

Weekly/Monthly

Buvidal[®]

BUPRENORPHINE

PROLONGED-RELEASE
SOLUTION FOR INJECTION

PATIENT INFORMATION BOOKLET

The information in this booklet does not replace the advice given to you by your healthcare team.

This booklet is intended for patients who have been prescribed Buvidal and should be read in conjunction with the patient information leaflet in the pack

Who is this booklet for?

This booklet is intended for patients with opioid dependence who have been prescribed Buvidal.

Buvidal is a long-acting medicine for the treatment of opioid dependence. Buvidal contains buprenorphine and is available for weekly or monthly subcutaneous injection (into the tissue between the skin and muscle).

Only healthcare professionals can prepare and administer Buvidal. Treatment with Buvidal should be part of a comprehensive programme that also includes social and psychological treatment.

It is important to remember that opioid dependence is a treatable condition. With the right support, you can significantly improve your health and quality of life.

You can receive additional support from a doctor, nurse, family, friends, support groups and patient organisations. Ask your doctor or other healthcare professional for information about local support groups and organisations.

IMPORTANT: The information in this booklet does not replace the advice given to you by your healthcare team.

About Buvidal

What is Buvidal?

Buvidal is a long-acting medicine containing buprenorphine for weekly and monthly administration by a healthcare professional. Buvidal is for the treatment of opioid dependence within a framework of medical, social and psychological treatment. Buvidal is intended for use in adults and adolescents aged 16 years or over.

Buvidal contains the active ingredient buprenorphine, which suppresses withdrawal and cravings associated with opioid dependence. Buprenorphine also has other therapeutic benefits, including blocking unwanted effects of illicit opioid use during treatment.

Buvidal is available for weekly or for monthly administration. Both are provided in pre-filled, single-dose syringes and come in different doses.

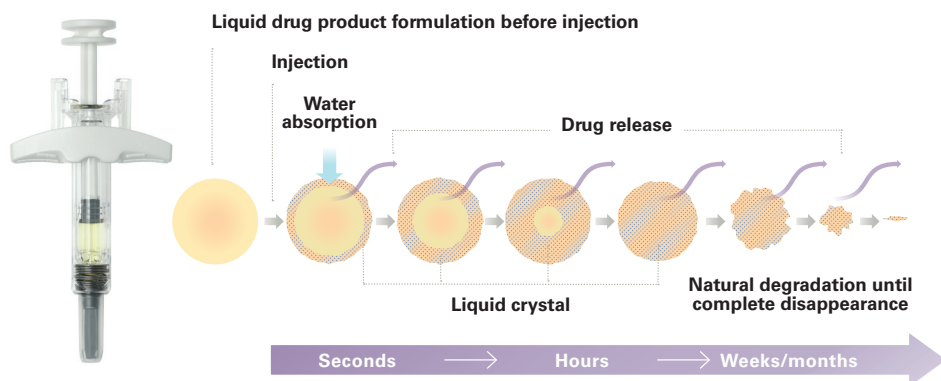
As you progress with your treatment on Buvidal, your doctor has the flexibility to work with you to adjust your doses up or down, depending on his or her clinical assessment and your individual needs.

How does Buvidal work in the body?

The long-acting properties of Buvidal are achieved by an innovative technology called FluidCrystal® injection depot.

Upon injection, Buvidal spontaneously transforms from a runny solution to a liquid crystalline gel that contains buprenorphine and releases it at a steady rate as the week or month progresses.

