Buvidal® : Weekly and Monthly Buprenorphine Depot Preparations

Intro

Buvidal® is a prolonged release buprenorphine product which is administered as a subcutaneous injection, either weekly or monthly, and is indicated for the treatment of opioid dependence within a framework of medical, social and psychological support. Treatment is intended for use in adults and adolescents aged 16 years or over.
The administration of Buvidal® must be carried out by a healthcare professional, competent in the administration of subcutaneous depot injections,

Preparation for prescribing

- Patient has had a comprehensive substance misuse assessment
- Patient must be counselled on potential risk/benefits of Buvidal®
- Patient must consent to treatment with Buvidal®

Precautions

Baseline LFTs and viral hepatitis status recommended pre-treatment. Patients who are positive for viral hepatitis, taking other medicines and/or existing liver dysfunction are at greater risk of liver injury.
Regular monitoring of liver function is recommended.

Contraindications

- Hypersensitivity to buprenorphine or to any excipients of Buvidal®.
- Severe respiratory insufficiency
- Severe hepatic impairment
- Acute alcoholism or delirium tremens

Interactions with other medicines, side effect profile etc, are the same as other buprenorphine products (as per current SPC/BNF)

Initiating treatment in patients not already receiving buprenorphine

To avoid precipitating symptoms of withdrawal, treatment with Buvidal® should be started when objective and clear signs of mild to moderate withdrawal are evident.

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 30mg/day before starting treatment with Buvidal® which should not be administered until at least 24 hours after the patient last received a methadone dose.

Patients who have not previously been exposed to buprenorphine should receive a oro-dispersible buprenorphine 4mg dose and be observed for an hour post administration before the first administration of weekly Buvidal® to confirm tolerability to buprenorphine. To avoid precipitating an opioid withdrawal syndrome, the first dose of buprenorphine should be started only when objective signs of mild to moderate withdrawal are evident.

Treatment with monthly Buvidal® can be started once patients have been stabilised on weekly treatment (four weeks or more where practical)

Starting dose recommendations

Day 1	During week 1	Week 2
16 mg injection	One or two additional 8mg doses at least one day apart. The target dose during the first week of treatment is 24mg or 32 mg	The recommended dose for the second treatment week is the total dose administered during the week of initiation

Switching from oro-dispersible buprenorphine products to Buvidal®

Patients treated with other formulations of 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. Close monitoring of patients is recommended during the dosing period after transition.

Oral buprenorphine daily treatment doses and recommended corresponding doses of weekly and monthly Buvidal®

Dose of daily sublingual buprenorphine (Espranor®)	Dose of weekly Buvidal®	Dose of monthly Buvidal®
2-6 mg (2-4mg)	8 mg	-
8-10 mg (6-8mg)	16 mg	64 mg
12-16 mg (10-12mg)	24 mg	96 mg
18-24 mg (14-18mg)	32mg	128mg

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.
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). The product must not be used if the safety syringe is broken or the packaging is damaged. The syringe must be handled carefully to avoid a needle stick injury. The safety syringe includes a needle protection safety device that will activate at the end of the injection. The cap should not be removed until ready to inject; once uncapped, never try to recap the needle. The safety syringe should be disposed of immediately after use. Do not re-use. The needle shield of the syringe may contain rubber latex that may cause allergic reactions in latex-sensitive individuals.

Maintenance treatment and dose adjustments

Doses may be adjusted up or down, and patients can be switched between weekly and monthly products when the next dose is due. A maximum of one supplemental Buvidal® 8mg dose may be administered at an unscheduled visit between regular weekly or monthly doses, based on individual patients' temporary needs.

The maximum dose per week for patients who are on weekly Buvidal® treatment is 32mg with an additional 8mg dose.
The maximum dose per month for patients who are on monthly Buvidal® treatment is 128mg with an additional 8mg dose.

Missed doses

To avoid missed doses:

- Weekly Buvidal® doses may be administered up to two days before or after the weekly scheduled appointment
- Monthly Buvidal® doses may be administered up to one week before or after the monthly scheduled appointment.

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

Termination of treatment
If Buvidal® treatment is discontinued; its prolonged-release characteristics and any withdrawal symptoms experience by the patient must be considered. If the patient is switched to treatment with sublingual buprenophine, this should be done one week after the last weekly dose or one month after the last monthly dose of Buvidal®, according to recommended dose equivalencies in first table above.

Adverse reactions

The adverse reactions most frequently reported for buprenorphine, including Buvidal®, are headache, nausea, hyperhidrosis, insomnia, drug withdrawal syndrome and pain.
The most common injection site reactions are injection side pain, injection site pruritis, and injection site erythema. The injection site reactions are normally mild or moderate in severity, and most events are transient.