Weekly/Monthly Buvidal®

BUPRENORPHINE

PROLONGED-RELEASE SOLUTION FOR INJECTION

Buvidal® Implementation Checklist for Drug Treatment Providers and Commissioners

BACKGROUND

The following checklist has been designed to support drug treatment providers and commissioners in mapping out and completing the relevant activities in order to implement Buvidal® prolonged-release buprenorphine solution for injection into their local opioid dependence treatment systems. Please note, this checklist serves as a guide and cannot include all the specific local requirements that may need to be fulfilled. Some activities listed below and the sequence in which they are listed may be irrelevant depending on the organisation. Therefore, users of this form are encouraged to make amendments to reflect their organisation's individual requirements.

CHECKLIST

First stage: engagement and buy-in from stakeholders	Step necessary Y/N	Completed (check box)	Dates	Comments
Buvidal presentation delivered by Camurus to Drug Treatment Service (DTS)/ Commissioner	Y/N	☐		
DTS/ Commissioner agrees to implement Buvidal into the pathway	Y/N	☐		
DTS/ Commissioner to consult with relevant Pharmacy Lead and establish Controlled Drug (CD) license status of premises and to decide on Buvidal dispensing/delivery model i.e. Onsite or Pharmacy	Y/N	☐		
If opting for a Pharmacy model, then budget holder to agree tariff/ contract with Pharmacist(s)	Y/N	☐		
DTS/ Commissioner develops proposal/ business case for implementing Buvidal including the financial impact and potential numbers of patients to receive Buvidal	Y/N	☐		
Proposal/ business case presented to relevant management team/ stakeholder group and approval secured for implementation	Y/N	☐		

Onsite model: Storage and administration at the DTS

This model can be considered provided the DTS has the required infrastructure e.g. a CD License or Registered Pharmacy (RP) status and can therefore stock Buvidal onsite, prescribing the medication to patients that they deem suitable.

Pharmacy model

Local Pharmacist(s) are identified who will administer Buvidal in a Pharmacy in the same way they administer other opioid substitution treatment. This will require a tariff to be paid to the Pharmacist.

Second stage: formulary approval[1] (this stage can run concurrently with first stage to avoid delays)	Step necessary Y/N	Completed (check box)	Dates	Comments
Identify a clinician that will support the Buvidal formulary submission	Y/N	☐		
Supporting clinician collates evidence required for the formulary submission	Y/N	☐		
Buvidal submission presented and approved at a relevant meeting (may commonly be referred to as drugs and therapeutic drugs and therapeutic committee meetings, formulary meetings, medicines management meetings etc)	Y/N	☐		

Third stage: staff training and clinical protocol development	Step necessary Y/N	Completed (check box)	Dates	Comments
All relevant staff receive training: (1) Buvidal presentation (safety profile and efficacy), (2) depot administration including video demonstration and practice using technical material (3) familiarisation with supporting materials i.e. Dosing Card, patient/ HCP information booklets, Quick Injection Guide etc.	Y/N	☐		
Clinical protocol development: DTS determine their patient selection criteria	Y/N	☐		
Clinical protocol development: DTS finalise their clinical protocol	Y/N	☐		
Clinical protocol development: clinical protocol is signed off by relevant clinician/ team	Y/N	☐		

Fourth stage: initiating Buvidal	Step necessary Y/N	Completed (check box)	Dates	Comments
Keyworkers/ clinicians identify patients on their caseloads using the agreed patient selection criteria	Y/N	☐		
Suitable patients are invited into a session where they are informed about Buvidal and given the patient information booklet	Y/N	☐		
Patients agreed to commence Buvidal are booked in to see the prescribing clinician	Y/N	☐		
Prescribers liaise with their respective pharmacy departments or local pharmacy to ensure that the correct dose/strength preparations of Buvidal are ordered in advance of patients commencing treatment	Y/N	☐		

[1]*Depending on the organisation, formulary approval may or may not be required for initiating Buvidal. It is advisable to gain input from the relevant Pharmacy Lead*

Prescribing Information for Buvidal®
(buprenorphine prolonged-release solution for injection)

Please refer to the Summary of Product Characteristics (SmPC) before prescribing

Active ingredient: Buprenorphine. Prolonged-release solution for injection in pre-filled syringes. Weekly injection (8 mg, 16 mg, 24 mg, 32 mg) or monthly injection (64 mg, 96 mg, 128 mg, 160 mg).