FluidCrystal® injection depot technology releasing buprenorphine over a period of a week or a month

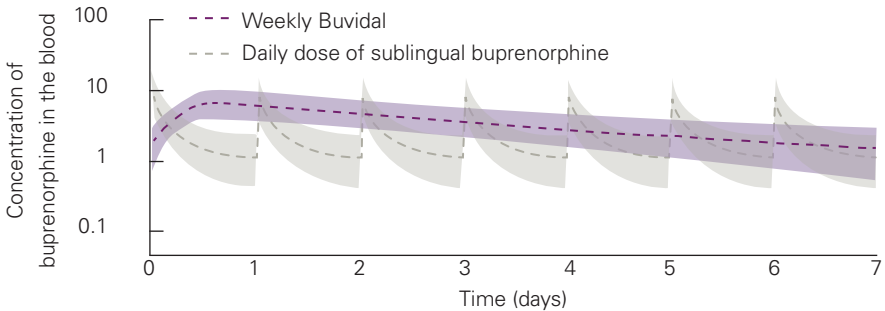


Can Buvidal adequately suppress my withdrawal and cravings associated with opioid dependence?

As soon as Buvidal has been injected, it begins to release buprenorphine and, within hours, suppresses withdrawal and cravings associated with opioid dependence. Buvidal provides a stable concentration of buprenorphine in the bloodstream over a period of a week or a month, depending on whether you receive weekly or monthly Buvidal.

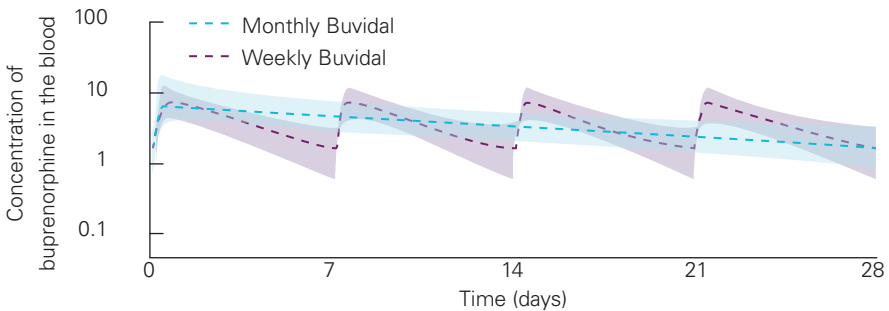
Weekly Buvidal compared with daily doses of sublingual buprenorphine

The blood level and effect of buprenorphine from weekly Buvidal is comparable with that achieved with daily doses of sublingual (under the tongue) buprenorphine.



Weekly Buvidal compared with monthly Buvidal over four weeks

Monthly Buvidal provides a stable blood level and effect concentration of buprenorphine and is comparable with that achieved with weekly Buvidal.



How is Buvidal administered?

Buvidal comes in a pre-filled syringe and is administered by a healthcare professional by injection into the tissue between the skin and the muscle.

IMPORTANT: Injecting Buvidal in any way other than subcutaneously is dangerous. Injecting Buvidal into a vein may cause serious harm. The product forms a small liquid gel structure upon contact with body fluids and may cause blocking of the blood vessels, local tissue damage and blood clots, including blood clots in the lungs, if administered in to the veins.

Is medication enough to treat my opioid dependence?

Opioid dependence is a chronic disease, like heart disease or diabetes, and often requires long-term care.

As with any other chronic condition, people with opioid dependence need support to help manage their condition. Opioid dependence treatment includes the use of medication along with counselling and psychosocial support. Your doctor and the other healthcare professionals involved in your treatment can work with you to help you manage your condition.

What is in the injection?

Buvidal contains the active medicine buprenorphine, which is a type of opioid.

The other ingredients in Buvidal are:

- **Weekly Buvidal:** soybean phosphatidylcholine, glycerol dioleate, ethanol anhydrous
- **Monthly Buvidal:** soybean phosphatidylcholine, glycerol dioleate, N-Methylpyrrolidone

Starting treatment with Buvidal

Flexible dosing and the adjustable duration of Buvidal allow for individualised therapy suited to your specific needs and treatment phase. Your doctor will work with you to determine an optimal treatment plan with Buvidal.

What is the correct dose of Buvidal for me?

Buvidal is available in weekly and monthly preparations, and each preparation comes in different doses. Your doctor will work with you to determine the correct dose of Buvidal for you, and together you can decide to have higher or lower doses to meet your needs.

