

Weekly/Monthly  
**Buvidal**®

**BUPRENORPHINE**

MODIFIED RELEASE SOLUTION FOR  
INJECTION FOR SUBCUTANEOUS USE

# Getting started

Information for people who have  
been prescribed Buvidal®



**camurus**®

# Table of contents

About this booklet	3
What is Buvidal®?	4
Why am I being given Buvidal®?	4
Before you start treatment with Buvidal®	5
When not to take Buvidal®	5
Things to tell your prescriber	6
Important safety information - side effects	8
Starting treatment - administration	9
Starting treatment - what can I expect?	10
Frequently asked questions	11
Can I drive or operate heavy machinery?	11
What if I want to change to monthly or weekly?	11
Can I stop Buvidal® treatment?	11
What if I become pregnant or am breastfeeding?	12
What should I do if I require medical treatment while I am on treatment with Buvidal®?	12
What if I miss a dose?	13
What if I am given too much (overdose)?	13
Important reminders	14
Take Home Naloxone Program	14
Additional support	15
Notes	16
My treatment goals	17

# About this booklet

**This booklet is for people who have been prescribed Buvidal®.**

All medicines have risks and benefits. Your prescriber has weighed the risks of you taking Buvidal® against the benefits they expect it will have for you.

This booklet contains information about Buvidal®. It is important that you also read the Buvidal® Consumer Medicines Information leaflet for a full list of important safety information, which can be accessed by scanning the QR code or visiting **ebs.tga.gov.au**.



**ebs.tga.gov.au**

It is important that you talk to your treatment provider about any questions or concerns you have about this medicine. You can also contact Camurus Medical Information on 1800 142 038, but please note that they cannot provide medical advice.

## WARNINGS

### **Risk of Serious Harm or Death with Intravenous Administration**

Buvidal® must not be injected into your veins as it could cause serious harm or death by stopping your blood flow and the possible formation of clots in your veins and lungs which could be life-threatening.

### **Hazardous and harmful use**

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. You should be monitored for an ongoing risk of hazardous and harmful use regularly during opioid substitution therapy with Buvidal®.

### **Life threatening respiratory depression**

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, especially at the start of treatment or following a change in dose.

### **Concomitant use of benzodiazepines and other central nervous system (CNS) depressants, including alcohol**

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. Patients and their caregivers should be made aware of the symptoms of respiratory depression. Patients and their caregivers should also be informed of the potential harms of consuming alcohol while being treated with Buvidal®.

## What is Buvidal®?¹,²

Buvidal® is a long-acting medicine which means it will last for a week or month, depending on which dose you have been prescribed.

Buvidal® contains the medicine buprenorphine. Buprenorphine is a partial opioid agonist that acts as a substitute for opioids and helps control symptoms of withdrawal.



## Why am I being given Buvidal®?¹,²

**Buvidal® is used for the treatment of opioid dependence within a framework of medical, social, and psychological support.**

This means that Buvidal® has been prescribed to help you manage your opioid dependence, but it is not meant to be used without other supports. Buvidal® should be offered with the additional support and medical care that you may need.



**Buvidal® Weekly** can be prescribed to start people on treatment, and as maintenance (ongoing) treatment.



**Buvidal® Monthly** can be prescribed for maintenance (ongoing) treatment only. People prescribed Buvidal® Monthly need to first be stabilised on Buvidal® Weekly or sublingual buprenorphine.

## Before you start treatment with Buvidal®¹,²



### WHEN NOT TO TAKE BUVIDAL®

**You must not receive Buvidal® treatment if you are:**

#### Under 16 years of age

#### Allergic to any of the following:

Buprenorphine

Soybean (phosphatidyl choline)

#### Medicines containing:

- Glyceryl Dioleate,
- Ethanol (used in Buvidal® Weekly)
- N-methyl-2-pyrrolidone (used in Buvidal® Monthly)

#### Diagnosed with:

Serious breathing problems

Serious liver problems

**Intoxicated from alcohol or have the 'shakes' and hallucinations (delirium tremens)**

**If you have any questions, or if you are concerned you might have one of these conditions, please speak to your prescriber.**



## THINGS TO TELL YOUR PRESCRIBER

### Medical history

Your prescriber will have reviewed your medical history, but be sure you tell them about any of the following that applies to you:

- Kidney disease,
- Liver problems,
- Low blood pressure,
- Recent head injury or brain disease,
- Urinary disorder (especially anything linked to enlarged prostate in men),
- Thyroid problems,
- Adrenocortical disorder (e.g. Addison's disease),
- Gallbladder problems,
- Excess alcohol use,
- History of seizures,
- Breathing problems.

