

# Focus On: Prolonged Release Buprenorphine (PRB)

*“The Ministry of Health is encouraging accredited prescribers to review patients on sublingual buprenorphine and assess their suitability and interest in switching to depot buprenorphine formulations such as Buvidal® and Sublocade®”*

Mongan D, Galvin B, Farragher L, Dunne M, Nelson M. Impact of COVID-19 on drug services in four countries. (Health Research Board, Ireland. 2020)

## Buprenorphine: Sublingual tablets vs oral lyophilisate wafers

Since the late 1990s, buprenorphine has been used as an effective medication in Opioid Substitution Treatment (OST) - *often referred to as Opiate Agonist Therapy (OAT)* – and marketed under the brand name Subutex.

The most common form of the medication has been as a sub-lingual (SL) tablet, designed to be slowly dissolved under the patient’s tongue. Subutex SL tablets come in two dosage strengths - 2mg and 8mg. Supervised consumption of Subutex (in pharmacies) would often incur additional costs due to the amount of time the patient had to stay in the pharmacy whilst the tablet dissolved, with a ‘typical’ 12mg starting dose of Subutex requiring three tablets.

In 2017, a new formulation of buprenorphine was approved for OST in the form of Espranor – a freeze dried wafer (oral lyophilisate) containing 2mg or 8mg of buprenorphine.

Espranor is now widely used across community prescribing services, but it has been particularly beneficial to healthcare teams working with OST patients within prison settings due to its oromucosal route of administration – for example, an 8mg dose typically takes around 15 seconds to dissolve on the tongue, rather than the 5-10mins needed for a sub-lingual tablet. This has had huge benefits in terms reducing long waiting times, freeing up prison officer resources and minimising the risk of oral doses being diverted for sale and misuse within the prison.

Within community settings, Espranor has been welcomed by pharmacists offering supervised consumption due to its rapid dissolving qualities. However, additional safeguarding steps are needed for patients being prescribed a take home dose, with safe storage boxes an essential requirement in households where there are young children. Also, patients need to take extra precautions with the medication when self-administering at home, ensuring to only touch it with dry fingers and avoiding swallowing and consuming food / drink for 2-5mins following dispersal, as such actions could have a dramatic impact on the efficacy of the buprenorphine.

## The impact of SARS-CoV-2

Since the outbreak of Covid and the resultant lockdown restrictions, most prescribing services throughout the UK have had to adapt their processes. Under new social distancing guidelines, many pharmacies are unable to offer daily supervised consumption. This has resulted in many clients being moved from ‘daily pick-up’ to a weekly or even fortnightly collection schedule. Whilst early signs indicate that this shift has been positively received

amongst service users - with CGL's National Service User Representative Tony Lee commenting that 'A lot of people have been really, really complimentary ... it improves choice, it improves flexibility' ('The Mother of Invention', DDN Sept 2020) - it has meant additional and ongoing risk assessment to minimise the risk of diversion and ensure controlled medication is stored safely within households.

This has resulted in many services looking at alternatives to the 'daily dose' approach of the more traditional OST/OAT medications Methadone and Buprenorphine, in particular towards the prolonged release solutions offered by Buvidal<sup>®</sup> and Sublocade<sup>®</sup>.

Buvidal<sup>®</sup> and Sublocade<sup>®</sup> are both administered as depot injections, liquids that turn to a solid gel once inside the body and release buprenorphine at a controlled rate over time.

## Buvidal<sup>®</sup>

Buvidal<sup>®</sup> can be prescribed under PGDs (Patient Group Directions - a legal framework which allows registered health professionals to supply /administer specific medicines to a pre-defined patient group) and comes in a prefilled syringe containing 8mg, 16mg, 24mg, 32mg, 64mg, 96mg or 128mg of buprenorphine, which should be injected slowly, into the subcutaneous tissue of the buttock, thigh, abdomen, or upper arm by a trained healthcare provider.

Buvidal<sup>®</sup> can be administered weekly or monthly, practitioners should ensure injection sites are rotated.

Buvidal<sup>®</sup> is stored at room temperature and has a shelf-life of 30 days.

## Sublocade<sup>®</sup>

Sublocade<sup>®</sup> is available as a monthly depot injection only. It comes in a prefilled syringe containing 100mg or 300mg of buprenorphine.

Sublocade<sup>®</sup> has been developed for abdominal subcutaneous injection only, to be administered between the transpyloric (Addison's) and transtuberular planes. Injections should be given with the patient laying down and injection sites should be rotated regularly.

Sublocade<sup>®</sup> needs to be stored in a refrigerator between 2 – 8°C. Once outside the refrigerator however, Sublocade<sup>®</sup> can be stored in its original packaging at room temperature for up to 7 days prior to administration. Any Sublocade<sup>®</sup> left at room temperature for longer than 7 days should be discarded.