- **Before starting treatment** – Your doctor will work with you to decide how best to start your treatment based on:
 - whether you are using short-acting opioids (e.g. morphine or heroin) or long-acting opioids (e.g. methadone)
 - whether you are already receiving sublingual (under the tongue) buprenorphine.

Monthly Buvidal can be used, if appropriate for you, once you have been stabilised on weekly treatment (four weeks treatment or more, where practical).

- **Continuing treatment and dose adjustment** – During continued treatment with Buvidal, your doctor will work with you to determine your individual treatment needs and may decrease or increase your dose. You may be switched from weekly to monthly treatment or from monthly to weekly treatment. Your doctor will prescribe the correct dose for you.

What if I have never previously taken buprenorphine?

If you have never previously been exposed to buprenorphine, then your healthcare professional will give you a small dose of sublingual buprenorphine (taken orally, under the tongue) and observe you for an hour. After this initial assessment, your healthcare professional will evaluate whether you can begin weekly treatment with Buvidal.

What if I am switching from sublingual buprenorphine treatment to Buvidal?

If you are already taking buprenorphine, you can be switched directly to weekly or monthly Buvidal, starting on the day after your last daily dose of sublingual buprenorphine. During the dosing period after the switch, it is recommended that your healthcare professional monitors you more closely.

Your doctor will calculate the appropriate dose to match the daily sublingual buprenorphine dose you were receiving.

What if I am switching from methadone to Buvidal?

If you are receiving methadone (a long-acting opioid), your dose of methadone will be reduced to below 30 mg per day before beginning with Buvidal. The first dose of this medicine will be given to you at least 24 hours after you last received methadone.

How will it feel when the medication starts to wear off?

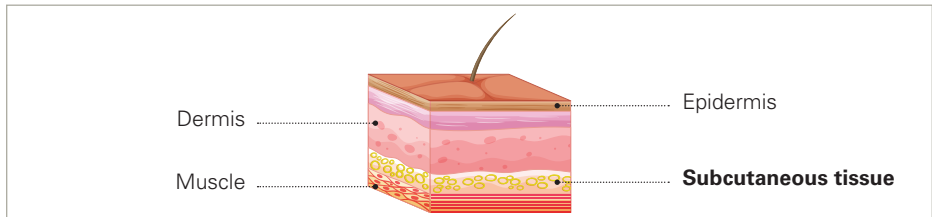
It is important to keep your scheduled treatment appointments to avoid experiencing symptoms of withdrawal. Symptoms of withdrawal include aches and pains, sweating, nausea and stomach cramps, anxiety and cravings.

If you experience any symptoms of withdrawal after starting on Buvidal, contact your healthcare professional and discuss the symptoms you are experiencing. Together you can decide if you need an extra low dose of Buvidal and if your weekly or monthly dose needs to be adjusted.

Where will I be injected with Buvidal?

Buvidal is given as a single injection under the skin in the subcutaneous tissue of any of the allowed injection areas (buttock, thigh, abdomen or upper arm). You can choose where to have the injection, provided there is enough subcutaneous tissue (innermost layer of skin, made up of fat and connective tissue). Each injection area can have multiple injection sites.

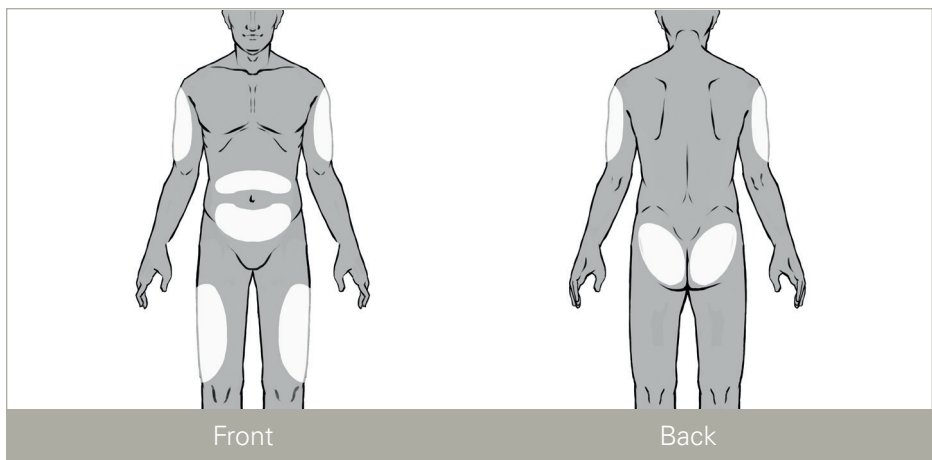
Subcutaneous tissue layer between the skin and the muscle



