

# **Buvidal<sup>®</sup> Monthly**

Buprenorphine

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## **Consumer Medicine Information**

### **Warning:**

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

**Serious harm or death could result if administered intravenously. Buvidal Monthly forms a gel depot upon contact with body fluids and may cause occlusion, local tissue damage and thrombo-embolic events, including life threatening pulmonary emboli, if administered intravenously.**

#### **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.**

## **What is in this leaflet**

This leaflet answers some common questions about Buvidal Monthly. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

**If you have any concerns about this medicine, ask your doctor or pharmacist.**

**Keep this leaflet.**

You may need to read it again.

## **What Buvidal Monthly is used for**

This medicine is used as maintenance treatment for opioid dependence in patients who are also receiving medical, social and psychological support. It contains the active substance buprenorphine.

Buprenorphine 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.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

## **Before you are given Buvidal Monthly**

### **When you must not receive it**

**You must not receive Buvidal Monthly if you have an allergy to or are:**

- any medicine containing buprenorphine

- any of the ingredients listed at the end of this leaflet.
- pregnant
- breast-feeding

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

**You must 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.

**You must 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)

**This medicine should not be given after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

**If you are not sure whether you should receive this medicine, talk to your doctor.**

## **Before you receive it**

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following 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.

**Important things to be aware of while you are receiving 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 to monitor the condition of your liver. Tell your doctor if you have any liver problems before you start treatment with Buvidal Monthly.

## **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.

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

### **Taking other medicines**

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

Some medicines and Buvidal Monthly may interfere with each other. These 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, anti-histamines, sedatives, barbiturates, some anxiolytics, neuroleptics, clonidine, and monoamine oxidase inhibitors
- strong pain killers such as morphine, methadone and fentanyl
- naltrexone and nalmefene, which are used to treat dependence disorders
- 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.
- certain medicines used to treat epilepsy such as phenobarbital, carbamazepine and phenytoin
- certain medicines used to treat tuberculosis such as rifampicin

These medicines may be affected by Buvidal Monthly or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

## **How Buvidal Monthly is given**

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

You will receive treatment with Buvidal Monthly in a hospital, clinic or pharmacy. Buvidal Monthly injection will be given to you by a healthcare professional.

## **How much you will 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.

## **How it will be given**

Buvidal Monthly is given by a healthcare professional as an injection under the skin (subcutaneously) in the buttock, thigh, abdomen or upper arm.

## **When it will be given**

### **Before starting treatment with Buvidal Monthly**

You will need to be stabilised on treatment for opioid dependence on buprenorphine before you are given Buvidal Monthly maintenance treatment.

If you have not been stabilised, then you will need to receive sublingual buprenorphine or buprenorphine/naloxone for at least seven days before treatment with Buvidal Monthly commences.

### **Starting treatment with Buvidal Monthly**

Once you are stabilised on sublingual buprenorphine or buprenorphine/naloxone, you can start receiving Buvidal Monthly the day after your last dose of the sublingual treatment. 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 can receive additional doses with Buvidal Weekly during the dosing period. The maximum dose is 128 mg a month or 32 mg a week.

### **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 doctor will prescribe the correct dose when you change between dosing intervals.

## **How long it will 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 miss a dose**

### **If you miss a dose of 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 have trouble remembering your appointments, ask your pharmacist for some hints.**

## **If you are given too much (overdose)**

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 Buvidal Monthly, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

If you are given too much Buvidal Monthly some of the symptoms which may or may not occur are listed in the Side effects section of this leaflet.

## **While you are using Buvidal Monthly**

### **Things you must do**

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

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon or anaesthetist 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.

## **Things you must not do**

Do not stop treatment without the agreement of your doctor. Stopping treatment may cause withdrawal symptoms

## **Things to be careful of**

**Be careful driving or operating machinery until you know how Buvidal Monthly affects you.**

This medicine 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.

**Be careful when drinking alcohol while you are taking this medicine.**

If you drink alcohol, dizziness and risk of respiratory failure may be increased.

## **Side effects**

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Buvidal Monthly.**

This medicine helps most people with opioid dependence, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- difficulty sleeping
- headache
- sleepiness
- upset stomach including, nausea, vomiting and diarrhoea or constipation

- redness, soreness, swelling or itching at the Buvidal Monthly injection site
- dizziness, feeling off balance
- dry mouth
- swelling of the legs and arms
- respiratory infection
- pain when urinating
- pain in joints,
- anxiety
- hives, rash, itching

Other side effects which may occur are:

- strong or irregular heart beat
- abnormal vision
- upset stomach including stomach pain, wind, indigestion
- malaise, yawning
- flushing
- dizziness or fainting when standing up
- tremor

- flu like symptoms, such as chills, fever, sore throat, coughing, runny nose, watery eyes and sweating
- shortness of breath, enlarged or sore lymph nodes
- pain in the abdomen, back, and muscles, leg cramps, chest pain, neck pain, menstrual pain, muscle weakness
- headache-migraine
- decreased appetite
- depression, abnormal thinking, agitation, nervousness, anger, hallucinations

The above list includes the more common side effects observed with other medicines containing buprenorphine.

**Tell your doctor as soon as possible if you notice any of the following:**

- severe fatigue (tiredness), have no appetite or if your skin or eyes look yellow. These may be symptoms of liver damage.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- 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).
- if you start to feel faint, as this may be a sign of low blood pressure.

**The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also 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.

## **Product description**

### **What it looks like**

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

The following pack sizes are available:

Pre-filled syringes containing, 64 mg/0.18 mL, 96 mg/0.27 mL, and 128 mg/0.36 mL solution for injection.

Each pack contains 1 pre-filled syringe with stopper, needle, needle shield, safety device and 1 plunger rod.

## **Ingredients**

The active substance is buprenorphine.

The following pre-filled syringes are available:

### **Monthly injection:**

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

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

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

### **Other ingredients**

The other ingredients are phosphatidyl choline [soybean], glyceryl dioleate, N-methyl-2-pyrrolidone

This medicine (64mg, 96mg and 128mg) contains soya bean product.

## **Sponsor**

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