## What are the benefits of prolonged release buprenorphine?

The main benefit of prescribing buprenorphine as an extended release depot injection is the minimisation – or elimination – of risks associated with:

- On-top use (of illicit opiates)
- Diversion
- Unsafe storage
- Missed pick-ups

In addition, both Buvidal® and Sublocade® are particularly useful for patients that may be resistant to engage in OST treatment, e.g.

- Those in full-time employment who may be unable to attend a chemist every day
- Individuals from families / communities where there is a lot of stigma around substance misuse / addiction
- Individuals suffering from domestic abuse whose dependency on a regular dose of medication makes it more difficult for them to flee controlling relationships

## The key challenges of delivering buprenorphine as a depot injection

Perhaps the biggest challenge is cost. For example, a 30-day supply of Buvidal® costs £239.70 (excluding VAT), irrespective of the strength prescribed. In contrast, a 30-day supply of Buprenorphine sub-lingual tablets costs between £140 to £250, with Methadone oral solution (at usual doses) costing between £15 and £30 for a 30-day supply.

For any service considering delivering Buvidal® or Sublocade® on-site, it will be necessary to:

- Have a safe installed that holds Controlled Drugs (CD) - *this would need to be refrigerated to hold Sublocade®*
- Apply for a Home Office CD license (approx. £2,000p/a per site)
- Train clinical staff to administer the injection
- Have a robust system to track clients to individual injections, including doses, expiry dates, date of administration etc.

In addition to the more administrative side of the process, it is important to consider how such a change - not just in medication, but also routine - is felt by the patient, and how the ongoing therapeutic support being delivered accommodates this.

For some people, not having to visit a chemist on a regular basis will undoubtedly give them more freedom and be hugely advantageous for people who have difficulties adhering to a daily supervised regime, are having to shield due to Covid, or simply for those that are working or in full-time education.

Conversely, others may feel 'trapped' by the medication, unable to self-administer medication to manage their withdrawal symptoms they may feel they have less control than they did before. For others, this drastic change in daily routine may feel disorientating, particularly when combined with the additional impact of going from methadone – with its sedative properties acting as 'emotional analgesic' – to buprenorphine, with its relative lack of sedative properties often revealing the emotional distress which the initial heroin use attempted to conceal.

It is important to consider that depot injections of buprenorphine may not be appropriate for every individual at any time. Before switching from OST/OAT to an 'extended release' option, workers should review Care Plans and treatment programmes to adapt to the psychological and physiological changes experienced by the patient.

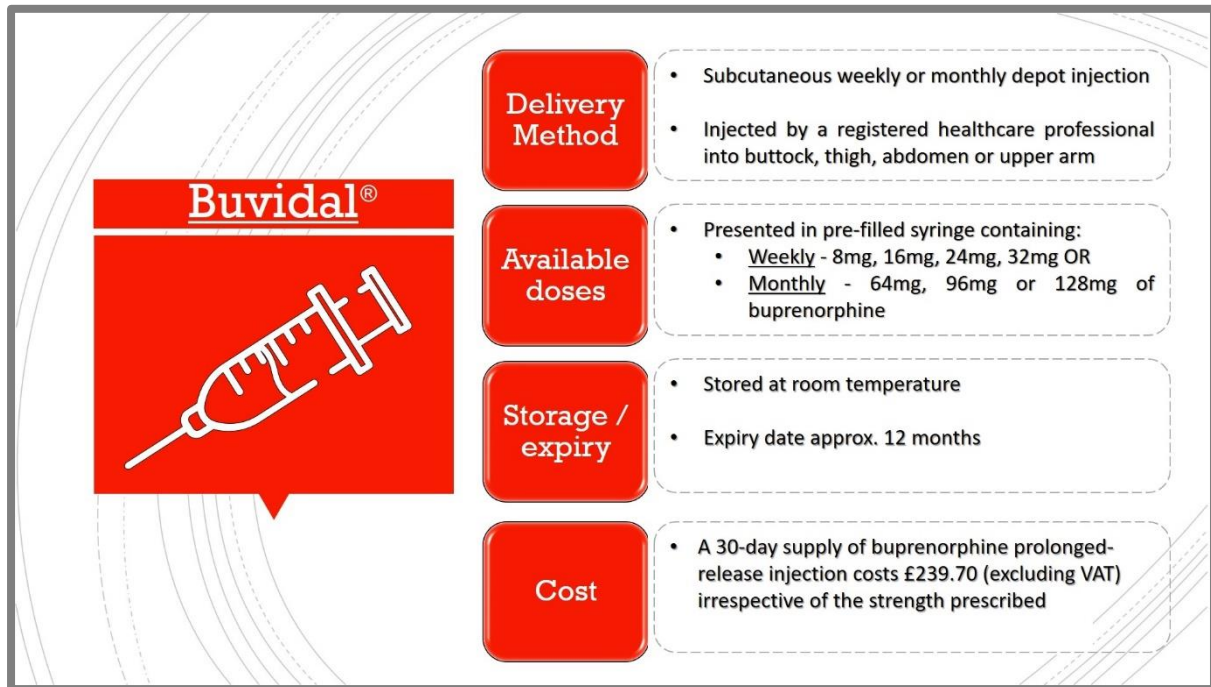
## How can ILLY help?