Injection sites should be rotated for both weekly and monthly injections.

A minimum of eight weeks should pass before re-injecting in a previously used injection site.

Injection areas for Buvidal



After starting treatment with Bupival

Can my Bupival dose be adjusted?

Doses of Bupival may be increased or decreased, and your doctor can switch between weekly and monthly injections according to your individual needs and their clinical judgement. Following switching, you may need closer monitoring for a period of time to ensure that the adjusted dose is optimal for you.

A maximum of one extra Bupival 8 mg dose may be administered at an unscheduled visit between regular weekly and monthly doses, based on your individual needs and your doctor's evaluation.

How often will I need to receive injections?

In consultation with your doctor and other members of your healthcare team, a decision will be made as to whether weekly or monthly injections of Bupival are best for you. If you are just starting on Bupival and this is the first time you are receiving buprenorphine, you will start on weekly injections. Then, after four weeks of treatment, you and your healthcare team can consider whether monthly injections of Bupival might work for you.

What will happen if I miss a dose?

It is very important to keep all your appointments to receive Bupival. If you miss an appointment, contact your healthcare team to schedule your next dose.

To help you remember your next appointment, write it down or add it to the patient card you have been provided with. Consider doing this when you are making the appointment.

Ask your support team for other tips and advice to help you keep your appointments if you are having trouble remembering them.

What should I do if I experience withdrawal symptoms or cravings after receiving Bupival?

It is unlikely that you will experience withdrawal symptoms or cravings. However, if this does happen, contact your doctor so that together you can assess the symptoms and evaluate if your dose needs to be supplemented and/or adjusted.

Are there important things I should be aware of?

Refer to the package insert or discuss with your doctor if you have any concerns regarding:

- breathing problems
- drowsiness
- dependency
- liver function
- withdrawal symptoms

- blood pressure changes
- pain sensitivity
- sleep related breathing disorders
- interactions with other medicines

What side effects can I expect from treatment with Bupival?

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects experienced with Bupival are generally similar to those experienced with sublingual buprenorphine, with the exception of injection site reactions.

Tell your doctor immediately or seek urgent medical attention if:

- You experience side effects such as sudden wheezing; difficulty breathing; swelling of the eyelids, face, tongue, lips, throat or hands; rash or itching, especially over your whole body. These may be signs of a life-threatening allergic reaction.
- You start to breathe more slowly or weakly than usual (respiratory depression).
- You start to feel faint, as this may be a sign of low blood pressure.

Also tell your doctor immediately if you get side effects, such as severe tiredness, if you have no appetite or if your skin or eyes look yellow. These may be symptoms of liver damage.

Other side effects may include:

- Very common side effects (may affect more than one in 10 people):
 - Insomnia (inability to sleep)
 - Headache
 - Nausea (feeling sick)
 - Sweating, drug withdrawal syndrome, pain
- Common side effects (may affect up to one in 10 people):
 - Infection, influenza, sore throat and painful swallowing, runny nose
 - Swollen glands (lymph nodes)
 - Hypersensitivity
 - Decreased appetite
 - Anxiety, agitation, depression, hostility, nervousness, abnormal thinking, paranoia
 - Sleepiness, feeling dizzy, migraine, burning or tingling in hands and feet, fainting, tremor, increase in muscle tension, speech disorders
 - Watery eyes, abnormal widening or narrowing of the pupil (the dark part of the eye)
 - Palpitations

