Weekly/Monthly

Buvidal®

BUPRENORPHINE

PROLONGED-RELEASE
SOLUTION FOR INJECTION

How to inject Buvidal®
USER GUIDE

This user guide is intended for Healthcare Professionals only

THIS GUIDE SHOULD NEVER BE GIVEN TO THE PATIENT

IMPORTANT: This material is not intended as a standalone document but should be read together with the Summary of Product Characteristics (SmPC).

To view a video showing the administration technique, please visit www.buvidal.co.uk

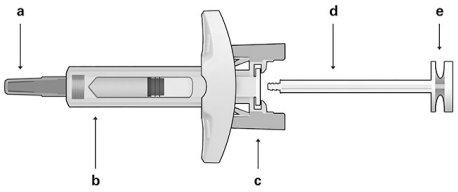
SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

Important information

- Administration should be made into the subcutaneous tissue.
- Intravascular, intramuscular and intradermal administration must be avoided.
- Injection site reactions could potentially be minimised by using the correct administration technique, as described in the SmPC for Buvidal and ensuring that the product is not injected intradermally.
- Must not be used if the safety syringe is broken or the packaging is damaged.
- The needle shield of the syringe may contain rubber latex that may cause allergic reactions in latex sensitive individuals.
- Handle the safety syringe carefully to avoid a needle stick. The safety syringe includes a needle protection safety device that will activate at the end of the injection. Do not uncap the safety syringe until you are ready to inject. Once uncapped, never try to recap the needle.
- Dispose of the used safety syringe right away after use. Do not re-use the safety syringe.

Safety syringe parts:

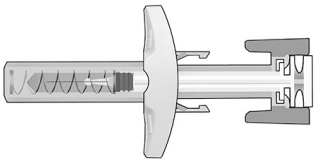
FIGURE 1.1



Safety Syringe: Before Use

a) Needle shield, **b)** Syringe Guard Body,
c) Syringe Guard Wings, **d)** Plunger, **e)** Plunger Head

FIGURE 1.2

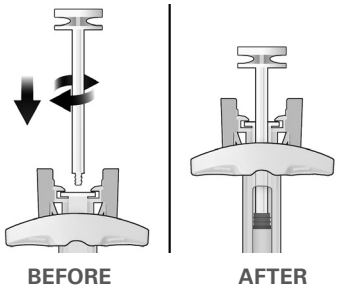


Safety Syringe: After Use

(With needle protection mechanism activated)

Please note that the smallest injection volume is barely visible in the viewing window as the spring of the safety device is "covering" part of the glass cylinder close to the needle.

FIGURE 2



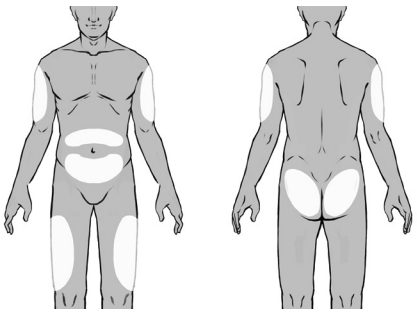
Administration

- Take the syringe out of the cardboard box: pick up the syringe by the syringe guard body.
- While holding the syringe by the needle shield, insert the plunger rod into the plunger stopper by gently rotating the plunger rod clockwise until secured (see **FIGURE 2**).

Inspect the safety syringe closely:

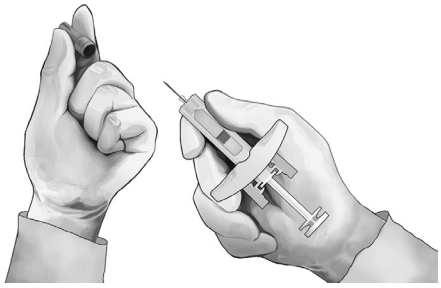
- Do not use the safety syringe after the expiration date shown on the cardboard box or on the syringe label.
- A small air bubble may be seen, which is normal.
- The liquid should be clear. Do not use the safety syringe if the liquid contains visible particles or is cloudy.

FIGURE 3



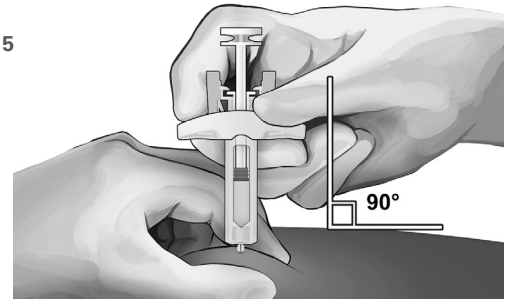
- Choose the injection site. Injections should be rotated between sites in the buttock, thigh, abdomen, or upper arm (see **FIGURE 3**) with a minimum of 8 weeks before re-injecting a previously used injection site. Each area can have multiple injection sites. Injections on the waistline or within 5 cm of the navel should be avoided.

FIGURE 4



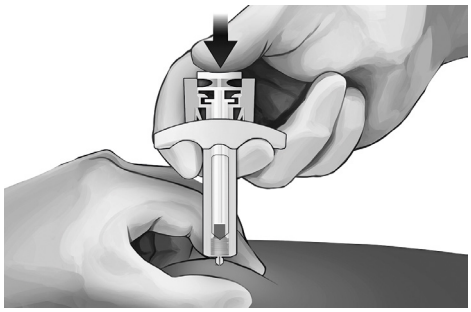
- Put on gloves and clean the injection site with a circular motion using an alcohol wipe (not provided in the pack). Do not touch the cleaned area again before injecting.
- While holding the safety syringe by the syringe guard body as shown (see **FIGURE 4**), carefully pull the needle shield straight off. Immediately dispose of the needle shield (never try to recap the needle). A drop of liquid may be seen at the end of the needle. This is normal.

FIGURE 5



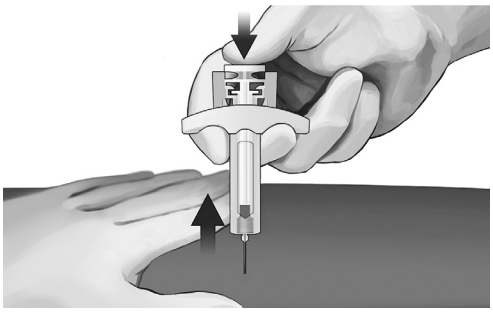
- Pinch the skin at the injection site between the thumb and finger as shown (see **FIGURE 5**).
- Hold the safety syringe as shown and insert the needle at an angle of approximately 90° (see **FIGURE 5**). Push the needle all the way in.

FIGURE 6



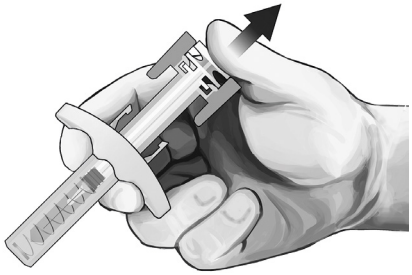
- While holding the syringe as shown (see **FIGURE 6**), slowly depress the plunger until the plunger head latches between the syringe guard wings and all the solution is injected.

FIGURE 7



- Gently pull the needle out of the skin. It is recommended that the plunger is kept fully depressed while the needle is carefully lifted straight out from the injection site (see **FIGURE 7**).

FIGURE 8



As soon as the needle has been completely removed from the skin, slowly take the thumb off the plunger and allow the syringe guard to automatically cover the exposed needle (see **FIGURE 8**). There may be a small amount of blood at the injection site, if required wipe with a cotton ball or gauze.

Disposing of the syringe

- Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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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