a locked door until the clinician can return to the clinic.

HHS does not need to supply UHBW/NBT with Buvidal® but can provide clinical guidance to practitioners to support Buvidal® patients whilst in hospital.

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## Ending treatment

### **A) Patients may elect to withdraw from the Buvidal® programme for a number of reasons:**

When there is a goal of opioid abstinence - This must be planned/ overseen by Buvidal® specialist Nurse or OST lead.

Where this is unplanned every effort must be made to safety net them from harm. This could include induction to alternative OST, provision of Naloxone, sign posting to Needle Exchange services, harm reduction advice. In some circumstances it may be suitable to involve external agencies to safeguard the patient from harm.

### **B) There may be certain circumstances where a patient needs to be removed from the programme against their wishes.**

A) Where a patient is banned from the HHS and referred to the Special allocations service – An alternative OST bridging script will be provided until next available appointment at Bristol Special Allocations Service.

B) Where a patient requests care transferred to a service where there is no Buvidal® programme - alternative OST can be prescribed by HHS prior to move if required or can be arranged with care provider at the requested destination.

C) Where a patient develops a health condition which contraindicates Buvidal® OST - This must be discussed with the patient before any changes are made, advice must be sought from a specialist on the condition of concern and Buvidal® specialist. Where appropriate alternative OST will be prescribed by HHS as part of a psychosocial framework

D) Where the patient fails to meet the agreed terms of the treatment plan. Where appropriate alternative OST will be prescribed by HHS as part of a psychosocial framework.

## Funding

HHS is mindful that the current funding stream for this project is temporary. Should the Buvidal® pilot be withdrawn patients will be supported to reduce and conclude OST or transfer to an alternative therapy.

## Monitoring

Content of document should be reviewed by the Buvidal® Team every three months to sense check compliance and discuss amendments. Reporting of Buvidal® outcomes is still being discussed with Recovery Orientated Alcohol & Drugs Service (ROADS) network (our Commissioners).

Compliance within the broader Medicines Management Policy should also be checked.



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### Change Register

Date	Version	Reviewed and amended by	Revision Details
06.04.2022	1.0	M.Taylor, R. Carter, J. Lees, N. Saatchi, D. Soddeen (HHS)	New Document