- Low blood pressure
 - Cough, shortness of breath, yawning, asthma, bronchitis
 - Constipation, vomiting (being sick), stomach pain, flatulence (wind), indigestion, dry mouth, diarrhoea
 - Rash, itching, hives
 - Joint pain, back pain, muscle pain, muscle spasms, neck pain, bone pain
 - Painful periods
 - Injection site reactions, for example pain, itching, red skin, swelling and hardening of skin, swelling of the ankles, feet or fingers, weakness, feeling unwell, fever, chills
 - Drug withdrawal syndrome in the new-born
 - Chest pain
 - Abnormal liver test results
- Uncommon side effects (may affect up to one in 100 people):
 - Skin infection at the injection site
 - A feeling of dizziness or spinning (vertigo)
 - Not known (frequency cannot be estimated from the available data):
 - Hallucinations, feeling of happiness and excitement (euphoria)
 - Abnormal redness of the skin
 - Painful or difficult urination
 - Injection site reactions e.g. open sores, a swollen area with collected pus, discolouration caused by death of cells or tissue at the injection site

Talk to your doctor if you experience any side effects, including any possible side effects not listed in this booklet. Also ask your doctor for advice on how to manage any side effects that you may experience.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

In the UK, you can report side effects directly via the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk/>

In ROI, reporting forms can be found at <https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form>

You can also report side effects directly to Camurus via email to safety@camurus.com

By reporting side effects, you can help provide more information on the safety of this medicine.

What should I do if I use too much buprenorphine?

As Buvidal is given to you by a healthcare professional, it is very unlikely that you will receive too much buprenorphine. Buvidal comes in a pre-filled syringe with the dose your doctor has prescribed for you.

If you use too much buprenorphine, or other kinds of opioids, you must immediately seek medical attention, as overdose may cause serious and life-threatening breathing problems. Symptoms of overdose may include:

- Excessive sweating
- Feeling more sleepy or drowsy than usual
- Excessive constriction of the pupil
- Feeling faint
- Nausea and/or vomiting
- Difficulty speaking, for example slurred speech

What if I do not like the experience of a long-acting injection and prefer to continue my treatment with a daily dose medication?

Buvidal has been designed to avoid the ups and downs of daily dosing. However, if you find that you do not like the experience of a depot injection, then you should discuss this with your doctor or other member of your healthcare team. They can advise you on the best way to switch to a daily dose treatment.

What if I want to stop treatment?

If you feel that you are ready to stop treatment, you should discuss this with your doctor or other member of your healthcare team. They can advise you on the best way to do this.

Can I transfer from Buvidal to other opioid dependence treatments?

After trying Buvidal, you may decide that it is not the best treatment for you and that you want to try another method to help you manage your opioid dependence.

If you are looking to change from treatment with Buvidal, discuss this with your doctor and other members of your healthcare team.

Can I use other medicines and other drugs while taking Buvidal?

Tell your doctor if you are taking, have recently taken or might take any other medicines. Some medicines may increase the side effects of Buvidal and may cause very serious reactions.

It is especially important to tell your doctor if you are taking:

- **benzodiazepines** (used to treat anxiety or sleep disorders). Taking too much of a benzodiazepine together with Buvidal may lead to death because both medicines can cause very slow and shallow breathing (respiratory depression). If you need a benzodiazepine, your doctor will prescribe the correct dose.
- **gabapentinoids** (gabapentin or pregabalin) (used to treat epilepsy or neuropathic pain). Taking too much of a gabapentinoid may lead to death because both medicines can cause very slow and shallow breathing (respiratory depression). You must use the dose that your doctor has prescribed for you.
- **alcohol or medicines containing alcohol**. Alcohol can worsen the sedative effect of this medicine.
- **other medicines that may make you feel sleepy and that are used to treat illnesses such as anxiety, sleeplessness, convulsions (fits) and pain**. When taken together with Buvidal, these medicines can slow down some brain activity and reduce alertness and how well you drive or operate machinery.

