

Buvidal[®] Monthly

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about being given this medicine, speak to your doctor or pharmacist.

WARNINGS

Risk of Serious Harm or Death with Intravenous Administration

Hazardous and harmful use.

Life threatening respiratory depression

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

1. Why am I being given Buvidal Monthly?

Buvidal Monthly contains the active ingredient buprenorphine. Buprenorphine acts as a substitute for opioids and helps withdrawal. Buvidal Monthly is used for maintenance treatment of opioid dependence.

For more information, see Section [1. Why am I being given Buvidal Monthly?](#) in the full CMI.

2. What should I know before I am given Buvidal Monthly?

Do not use if you have ever had an allergic reaction to Buvidal Monthly or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

Tell your doctor if you have or have had any of the following medical conditions: kidney disease, liver problems, problems with excess alcohol use, history of seizures or breathing problems

For more information, see Section [2. What should I know before I am given Buvidal Monthly?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Buvidal Monthly and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How am I given Buvidal Monthly?

- Your doctor will prescribe the correct starting dose of Buvidal Monthly for you. During treatment with Buvidal Monthly, your doctor may decrease or increase the dose of Buvidal Monthly according to your needs.

More instructions can be found in Section [4. How am I given Buvidal Monthly?](#) in the full CMI.

5. What should I know while being given Buvidal Monthly?

Things you should do	<ul style="list-style-type: none">● Remind any doctor, dentist or pharmacist you visit that you are being given Buvidal Monthly.
Things you should not do	<ul style="list-style-type: none">● Do not stop treatment of this medicine suddenly, you should discuss stopping your treatment with your doctor. Stopping treatment may cause withdrawal symptoms.
Driving or using machines	<ul style="list-style-type: none">● Be careful driving or operating machinery until you know how Buvidal Monthly affects you. This medicine may cause dizziness and drowsiness in some people.
Drinking alcohol	<ul style="list-style-type: none">● If you drink alcohol with this medicine, the risk of

	breathing problems may be increased.
--	--------------------------------------

For more information, see Section [5. What should I know while being given Buvidal Monthly?](#) in the full CMI.

6. Are there any side effects?

- Serious side effects that could occur while you are receiving Buvidal Monthly include wheezing, difficulty breathing, swelling of the eyelids, face, tongue, lips, throat or hands; rash or itching especially those covering your whole body. These may be signs of a life-threatening allergic reaction.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING: Risk of Serious Harm or Death with Intravenous Administration

Buvidal Monthly 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 Monthly 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 Monthly.

Life threatening respiratory depression

Serious, life-threatening or fatal respiratory depression may occur with the use of Buvidal Monthly. Be aware of situations which increase the risk of respiratory depression, and monitor patients closely, especially on initiation or following a dose increase.

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 taking Buvidal Monthly.

Buvidal[®] Monthly

Active ingredient(s): Buprenorphine

Consumer Medicine Information (CMI)

This leaflet provides important information about using Buvidal Monthly. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Buvidal Monthly.**

Where to find information in this leaflet:

- [1. Why am I being given Buvidal Monthly ?](#)
- [2. What should I know before I am given Buvidal Monthly?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given Buvidal Monthly?](#)
- [5. What should I know while being given Buvidal Monthly?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given Buvidal Monthly?

Buvidal Monthly contains the active ingredient buprenorphine.

Buvidal Monthly is Schedule 8 medicine classification, it contains buprenorphine which acts as a substitute for opioids and it helps withdrawal from opioids over a period of time. This medicine is available only with a doctor's prescription.

Buvidal Monthly is used 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.

2. What should I know before I am given Buvidal Monthly?

Warnings

Do not receive Buvidal Monthly if:

- you are allergic to buprenorphine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- **Do not receive Buvidal Monthly if you are under 16 years of age.** Safety and effectiveness in children younger than 16 years has not been established.
- **Do not receive Buvidal Monthly if you have serious medical problems:**
 - with your liver
 - with your breathing such as asthma
 - if you are intoxicated due to alcohol or have delirium tremens (the 'shakes' and hallucinations)

Check with your doctor if you:

- Have any other medical conditions:
 - any kidney disease
 - liver problems such as hepatitis
 - low blood pressure
 - recently suffered a head injury or brain disease
 - a urinary disorder (especially linked to enlarged prostate in men)
 - thyroid problems
 - an adrenocortical disorder (eg Addison's disease)
 - gall bladder problems
 - problems with excess alcohol use
 - history of seizures.

