

Buvidal® Weekly and 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, nurse practitioner or pharmacist.

WARNING

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?

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

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

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

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

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

Tell your healthcare professional 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?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Buvidal 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?

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

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

5. What should I know while being given Buvidal?

| | |
|----------------------------------|--|
| Things you should do | <ul style="list-style-type: none">Remind any doctor, dentist, nurse practitioner or pharmacist or other healthcare professionals you visit that you are being given Buvidal. |
| 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 healthcare professional. 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 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?](#) in the full CMI.

6. Are there any side effects?

- Serious side effects that could occur while you are receiving Buvidal 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 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, 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.

Buvidal[®] Weekly and Buvidal[®] Monthly

Active ingredient(s): Buprenorphine

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I being given Buvidal?

Buvidal contains the active ingredient buprenorphine.

Buvidal 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 or nurse practitioner's prescription.

Buvidal Weekly is used for initiation and maintenance treatment of opioid dependence, with or without prior stabilisation on sublingual buprenorphine or buprenorphine/naloxone, within a framework of medical, social and psychological support.

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?

Warnings

Do not receive Buvidal 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 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 if you have serious medical problems:**
 - with your liver
 - with your breathing
 - if you are intoxicated due to alcohol or have delirium tremens (the 'shakes' and hallucinations)

Check with your healthcare professional if you:

- Have any other medical conditions:
- any kidney disease
- liver problems such as hepatitis

- respiratory conditions such as asthma or chronic obstructive pulmonary disease (COPD)
- 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 (e.g. 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 healthcare professional about any of the above, tell him/her before you receive Buprenorphine.

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 healthcare professional if you are pregnant or intend to become pregnant.

Talk to your healthcare professional if you are breastfeeding or intend to breastfeed.

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

3. What if I am taking other medicines?

Tell your healthcare professional 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 Buprenorphine and affect how it works.

Medicines that may increase the effect of Buprenorphine 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 Buprenorphine include:

- naltrexone and nalmefene, which can be used to treat dependence disorders or for weight loss
- 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 Buprenorphine

- Medicines that may increase serotonin levels, such as certain antidepressants

Check with your healthcare professional if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Buprenorphine.

4. How am I given Buprenorphine?

How much will I be given

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

Starting treatment with Buprenorphine

Your healthcare professional will prescribe the correct starting dose of Buprenorphine for you.

Maintenance treatment and dose adjustment

- During maintenance treatment with Buprenorphine, your healthcare professional may decrease or increase the dose of this medicine according to your needs. If required, you may receive one 8 mg dose on top of your regular weekly or monthly doses. The maximum weekly dose of Buprenorphine Weekly treatment that you can receive is 32 mg plus an additional 8 mg dose. The maximum dose for Buprenorphine Monthly that can be received each month is 160 mg.

Changing between weekly treatment and monthly treatment

You may be changed from weekly dosing to monthly dosing or from monthly dosing to weekly dosing. Your healthcare professional 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 healthcare professional 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 healthcare professional 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

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

If you are given too much Buvidal

As Buvidal is given to you under the supervision of your healthcare professional, it is very unlikely that you will receive too much. Buvidal comes in a syringe pre-filled with the dose your doctor or nurse practitioner has prescribed. However, if you feel you have been given too much of Buvidal 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?

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 healthcare professional if you are being given this medicine.

Things you should do

If you are about to be started on any new medicine, remind your healthcare professional that you are receiving Buvidal.

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

If you become pregnant while receiving this medicine, tell your doctor or nurse practitioner immediately.

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

Keep all of your healthcare professional'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, nurse practitioner or pharmacist or other healthcare professional you visit that you are receiving Buvidal.

Things you should not do

Do not stop treatment with this medicine suddenly, you should discuss stopping your treatment with your healthcare professional. 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 affects you.

Buvidal 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 healthcare professional if you drink alcohol.

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

Looking after your medicine

The hospital, clinic, or pharmacy where you receive your treatment will store Buvidal 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 healthcare professional 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 • 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 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 throat, coughing, runny nose, watery eyes and sweating • respiratory infection <p>Effects on the body - Psychiatric related</p> <ul style="list-style-type: none"> • depression, abnormal thinking, agitation, nervousness, anger, hallucinations | <p>Speak to your healthcare professional 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"> • 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> <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 may be symptoms of liver damage. • if you start to feel faint, as this may be a sign of low blood pressure. | <p>Call your healthcare professional straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

Tell your healthcare professional 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 healthcare professional before you decide to stop taking any of your medicines.

7. Product details

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

What Buvidal Weekly contains

| | |
|---|--|
| Active ingredient (main ingredient) | buprenorphine |
| Other ingredients (inactive ingredients) | phosphatidyl choline [soybean], glyceryl dioleate, ethanol absolute (alcohol), less than 100 mg per dose |
| Potential allergens | Contains soya bean products |

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 receive this medicine if you are allergic to any of these ingredients.

What Buvidal looks like

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

Buvidal Weekly:

Pre-filled syringe containing 8 mg buprenorphine in 0.16 ml solution - AUST R 294997.

Pre-filled syringe containing 16 mg buprenorphine in 0.32 ml solution - AUST R 295010

Pre-filled syringe containing 24 mg buprenorphine in 0.48 ml solution - AUST R 295013

Pre-filled syringe containing 32 mg buprenorphine in 0.64 ml solution - AUST R 295042

Buvidal Monthly:

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?

Camurus Pty Ltd

223 Liverpool St

Darlinghurst, NSW, 2010

Phone Toll Free: 1800 142 038

* = Registered Trademark

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