### Using other medicines or drugs during treatment

It is important that you tell your treatment provider about any medicines, vitamins, or supplements that you are taking, and any alcohol or drug use before starting treatment with Buvidal®. This will help to determine whether it is safe for you to be treated with Buvidal®, or whether they need to make changes to your medications.

**Due to the modified release properties of Buvidal® if you are taking other medications and/or if you have other health conditions, your treatment provider may need to monitor you for signs and symptoms of toxicity, overdose, or withdrawal caused by increased or decreased levels of buprenorphine.<sup>3,4</sup>**

### Examples of the types of medicines and substances that may affect how Buvidal® works:

Alcohol
Antibiotics
Antidepressants and other medicines that may increase serotonin levels
Antifungal medicines
Anxiety medicines
Cannabis
Epilepsy medicines
Gabapentinoids
HIV/AIDS medicines
Opioids
Sleep disorder medicines
Tuberculosis medicines

**Please read the Buvidal® Consumer Medicines Information leaflet for a full list of medicines and substances that may interfere with how Buvidal® works.**

## Important safety information - side effects<sup>1,2</sup>

All medicines can have side effects. However, some side effects may need medical attention. Read the information below and ask your treatment provider if you have any further questions about side effects.

**Commonly reported side effects from Buvidal<sup>®</sup> clinical trials, include, but are not limited to:<sup>3,4</sup>**

Redness, soreness, swelling or itching at the injection site

Headache

Upset stomach, including nausea, vomiting, diarrhoea, and constipation

Difficulty sleeping

### Serious side effects

Serious side effects of Buvidal<sup>®</sup> may require urgent medical attention.

**If you experience any of the following serious side effects, tell your treatment provider immediately, call 000 or go to nearest Hospital Emergency Department as you may need urgent medical attention.**

#### Possible signs of an allergic reaction:

Sudden wheezing, difficulty breathing, swelling of the eyelids, face, tongue, lips, throat, or hands; rash or itching especially those covering your whole body.

#### Possible sign of respiratory depression:

If you start to breathe more slowly or weakly than expected.

#### Possible symptoms of liver damage:

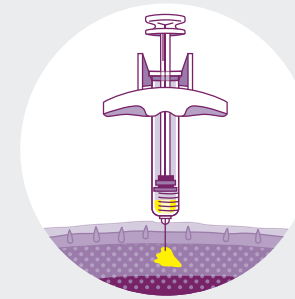
Severe tiredness (fatigue), have no appetite, your skin or eyes look yellow.

#### Possible sign of low blood pressure:

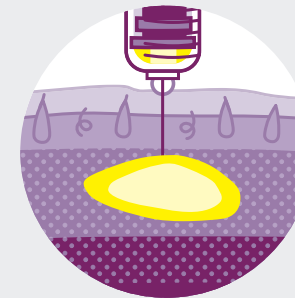
If you start to feel faint.

**Please read the Buvidal<sup>®</sup> Consumer Medicines Information leaflet for a full list of side effects.**

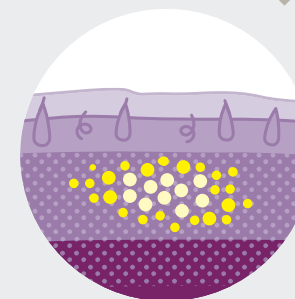
## Starting treatment - administration<sup>5</sup>



**BUVIDAL<sup>®</sup> IS A CLEAR YELLOW LIQUID THAT IS INJECTED UNDER YOUR SKIN.**



**THE LIQUID FORMS A SMALL GEL MASS THAT CAN SOMETIMES BE SEEN OR FELT.**



**THE GEL WILL SLOWLY BREAK DOWN OVER TIME UNTIL IT IS GONE.**

As it breaks down, the gel slowly releases medicine over time. How long this takes is determined by whether you are taking Buvidal<sup>®</sup> Weekly or Buvidal<sup>®</sup> Monthly.

