Buvidal® Weekly and Buvidal® Monthly

BUPRENORPHINE
MODIFIED RELEASE SOLUTION FOR INJECTION
FOR SUBCUTANEOUS USE

EDUCATIONAL MATERIAL FOR PATIENTS

Risk of Serious Harm or Death with Intravenous Administration
Serious harm or death could result if administered intravenously. Buvidal® Weekly and 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.

Contents

Why have I received this information?

- You have received this information because you are being treated with Buvidal® Weekly or Buvidal® Monthly (buprenorphine modified release solution for injection). This material should not be read as a standalone document but should be read together with the Consumer Medicines Information which can be provided by your health care professional.
- Your doctor or another healthcare professional will have informed you about Buvidal® and the benefits and risks associated with the use of the product. The following describes measures you as a patient should take in order to use the product in a safe manner and reduce the risks associated with it.

Are there any circumstances in which Buvidal® should not be used as treatment?

- You must not receive Buvidal® if you have:
  - An allergy to any medicine containing buprenorphine or phosphatidyl choline (soybean), glyceryl dioleate, ethanol (Buvidal® Weekly only) and N-methyl-2-pyrrolidone (Buvidal® Monthly only)
  - 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)
- You must not receive Buvidal® if you are:
  - Pregnant or breast-feeding
  - Below 16 years of age

Can I use other medicines and other drugs?

- The active substance in Buvidal, buprenorphine, is known to interact with other medicines and substances, for example:
  - Certain medicines for treating anxiety and sleeping disorders such as benzodiazepines
  - Gabapentinoids (such as pregabalin and gabapentin)
  - Alcohol

  - 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, antidepressants, 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
- Taking these medicines while being treated with Buvidal® may cause potentially life-threatening conditions such as difficulty breathing or drowsiness.
- It is important that you consult your doctor about any medicines that you are taking and your alcohol and drug consumption before starting treatment with Buvidal. That way, your doctor can judge what medicines you can continue to take while being treated with Buvidal® or if you might need to take other medicines instead.

How will I receive the treatment?

- Buvidal® will be given to you in a hospital or clinic by a trained healthcare professional, for example, your doctor or a nurse. **Self-administration is not allowed.**
- The product must only be injected in the subcutaneous tissue, that is, the tissue directly beneath the skin. **Injecting the product any other way is potentially dangerous. Injecting the product into a vein may cause serious harm or death.** The product forms a gel-like substance upon contact with body fluids and may cause blocking of the blood vessels, local tissue damage and blood clots, including life threatening blood clots in the lungs, if administered intravenously.

- Buvidal® is given as an injection in the buttock, thigh, abdomen or upper arm. The injected volume is dependent on the dose, but it is very small (the maximum volume is 0.64 mL). The injection is given under the skin where it will form a small gel which may sometimes be seen or felt on the skin. **Do not try to remove the gel.**
- You will need to be stabilised on treatment for opioid dependence on sublingual buprenorphine before you are given Buvidal. If you have not been stabilised, then you will need to receive sublingual buprenorphine or buprenorphine/naloxone for at least 7 days before treatment with Buvidal® commences.
- Once you are stabilised, you can start Buvidal® treatment the day after your last dose of the sublingual treatment.
- Your doctor will determine the best dose for you. During your treatment, the doctor may increase or decrease the dose, depending on how you respond to the medicine. The maximum dose is 128 mg a month or 32 mg a week.
- You may be changed from weekly dosing to monthly dosing or from monthly dosing to weekly dosing.
- It is very important for you to keep all your appointments to receive Buvidal. If you miss an appointment, ask your doctor when to schedule your next dose.
- You should continue treatment with Buvidal® 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 Buvidal® 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.

Which side effects might I experience and what should I do if I experience a side effect?

- All medicines can have side effects. Sometimes they are serious, most of the time they are not.
- You should tell your doctor if you notice anything that is making you feel unwell.
- **Common side effects** of Buvidal® include:
  - Redness, soreness, swelling or itching at the Buvidal® injection site
  - Upset stomach including nausea, vomiting, diarrhea, and constipation
  - Headache
  - Dizziness, feeling off balance
- Tell your doctor if you experience such common side effects if they worry you.
- **Serious side effects** of Buvidal® are rare but may include symptoms of liver damage such as severe tiredness, loss of appetite or yellowing of skin or eyes. Tell your doctor as soon as possible if you think you are experiencing a serious side effect.
- In case you experience a **very serious side effect** such signs of an allergic reaction (e.g. sudden wheezing, difficulty breathing, swelling of the eyelids, face, tongue, lips, throat or hands; rash or itching), if you start to breathe more slowly or weakly than expected or if you start to feel faint you should **immediately tell your doctor or pharmacist or go to the Accident and Emergency at your nearest hospital.** You may need urgent medical attention.
- Ask your doctor any questions you may have regarding side effects.

What should I do if I am given too much (overdose)?

- As Buvidal® is given to you under the supervision of your doctor or nurse, it is very unlikely that you will receive a too high dose of buprenorphine. The product comes in a syringe pre-filled with the dose your doctor has prescribed for you.
- However, if you feel you have been given too much Buvidal, immediately call your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital. You may need urgent medical attention.

What if I become pregnant or if I am breast-feeding?

- Tell your doctor if you are planning to become pregnant before starting or during treatment with Buvidal. Buvidal® is not intended for use during pregnancy.
- If you become pregnant during treatment with Buvidal, your doctor will make a decision about your treatment.
- The active substance in Buvidal, buprenorphine, is excreted into breast milk, therefore Buvidal® should not be used if you are breast-feeding.

What should I do if I require medical treatment other than Buvidal® Weekly or Buvidal® Monthly?

- If you for any reason are admitted to hospital, tell the staff you are being treated with Buvidal® Weekly or Buvidal® Monthly, as it may affect treatments you receive.
- You will receive a Patient Alert Card which you should carry with you. The Patient Alert Card contains important information for health care professionals in case you need emergency treatment such as your current Buvidal® dose, whether you are being treated with weekly or monthly injections and the date of last injection.
- Ask your doctor any questions you may have regarding your condition or treatment.

Further information

- For further information about drug addiction services and support programs:
  - Please visit the Alcohol and Drug Foundation home page (adf.org.au) or call their information line on 1300 85 85 84.
  - Please call the Alcohol and Drug Information Service for each state/territory: ACT (02) 62079977, NSW (02) 9361 8000, NT 1800 131 350, QLD 1800 177 833, SA 1300 131 340, WA (08) 94425000.
  - Please call the Drug and Alcohol Clinical Advisory Service (VIC) 1800 888 236.

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