Indication: Treatment of opioid dependence within a framework of medical, social and psychological treatment. Treatment is intended for use in adults and adolescents aged 16 years or over.

Dosage: To avoid precipitated withdrawal, initiate when objective and clear signs of mild to moderate withdrawal are evident, considering the duration of action of the opioid, time since last dose and degree of opioid dependence. Do not start until ≥6 hours after last heroin or short-acting opioid. Reduce methadone to ≤30 mg/day and start Buvidal® ≥24 hours after the last methadone dose. Buvidal® may trigger withdrawal symptoms in methadone-dependent patients. *Initiation in patients not already receiving buprenorphine:* Patients not previously exposed to buprenorphine, administer 4 mg sublingual buprenorphine and observe for an hour to confirm tolerability. Recommended starting dose of Buvidal® is 16 mg, with one or two additional 8 mg doses at least 1 day apart (target dose of 24 mg or 32 mg during the first week). The dose for the second week is the total dose administered during the first week. May transfer to monthly Buvidal® after four weeks and once stabilised. *Switching from sublingual buprenorphine:* Switch directly to weekly or monthly Buvidal®, starting on the day after the last sublingual buprenorphine dose. See SmPC for dose recommendations. *Maintenance:* Weekly or monthly as needed. One supplemental Buvidal® 8 mg dose may be administered between regular weekly or monthly doses (except 160 mg). The maximum dose is 32 mg weekly, with an additional 8 mg dose, or 160 mg monthly. Weekly doses may be administered up to 2 days before or after the weekly time point, and monthly doses may be administered up to 1 week before or after the monthly time point. If a dose is missed, administer the next dose as soon as practical. *Termination:* Consider prolonged-release characteristics and any withdrawal symptoms. If switching to sublingual buprenorphine, do so one week after the last weekly dose or one month after the last monthly dose of Buvidal®. *Elderly:* No dosing recommendations over 65 years. Consider renal and hepatic function.

Administration: Administration of Buvidal® is restricted to healthcare professionals only. For subcutaneous administration only. Inject slowly and completely into sufficient subcutaneous tissue of the buttock, thigh, abdomen, or upper arm area. Do not re-inject the same injection site for at least 8 weeks (each area can have multiple injection sites).

Contraindications: Hypersensitivity to buprenorphine or excipients. Severe respiratory insufficiency. Severe hepatic impairment. Acute alcoholism or *delirium tremens*.