## Starting treatment - what can I expect?<sup>1,2</sup>

- Your prescriber will have talked to you about the dosing options available and will prescribe the correct starting dose.
- Buvidal® can only be administered to you by a trained healthcare professional, for example, a pharmacist, doctor or nurse. Buvidal® cannot be taken home or be self-administered.
- You will be administered Buvidal® by subcutaneous injection (under the skin). **Injecting Buvidal® in any other way is potentially dangerous. Injecting Buvidal® into a vein may cause serious harm or death.**
- Buvidal® may be injected into your buttocks, thigh, abdomen, or upper arm.
- You may experience temporary redness, swelling, or itching at the injection site.
- It is very important for you to keep all your appointments to receive Buvidal®. If you miss an appointment, ask your treatment provider when to schedule your next dose.
- You may receive treatment once weekly or once monthly. You can also change between weekly and monthly dosing depending on your circumstances, and in consultation with your prescriber.
- During your treatment, your prescriber may talk to you about increasing or decreasing your dose, depending on how you respond to the medicine. If required, you may receive one additional 8 mg dose of Buvidal® Weekly between regular doses.
- After you have been on treatment for a period of time, your prescriber may talk to you about gradually reducing your dose under careful medical supervision.
- You should continue treatment with Buvidal® for as long as your prescriber has recommended. If you want to stop treatment, it is important to discuss this with your prescriber first.

## Frequently asked questions<sup>1,2</sup>



### CAN I DRIVE OR OPERATE HEAVY MACHINERY?

- Be careful driving or operating machinery until you know how Buvidal® affects you.
- This medicine may cause dizziness and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous. This feeling is more likely at the start of treatment or if your dose is changed. This effect can be worse if you drink alcohol or take other sedative medicines.
- Be careful when drinking alcohol because Buvidal® increases the risk of dizziness and respiratory failure.



### WHAT IF I WANT TO CHANGE TO MONTHLY OR WEEKLY?

- It is possible to switch between Buvidal® Weekly and Buvidal® Monthly. Talk with your prescriber if this is something you would like to consider.



### CAN I STOP BUVIDAL® TREATMENT?

- You should not stop Buvidal® treatment without discussing it with your prescriber. Continue treatment with Buvidal® for as long as your prescriber advises. Stopping treatment may cause withdrawal symptoms. If you feel unwell, let your prescriber know.
- Your prescriber may suggest gradually reducing your Buvidal® dose. Depending on your situation, your dose may continue to be reduced under careful medical supervision.





## WHAT IF I BECOME PREGNANT OR I AM BREASTFEEDING?

- Tell your prescriber if you are planning to become pregnant before starting or during treatment with Buvidal®.
- If you become pregnant during treatment with Buvidal®, talk to your prescriber immediately. They will discuss your treatment options with you.
- Talk to your prescriber if you are breastfeeding, or plan to breastfeed.



## WHAT SHOULD I DO IF I REQUIRE MEDICAL TREATMENT WHILE I AM ON TREATMENT WITH BUVIDAL®?

- Talk to your healthcare provider about any medical conditions or treatments you may need.
- If you are admitted to hospital for any reason, tell the staff you are being treated with Buvidal®, as it may affect the treatments you receive.
- A Buvidal® Patient Alert Card is available which you should carry with you. In case you need emergency medical treatment, the Patient Alert Card contains important information for health care professionals such as your current Buvidal® dose, whether you are being treated with weekly or monthly injections and the date of last injection.
- You should request your prescriber to add their phone number on the Patient Alert Card just in case you need to contact them.



## WHAT IF I MISS A DOSE?

- Try to organise your appointments at a time that will suit your regular attendance.
- If you miss an appointment, contact your treatment provider as soon as you can so you can schedule your next dose.
- Missing doses can result in symptoms of withdrawal. If you find it hard to remember your appointment, talk to your treatment provider about ways that may help.



## WHAT IF I AM GIVEN TOO MUCH (OVERDOSE)?

- Buvidal® is given to you under the supervision of a healthcare professional. Buvidal® comes in a syringe pre-filled with the dose you have been prescribed, so it is very unlikely you will be given too much.
- If you feel you have been given too much Buvidal® you may need urgent medical attention. **You should immediately:**



Contact your prescriber, or call 000



Go to the Emergency Department at the nearest hospital, or



Call the Poisons Information Centre (13 11 26) for advice.





**You should do this even if there are no signs of discomfort or poisoning.**

If you have any further questions, please contact your prescriber for advice.

