Guidance for Buvidal® (buprenorphine) administration and dose conversion

Weekly/Monthly Buvidal®

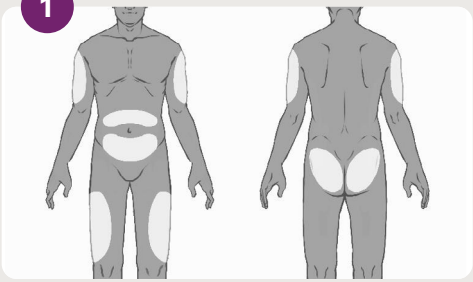
BUPRENORPHINE

MODIFIED RELEASE SOLUTION FOR INJECTION FOR SUBCUTANEOUS USE

camurus®

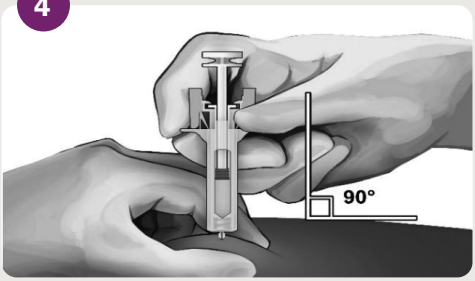
Step-by-step guidance for administration of Buvidal® Weekly and Buvidal® Monthly:[1]

1



Injection site: Injections should be rotated and alternated between sites in the buttock, thigh, abdomen, or upper arm. Injections on the waistline or within 5 cm of the navel should be avoided.

4

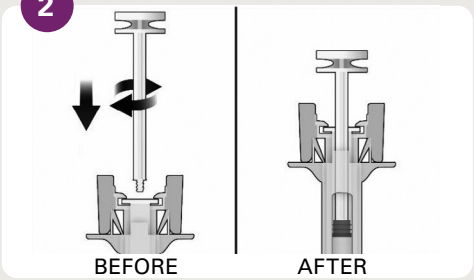


Pinch the skin at the injection site between the thumb and finger as shown. Hold the safety syringe as shown and smoothly insert the needle at an angle of approximately 90°. Push the needle all the way in.

5

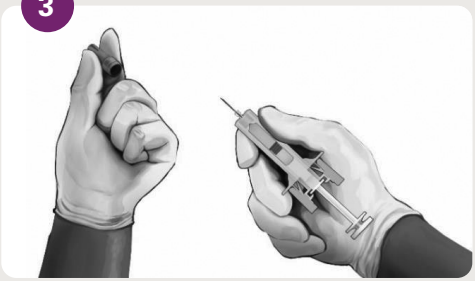
While holding the syringe as shown below, slowly depress the plunger until the plunger head latches between the syringe guard wings and all the solution is injected.

2



While holding the syringe by the needle cap, insert the plunger rod into the plunger stopper by gently rotating the plunger rod clockwise until secured.

3



While holding the safety syringe by the syringe guard body as shown, carefully pull the needle cap straight off. Immediately dispose of the needle cap (never try to recap the needle). A drop of liquid may be seen at the end of the needle.

6

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.

7

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. There may be a small amount of blood at the injection site, if required wipe with a cotton ball or gauze.

For full administration guidance please refer to the full product information.

Buvidal® recommended dose conversion[1,2]

Transitioning patients from SL-BPN* to Buvidal®†

Patients stabilised on and/or currently maintained on SL-BPN may be switched directly to Buvidal® Weekly or Buvidal® Monthly.[1]

Buvidal® treatment should start on the day after the last daily SL-BPN dose in accordance with the dosing recommendations below.[1]

Switching patients between Buvidal® Weekly and Buvidal® Monthly†

Doses may be increased or decreased, and patients can be switched between weekly and monthly products according to their individual needs and treating physician's clinical judgement, as per dosing recommendations below.[1]

SL-BPN daily dose and recommended corresponding doses of Buvidal® Weekly and Monthly[1]

Dose of daily sublingual buprenorphine	Dose of Buvidal® Weekly	Dose of Buvidal® Monthly
2-6 mg	8 mg	-
8-10 mg	16 mg	64 mg
12-16 mg	24 mg	96 mg
18-24 mg	32 mg	128 mg

Dosing window

Weekly dose may be administered up to 2 days before or after the weekly time point.

Monthly dose may be administered up to 1 week before or after the monthly time point.

Dose adjustments†

A maximum of one Buvidal® Weekly 8 mg injection may be given during a dosing period, if required. Supplementary 8 mg doses are now approved for use in addition to the 32 mg Buvidal® Weekly dose and 128 mg Buvidal® Monthly dose. Please refer to the Product Information for further details.

*SL-BPN: sublingual buprenorphine

†Following a change in treatment, patients may require close monitoring

Buvidal® offers a range of dosing options:[1,2]

Buvidal® is supplied as a ready-for-use pre-filled syringe:[1,2]

Photo for demonstration purposes only

- Small volume fixed dosages (0.16 – 0.64 mL)*
- 23-gauge needle
- The syringe is supplied in a safety device to prevent needlestick injury

*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.

Buvidal® does not require refrigeration

- Store at room temperature (< 25°C), do not refrigerate or freeze.

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PLEASE REVIEW THE BUVIDAL® WEEKLY AND BUVIDAL® MONTHLY PRODUCT INFORMATION BEFORE PRESCRIBING. PRODUCT INFORMATION IS AVAILABLE BY CALLING 1800 142 038

PBS Information:

Buvidal® Weekly (8 mg, 16 mg, 24 mg and 32 mg) and Buvidal® Monthly (64 mg, 96 mg and 128 mg) are listed on the PBS as a Section 100 Opiate Dependence Items. Refer to PBS Schedule for full authority information.