- take any medicines for any other condition

If you have not told your doctor about any of the above, tell him/her before you receive Buvidal Monthly.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

If you become pregnant while taking this medicine, tell your doctor immediately.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Buvidal Monthly and affect how it works.

Medicines that may increase the effect of Buvidal Monthly include:

- certain medicines for treating anxiety and sleeping disorders such as benzodiazepines
- gabapentinoids
- alcohol
- cannabis
- medicines that may make you feel sleepy, which may be used for treating depression, convulsion, pain and high blood pressure. These may include methadone, anti-cough medications, anti-depressants, antihistamines, sedatives, barbiturates, some anxiolytics, neuroleptics, clonidine, and monoamine oxidase inhibitors
- strong pain killers such as morphine, methadone and fentanyl
- certain medicines for treating HIV/AIDS such as ritonavir, nelfinavir or indinavir
- certain medicines for treating fungal and bacterial infections such as ketoconazole, itraconazole or macrolide antibiotics.

Medicines that may reduce the effect of Buvidal Monthly include:

- naltrexone and nalmefene, which are used to treat dependence disorders
- certain medicines used to treat epilepsy such as phenobarbital, carbamazepine and phenytoin
- certain medicines used to treat tuberculosis such as rifampicin

Medicines that may be affected by Buvidal (Monthly)

- Medicines that may increase serotonin levels, such as escitalopram, duloxetine, venlafaxine, tricyclic antidepressants, and phenelzine

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Buvidal Monthly.

4. How am I given Buvidal Monthly?

How much will I be given

- Your doctor will determine the best dose for you. During your treatment, the doctor may adjust the dose, depending on how you respond to the medicine.
- You will receive treatment with Buvidal Monthly in a hospital, clinic or pharmacy.
- Buvidal Monthly is given by a healthcare professional as an injection under the skin (subcutaneously) in the buttock, thigh, abdomen or upper arm.

Starting treatment with Buvidal Monthly

Buvidal Monthly is for maintenance treatment only. Your doctor will prescribe the correct starting dose of Buvidal Monthly for you.

Maintenance treatment and dose adjustment

- During maintenance treatment with Buvidal Monthly, your doctor may decrease or increase the dose of this medicine according to your needs. If required, you may receive one 8 mg dose of Buvidal Weekly on top

of your regular monthly doses. The maximum dose for Buvidal Monthly that can be received each month is 160 mg.

Changing between Monthly treatment and Weekly treatment

You may be changed from Monthly dosing to Weekly dosing or from Weekly dosing to Monthly dosing. Your doctor will prescribe the correct dose when you change between dosing intervals.

How long will it be given for

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

After a period of successful treatment, your doctor may gradually reduce your dose. Depending on your condition, your dose may continue to be reduced under careful medical supervision.

If you forget your treatment with Buvidal Monthly

It is very important for you to keep all your appointments to receive Buvidal Monthly. If you miss an appointment, ask your doctor when to schedule your next dose.

If you are given too much Buvidal Monthly

As Buvidal Monthly is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. Buvidal Monthly comes in a syringe pre-filled with the dose your doctor has prescribed. However, if you feel you have been given too much of Buvidal Monthly you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

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

5. What should I know while being given Buvidal Monthly?

Important things to be aware of while you are being given this medicine

- **Breathing problems**

Some people have died from the reduced ability to breathe (respiratory depression) because they took a similar medicine also containing buprenorphine, together with central nervous system depressants such

as benzodiazepines, gabapentinoids, alcohol or other opioids.

- **Drowsiness**

This medicine may cause drowsiness especially when taken with alcohol or other central nervous system depressants such as benzodiazepines, tranquilisers, sedatives, gabapentinoids or hypnotics.

- **Dependence**

This medicine can cause dependence.

- **Liver damage**

Liver damage has been reported after taking buprenorphine, especially when the medicine is misused. This could also be due to viral infections (chronic hepatitis C), alcohol abuse, anorexia or use of other medicines with the ability to harm your liver. Regular blood tests may be conducted by your doctor

- **Blood pressure**

This product may cause your blood pressure to drop suddenly, causing you to feel dizzy, if you get up too quickly from sitting or lying down.

- **Athletes**

Athletes should be aware that this medicine may cause a positive reaction to "anti-doping" tests.

- **Elderly**

The safety and effectiveness in patients over 65 years of age has not been established.

- **Diagnosis of unrelated medical conditions**

This medicine may mask pain symptoms that could assist in the diagnosis of some diseases. Do not forget to advise your doctor if you are being given this medicine.

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Buvidal Monthly.