## Important reminders<sup>1,2</sup>

The following is a list of things you should do while on treatment with Buvidal®:



-  Tell any other healthcare providers who treat you, including dentists and pharmacists, that you are taking Buvidal®. If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine as it may affect other medicines used during surgery.
-  If you are thinking of becoming pregnant or become pregnant while taking this medicine, tell your prescriber immediately.
-  If you are about to have any blood tests, tell your healthcare provider that you are taking this medicine. It may interfere with the results of some tests.
-  Keep all your appointments so your prescriber can check your progress. Your prescriber may do some tests to check your liver function to make sure the medicine is working and to prevent unwanted side effects.

## Take Home Naloxone Program<sup>6</sup>

Under the national Take Home Naloxone Program, **naloxone is available free of charge and without a prescription across all participating pharmacies in Australia.** For a list of participating pharmacies in your area, visit <https://www.ppaonline.com.au/take-home-naloxone> or scan the QR code.



Naloxone is also available over the counter from non-participating pharmacies for a fee.

Naloxone is a drug that can temporarily reverse the effects of an opioid overdose or adverse reaction. For more information about how it works, and how to use naloxone, speak to a pharmacist.

## Additional support

Medicine is only part of your treatment. If you need additional support, you can start by talking with your prescriber. If you would like more information or wish to find other services experienced in supporting individuals with opioid dependence, there are a number of resources and options available to help you, see table below (note: this is not a full list of all available services).

TYPE	NAME	DESCRIPTION	PHONE	WEBSITE
INFORMATION AND REFERRAL SERVICE	National Alcohol and Other Drug Hotline	Provides support and information over the phone. You can choose to share your details or to remain anonymous. When you call this number, you will be automatically directed to your nearest alcohol and other drug service.	1 800 250 015	none
INFORMATION AND COUNSELLING	Counselling ONLINE	A free and confidential service that provides 24/7 support to people across Australia affected by alcohol or drug use. Accessed by website only.	none	counselling online.org.au
PEER SUPPORT	Narcotics Anonymous	A non-profit association supporting people for whom drugs have become a major problem.	1300 652 820	na.org.au
PEER SUPPORT	SMART Recovery Australia	Non-profit organisation that delivers mutual aid meetings supporting people with behaviours of concern (addictive behaviours) across Australia.	none	smartrecovery australia.com.au

LIFELINE 13 11 14 (available 24 hours a day / 7 days a week)



[illegible]

Now you have a week or a month between your doses.



It's likely you'll have more time to focus on your goals.



The purpose of the following pages is to assist you in setting and achieving your goals.



You can use the prompts to reflect on the reasons you chose a long-acting treatment and your goals for treatment.

You can revisit the following pages later to remind yourself of why you started treatment and to give you motivation to achieve your goals.

## What does long-acting treatment mean for me?

These are the top 3 reasons I chose long-acting treatment:

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_

These are 5 things I can do with the time between doses:

1. \_\_\_\_\_  
\_\_\_\_\_
2. \_\_\_\_\_  
\_\_\_\_\_
3. \_\_\_\_\_  
\_\_\_\_\_
4. \_\_\_\_\_  
\_\_\_\_\_
5. \_\_\_\_\_  
\_\_\_\_\_

## My goals

Goal #1 \_\_\_\_\_

What steps do I need to take to achieve this?

\_\_\_\_\_  
\_\_\_\_\_

Progress



Goal started ☐

How confident do I feel about achieving this goal?



Goal finished ☐

Goal #2 \_\_\_\_\_

What steps do I need to take to achieve this?

\_\_\_\_\_  
\_\_\_\_\_

Progress



Goal started ☐

How confident do I feel about achieving this goal?



Goal finished ☐

Goal #3 \_\_\_\_\_

What steps do I need to take to achieve this?

\_\_\_\_\_  
\_\_\_\_\_

Progress



Goal started ☐

How confident do I feel about achieving this goal?



Goal finished ☐

**REFERENCES:** **1.** Buvidal® Weekly Consumer Medicine Information March 2023. **2.** Buvidal® Monthly Consumer Medicine Information March 2023. **3.** Buvidal® Weekly Australian Approved Product Information 19 July 2024. **4.** Buvidal® Monthly Australian Approved Product Information 19 July 2024. **5.** Australian Public Assessment Report for Buprenorphine, 2019. **6.** Australian Government, Department of Health and Aged Care (2023). About the Take Home Naloxone program. Accessed 19 July 2024 at: <<https://www.health.gov.au/our-work/take-home-naloxone-program/about-the-take-home-naloxone-program>>.

**camurus**®

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