Buvidal® Monthly 160 mg is not listed on the PBS.

Please note that Buvidal® prescribing must comply with State and Federal regulations for opioids

BOXED WARNINGS

RISK OF SERIOUS HARM OR DEATH WITH INTRAVENOUS INJECTION: Serious harm or death could result if administered intravenously. Buvidal® forms a gel depot upon contact with body fluids and may cause occlusion, local tissue damage and thrombo-embolic events, including life threatening pulmonary emboli, if administered intravenously.

Additional warnings are associated with **HAZARDOUS AND HARMFUL USE, LIFE THREATENING RESPIRATORY DEPRESSION, CONCOMITANT USE OF BENZODIAZEPINES AND OTHER CENTRAL NERVOUS SYSTEM (CNS) DEPRESSANTS, INCLUDING ALCOHOL.**

Please refer the Buvidal® Weekly and Buvidal® Monthly Product Information for the full boxed warnings.

MINIMUM PRODUCT INFORMATION Buvidal® Weekly (8 mg, 16 mg, 24 mg and 32 mg) and Buvidal® Monthly (64 mg, 96 mg, 128 mg and 160 mg) buprenorphine modified release solution for injection for subcutaneous use. **BUVIDAL® WEEKLY INDICATION:** Buvidal® Weekly is indicated for initiation and maintenance treatment of opioid dependence, with or without prior stabilisation on sublingual buprenorphine or buprenorphine/naloxone, within a framework of medical, social and psychological support. **BUVIDAL® MONTHLY INDICATION:** Buvidal® Monthly is indicated for maintenance treatment of opioid dependence with prior stabilisation on Buvidal® Weekly or sublingual buprenorphine or buprenorphine/naloxone within a framework of medical, social and psychological support. **CONTRAINDICATIONS:** Hypersensitivity to buprenorphine or to any of the excipients, children <16 years, severe respiratory or hepatic insufficiency (Child-Pugh C), acute alcoholism or delirium tremens. **PRECAUTIONS:** Concomitant use of opioids with benzodiazepines, gabapentinoids, antihistamines, tricyclic antidepressants, antipsychotics, cannabis or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Opioids may cause orthostatic hypotension and should be used with caution in patients with: head injury, intracranial lesions, where cerebrospinal pressure may be increased, or history of seizure, hypotension, prostatic hypertrophy, urethral stenosis, myxoedema, hypothyroidism, or adrenal cortical insufficiency (e.g. Addison's disease), dysfunction of the biliary tract; the elderly or debilitated. Opioid-induced miosis, changes in the level of consciousness or the perception of pain may interfere with patient evaluation or obscure the diagnosis or clinical course of concomitant disease. Buprenorphine is subject to misuse, abuse and diversion, and can lead to dependence, similar to other opioids, legal or illicit. Although Buvidal® is indicated for the treatment of opioid dependence it still poses risks of hazardous and harmful use which can lead to overdose and death. Monitor the patient's ongoing risk of hazardous and harmful use regularly during opioid substitution therapy with Buvidal® treatment. Serious, life-threatening or fatal respiratory depression may occur with the use of Buvidal®, be aware of situations which increase the risk of respiratory depression. Buvidal® should be used with care in patients with respiratory insufficiency. May cause severe, possibly fatal, respiratory depression in children and non-dependent persons who accidentally or deliberately take it. When initiating treatment with Buvidal®, the partial agonist profile of buprenorphine may lead to precipitated withdrawal symptoms in opioid dependent patients if the agonist effects from recent opioid use have not subsided. Use with caution in patients with moderate hepatic impairment and when dosing patients with severe renal impairment (creatinine clearance < 30 ml/min). Patients should be cautioned about operating hazardous machinery. Should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus. Should be used with caution during breastfeeding. **INTERACTIONS:** Care should be taken when used with benzodiazepines, gabapentinoids, alcohol, other CNS depressants: other opioid derivatives; certain antidepressants, antihistamines , barbiturates, anxiolytics, opioid analgesics, cannabis, naltrexone, CYP3A4 inhibitors and inducers, MAO inhibitors, serotonergic medicines. **ADVERSE EFFECTS:** In a phase 3 efficacy study, common TEAEs (≥1%) were injection site: pain, pruritis, erythema, swelling, reaction, induration or mass. Other common TEAEs were constipation, headache, nausea, insomnia, urinary tract infection, upper respiratory tract infection, vomiting, arthralgia, diarrhoea, anxiety, tachycardia, cough, nasopharyngitis, laceration, alanine aminotransferase increased, aspartate aminotransferase increased, pain in extremity, hypoaesthesia, weight decreased, ear pain, toothache, pyrexia, oral herpes, back pain, depression and nasal congestion, tooth abscess, muscle spasm, neck pain, dizziness. (See PI for further information) **DOSAGE AND ADMINISTRATION:** Administration of Buvidal® is restricted to healthcare professionals. Maximum dose is 32 mg/week with an additional 8 mg supplementary dose or 160 mg/month. (See PI for further information). Based on Approved Product Information: 29 Apr 2021

References: 1. Buvidal® Weekly Australian Approved Product Information April 2021. 2. Buvidal® Monthly Australian Approved Product Information April 2021