If you are going to have surgery, tell the surgeon or anesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests to check your liver function from time to time to make sure the medicine is working and to prevent unwanted side effects.

Remind any doctor, dentist or pharmacist you visit that you are using Buvidal Monthly.

Things you should not do

Do not stop treatment with this medicine suddenly, you should discuss stopping your treatment with your doctor. Stopping treatment may cause withdrawal symptoms.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Buvidal Monthly affects you.

Buvidal Monthly may cause dizziness and drowsiness in some people. This is more likely to happen at the start of treatment and when your dose is being changed. This effect can be worse if you drink alcohol or take other sedative medicines. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may cause dizziness and risk of respiratory failure may be increased.

Looking after your medicine

The hospital, clinic, or pharmacy where you receive your treatment will store Buvidal Monthly under the required conditions.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">● Effects on the body - General:● flushing● tremor● decreased appetite● pain when urinating● swelling of the legs and arms <p>Effect on the body - Nervous system related:</p> <ul style="list-style-type: none">● difficulty sleeping● headache● sleepiness● dizziness, feeling off balance	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● malaise, yawning ● dizziness or fainting when standing up ● headache-migraine <p>Effect on the body - Stomach related:</p> <ul style="list-style-type: none"> ● upset stomach including, nausea, vomiting and diarrhoea or constipation ● upset stomach including stomach pain, wind, indigestion ● dry mouth <p>Effect on the body - Skin related:</p> <ul style="list-style-type: none"> ● redness, soreness, swelling or itching at the Buvidal Monthly injection site ● hives, rash, itching <p>Effects on the body - Eye related:</p> <ul style="list-style-type: none"> ● abnormal vision <p>Effects on the body - Infection related:</p> <ul style="list-style-type: none"> ● flu like symptoms, such as chills, fever, sore 	

Less serious side effects	What to do
<p>throat, coughing, runny nose, watery eyes and sweating</p> <ul style="list-style-type: none"> ● respiratory infection <p>Effects on the body - Psychiatric related</p> <ul style="list-style-type: none"> ● depression, abnormal thinking, agitation, nervousness, anger, hallucinations ● anxiety <p>Effect on the body - Pain related:</p> <ul style="list-style-type: none"> ● pain in the abdomen, back, and muscles, leg cramps, chest pain, neck pain, menstrual pain, muscle weakness ● pain in joints, <p>Effect on the body - Breathing related:</p> <ul style="list-style-type: none"> ● shortness of breath, enlarged or sore lymph nodes <p>Effects on the body - heart related:</p>	

Less serious side effects	What to do
<ul style="list-style-type: none"> • strong or irregular heartbeat 	

Serious side effects

Serious side effects	What to do
<p>Effects on the body-breathing related:</p> <ul style="list-style-type: none"> • sudden wheezing, difficulty breathing, swelling of the eyelids, face, tongue, lips, throat or hands; rash or itching especially those covering your whole body. These may be signs of a life-threatening allergic reaction. • if you start to breathe more slowly or weakly than expected (respiratory depression). <p>Effect on body- General:</p> <ul style="list-style-type: none"> • severe fatigue (tiredness), have no appetite or if your skin or eyes look yellow. These 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>may be symptoms of liver damage.</p> <ul style="list-style-type: none"> • if you start to feel faint, as this may be a sign of low blood pressure. 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Some of these side effects such as liver problems can only be found when your doctor does tests from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Buvidal Monthly contains

Active ingredient (main ingredient)	buprenorphine
Other ingredients (inactive ingredients)	phosphatidyl choline [soybean], glyceryl dioleate, N-methyl-2-pyrrolidone
Potential allergens	Contains soya bean products

Do not take this medicine if you are allergic to any of these ingredients.

What Buvidal Monthly looks like

Buvidal Monthly is a modified release solution for injection. Each pre-filled syringe contains a yellowish to yellow clear liquid.

Pre-filled syringe containing 64 mg buprenorphine in 0.18 ml solution - AUST R 295045

Pre-filled syringe containing 96 mg buprenorphine in 0.27 ml solution - AUST R 295048

Pre-filled syringe containing 128 mg buprenorphine in 0.36 ml solution - AUST R 295051

Pre-filled syringe containing 160 mg buprenorphine in 0.45ml solution - AUST R 341073

Who distributes Buvidal Monthly?

Camurus Pty Ltd
223 Liverpool St
Darlinghurst, NSW, 2010

Phone Toll Free: 1800 142 038

® = Registered Trademark

This leaflet was prepared in March 2023.