Special warnings and precautions for use: Must not be administered intravenously, intramuscularly or intradermally. Monitor for any attempts to remove the depot. Some precautions associated with buprenorphine class. *Prolonged-release properties* of the product should be considered during treatment. Patients with concomitant medicines and/or co-morbidities should be monitored for signs and symptoms of toxicity, overdose or withdrawal. *Respiratory depression:* Deaths reported with buprenorphine. Care in respiratory insufficiency. *CNS depression:* Buprenorphine may cause drowsiness. *Dependence:* Chronic administration of buprenorphine can produce opioid dependence. *Serotonin syndrome:* Concomitant serotonergic agents (e.g. monoamine oxidase inhibitors, selective serotonin re-uptake inhibitors, serotonin and noradrenaline re-uptake inhibitors or tricyclic antidepressants) may result in serotonin syndrome, a potentially life-threatening condition - if clinically warranted, observe carefully, particularly during initiation and dose increases and consider reducing or discontinuing therapy if serotonin syndrome is suspected. *Hepatitis, hepatic events and hepatic impairment:* Recording of baseline liver function tests and viral hepatitis status recommended. Hepatic injury reported with buprenorphine. Caution with buprenorphine in moderate hepatic impairment – monitor for signs and symptoms of opioid withdrawal, toxicity and overdose. Monitor hepatic function regularly. *Drug withdrawal syndrome (GB):* Before starting any opioids, discuss withdrawal strategy with the patient. Dose tapering over weeks or months may be required. Risk of neonatal withdrawal syndrome following use in pregnancy. *Precipitation of opioid withdrawal syndrome:* Buprenorphine products have precipitated withdrawal symptoms in opioid-dependent patients when administered before the agonist effects from recent opioid use or misuse have subsided. *Renal impairment:* Caution in severe renal impairment. *QT-prolongation:* Caution with other medicines that prolong the QT interval and in patients with a history of long QT syndrome or other risk factors for QT prolongation. *Acute pain management:* A combination of opioids with high mu-opioid receptor affinity, non-opioid analgesics and regional anaesthesia might be necessary. Monitor and titrate, considering potential risk of overdose and/or death. *Sleep-related breathing disorders:* Opioids can cause sleep-related breathing disorders. *Opioid class effects:* See SmPC for details. *Interactions:* See SmPC for buprenorphine interactions. *Pregnancy and lactation:* Caution – see SmPC for details. *Driving and operating machines:* Minor to moderate influence, including drowsiness, dizziness or impaired thinking – likely to be pronounced by alcohol or CNS depressants. See SmPC for details of what individual patients should be told by the prescriber.

Undesirable effects: *Very common:* insomnia, headache, nausea, hyperhidrosis, drug withdrawal syndrome, pain. *Common:* infection, influenza, pharyngitis, rhinitis, lymphadenopathy, hypersensitivity, decreased appetite, anxiety, agitation, depression, hostility, nervousness, abnormal thinking, paranoia, medical dependence, somnolence, dizziness, migraine, paraesthesia, syncope, tremor, hypertonia, speech disorders, lacrimal disorder, mydriasis, miosis, palpitations, vasodilation, hypotension, cough, dyspnoea, yawning, asthma, bronchitis, constipation, vomiting, abdominal pain, flatulence, dyspepsia, dry mouth, diarrhoea, gastrointestinal disorder, rash, pruritus, urticaria, arthralgia, back pain, myalgia, muscle spasms, neck pain, bone pain, dysmenorrhea, injection site reactions (pain, pruritus, erythema, swelling, reaction, induration, mass), peripheral oedema, asthenia, malaise, pyrexia, chills, neonatal withdrawal syndrome, chest pain, abnormal liver function tests. *Other:* urinary retention, injection site reactions (abscess, ulceration and necrosis). See SmPC for further details.

Overdose: Apply general supportive measures, closely monitoring and treating respiratory and cardiac status. Consider long duration of action of buprenorphine and prolonged release from the depot.

Package quantities and UK net price: 1 pre-filled syringe per pack. Weekly injection (8 mg (0.16 ml), 16 mg (0.32 ml), 24 mg (0.48 ml), 32 mg (0.64 ml)): £55.93. Monthly injection (64 mg (0.18 ml), 96 mg (0.27 ml), 128 mg (0.36 ml), 160 mg (0.45 ml)): £239.70. **Marketing authorisation numbers:** *GB:* PLGB 42800/0001, PLGB 42800/0003-9. **ROI and NI:** EU/1/18/1336/001-7, EU/1/18/1336/009. **Legal category:** POM. **Marketing authorisation holder:** Camurus AB, Ideon Science Park, SE-223 70 Lund, Sweden. Email: Camurus.uk@camurus.com Additional information available on request.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard (or search for MHRA Yellow Card in the Google Play or Apple App Store) for the UK and http://www.hpra.ie/homepage/about-us/report-an-issue for Ireland. Adverse events should also be reported to Camurus AB via email: safety@camurus.com

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For information concerning CD Licenses: www.gov.uk/guidance/controlled-drugs-licences-fees-and-returns