Examples of medicines that can make you feel sleepy or less alert include:

- Other opioids, such as methadone and certain painkillers and cough medicines (these medicines may also increase the risk of opioid overdose)
 - Antidepressants (used to treat depression)
 - Sedative antihistamines (used to treat allergic reactions)
 - Barbiturates (used to cause sleep or sedation)
 - Certain anxiolytics (used to treat anxiety disorders)
 - Antipsychotics (used to treat psychiatric disorders such as schizophrenia)
 - Clonidine (used to treat high blood pressure)
 - Opioid painkillers (these medicines may not work properly when taken together with Buvidal and they may increase the risk of overdose)
- **opioid painkillers**. These medicines may not work properly when taken together with Buvidal and they may increase the risk of overdose.
 - **naltrexone and nalmefene** (used to treat addiction disorders) as they can stop Buvidal from working properly. You should not take them at the same time as this medicine.

- **certain antiretrovirals** (used to treat HIV infection) such as ritonavir, nelfinavir or indinavir as they may increase the effects of this medicine.
- **certain antifungal medicines** (used to treat fungal infections) such as ketoconazole, itraconazole as they may increase the effects of this medicine.
- **macrolide antibiotics** (used to treat bacterial infections) such as clarithromycin and erythromycin as they may increase the effects of this medicine.
- **certain antiepileptic medicines** (used to treat epilepsy) such as phenobarbital, carbamazepine and phenytoin as they may decrease the effect of Buvidal.
- **rifampicin** (used to treat tuberculosis). Rifampicin may decrease the effect of Buvidal.
- **monoamine oxidase inhibitors** (used to treat depression) such as phenelzine, isocarboxazid, iponiazid and tranylcypromine as they may increase the effects of this medicine.
- **anti-depressants** such as moclobemide, tranylcypromine, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepine, or trimipramine. These medicines may interact with Buvidal and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

Can I continue with hepatitis C or HIV (human deficiency virus) treatment?

You can and should continue any antiretroviral treatment or hepatitis treatment while on Buvidal. However, you should speak to your doctor, as adjustments to your medications may be needed.

Can I take pain relief medications while on Buvidal?

You must consult your doctor about pain relief medications. Your doctor can judge which medications you can continue to take while being treated with Buvidal or whether you might need to take other medications.

Can I drink alcohol while taking Buvidal?

Using alcohol with this medicine may increase drowsiness and the risk of breathing problems.

Can I drive a car or operate heavy machinery while taking Buvidal?

Buvidal may make you sleepy and dizzy. This is more likely at the start of treatment and when your dose is being changed. These effects can be worse if you drink alcohol or take other sedative medicines. Do not drive, use any tools or machinery, or perform dangerous activities until you know how Buvidal affects you.

Can I use Buvidal while pregnant or breastfeeding?

If you are pregnant or breastfeeding, think you may become pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine. The risks of using Buvidal in pregnant women are not known. Your doctor will help you decide if you should continue taking the medicine during pregnancy. If you become pregnant while taking Buvidal, talk to your doctor.

Using this medicine during late pregnancy may cause drug withdrawal symptoms, including breathing problems, in your newborn baby. This may happen from several hours to several days after birth.

Check with your doctor before using Buvidal during breastfeeding as the medicine can pass into breast milk.

Seeking medical treatment not related to Buvidal

What should I do if I require medical treatment other than Buvidal?

If for any reason you are admitted to hospital, tell the staff that you are being treated with Buvidal, as it may affect your treatments. Ask the staff to contact your doctor if there is any doubt about what medical treatments are appropriate.

It is a good idea to carry a Patient Alert Card with you. A Patient Alert Card contains important information for healthcare professionals if you need emergency treatment. Ask your healthcare professional for a Patient Alert Card, complete it and keep it with you at all times. Alternatively, keep a note in your wallet with an emergency contact number of a friend, family member or healthcare professional who has knowledge about your condition and current treatment.

If you have any further questions please speak to your healthcare team.

Questions and notes

Write down your questions and notes about Buvidal and opioid dependence treatment here and discuss them with your healthcare professional at your next appointment.

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