LINKS CarePath is widely used across the UK by prescribing services who need a flexible and comprehensive system to deliver a wide range of medications for their OST clients. Also, as LINKS CarePath has a number of inbuilt reporting and monitoring functionality,

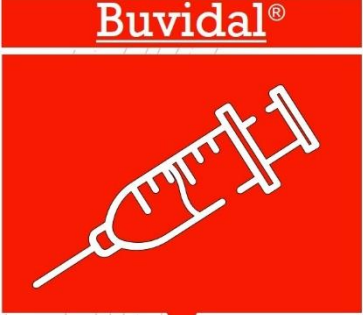
we're confident that the system could keep track of clients *and* their medication – *including information on dose / date of administration; dashboard reminders about expiry dates etc.*

## Next Steps:

Configuring LINKS CarePath to manage Buvidal® or Sublocade® prescribing is a simple process – if you would like more information on this then please contact us using the details below.



**Buvidal®**



**Delivery Method**

- Subcutaneous weekly or monthly depot injection
- Injected by a registered healthcare professional into buttock, thigh, abdomen or upper arm

**Available doses**

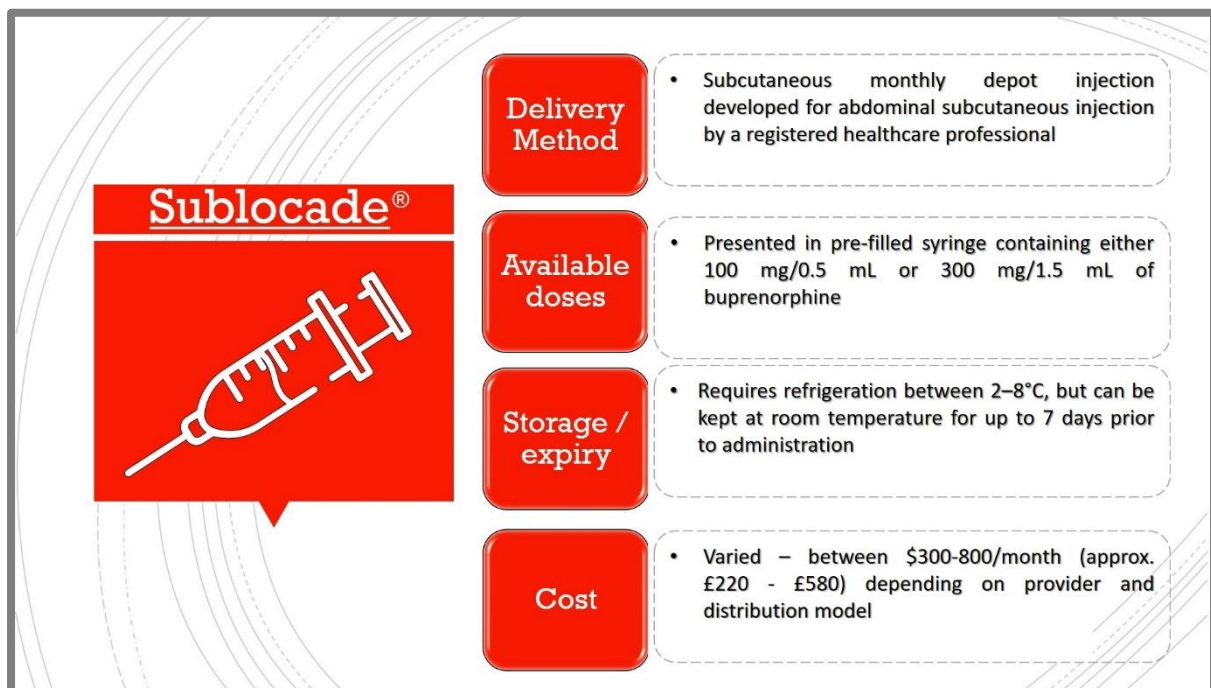
- Presented in pre-filled syringe containing:
  - Weekly - 8mg, 16mg, 24mg, 32mg OR
  - Monthly - 64mg, 96mg or 128mg of buprenorphine

**Storage / expiry**


- Stored at room temperature
- Expiry date approx. 12 months

**Cost**

- A 30-day supply of buprenorphine prolonged-release injection costs £239.70 (excluding VAT) irrespective of the strength prescribed



**Sublocade®**



**Delivery Method**

- Subcutaneous monthly depot injection developed for abdominal subcutaneous injection by a registered healthcare professional

**Available doses**

- Presented in pre-filled syringe containing either 100 mg/0.5 mL or 300 mg/1.5 mL of buprenorphine

**Storage / expiry**

- Requires refrigeration between 2–8°C, but can be kept at room temperature for up to 7 days prior to administration

**Cost**

- Varied – between \$300-800/month (approx. £220 - £580) depending on provider and distribution model