

Consumer Medicine Information

Biodone, Biodone Forte, Biodone Extra Forte

Methadone hydrochloride 2 mg/ml (Biodone), 5 mg/ml (Biodone Forte) and 10 mg/ml (Biodone Extra Forte).

References to "Biodone" in the following information refer to all strengths.

What is in this leaflet

This leaflet answers some common questions about Biodone. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have benefits and risks. Your doctor has weighed the risks of you taking Biodone against the expected benefits that it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need it again.

What Biodone is used for and how it works

Biodone is a medicine to be taken by mouth to suppress the craving for opiate-type drugs in people who are addicted to them. Methadone, the active ingredient in Biodone, is a synthetic opiate similar to morphine because it acts on the central nervous system to suppress withdrawal symptoms. Biodone must not be used for indications other than suppression of opioid withdrawal symptoms unless approved by your doctor.

Biodone is only available on prescription from doctors authorised to prescribe controlled drugs for the treatment of opioid dependence.

Biodone is itself addictive.

Before you take Biodone

Do not take Biodone if

- You are allergic to methadone or to the colouring substances used.
- If your breathing is shallow, especially in the presence of cyanosis (blue coloured skin) or excessive lung secretions.
- You are having an attack of asthma.
- You have acute alcoholism, a head injury or raised blood pressure in the head.
- You are taking certain types of antidepressants known as monoamine oxidase inhibitors (MAOI).
- You have ulcerative colitis.
- You have severe liver or kidney disease.

The presence of the above conditions may mean that you cannot take Biodone or that your dose level may need to be modified. Your doctor will advise you.

Before you take Biodone, you must tell your doctor if

- You have problems with your central nervous system function or acute stomach conditions. Biodone may interfere with the diagnosis of these conditions.
- You experience low blood pressure (feeling faint or dizzy). You may be more sensitive to these effects while on Biodone.
- You find it difficult to pass urine.
- Your sexual drive is decreased.
- You have liver or kidney problems, especially if you are elderly. Careful monitoring of patients with these conditions is advised because methadone may build up in the system.
- You are taking medicine to control your heart rhythm.
- You are, or become, pregnant while on Biodone. The main risks to mother and baby relate to changing methadone levels, particularly if this leads to withdrawal symptoms. Your healthcare professional will provide you with information relating to the effect of methadone maintenance therapy, smoking, alcohol and illicit drug use on your baby.
- You are breastfeeding or intending to breastfeed. The methadone level in milk is very low and will not harm your baby. When you decide to wean your baby you should do so slowly to avoid a sudden change in baby's methadone level.

Driving and using machinery

If you are well stabilised on Biodone, you may continue to drive and operate machinery as part of normal activities. If your Biodone dosage has not been stabilised or is changed for any reason you need to be careful because drowsiness may be increased and there may be other side effects while you get used to the new dose.

Taking other medicines

It is important to tell your doctor if you are taking any other medicines, including medicines you can buy without a prescription from a pharmacy, supermarket or health food shop.

Your doctor or pharmacist has a complete list of medicines that interfere with Biodone.

Some of the more important medicines that may interact with Biodone are listed below.

Alcohol, benzodiazepines, buprenorphine, carbamazepine, chloromethiazole, cyclizine and other non-sedating antihistamines, desipramine, fluoxetine, fluvoxamine, indinavir, ketoconazole, naltrexone, naloxone, nevarapine, phenobarbitone, phenytoin, rifampicin, ritonavir, urine acidifiers such as ascorbic acid (vitamin C), urine alkalinisers such as sodium bicarbonate, zidovudine, zopiclone, other opioid drugs and other drugs that depress the central nervous system.

You should tell your doctor or pharmacist before taking any of the above drugs.

How to use Biodone properly

Biodone is intended to be taken only by mouth. The dose varies very widely for different individuals. It is very important that you take your Biodone, including takeaway doses, exactly as prescribed and at the time advised, to keep your blood levels stable.

Biodone has a very unpleasant taste due to the methadone it contains. You may like to drink some water or a flavoured beverage after taking your Biodone to help remove the after taste.

Do not give your Biodone dose to anyone else.

Do not stop taking Biodone or change your dosage unless you have first discussed this with your doctor.

Side effects

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

All medicines have side effects. Sometimes they are serious and require medical treatment, but mostly they require some change to the dosage level.

The most common side effects with Biodone are nausea, vomiting, constipation, drowsiness and confusion.

Other side effects include sweating, facial flushing, dizziness, irregular heartbeat, palpitations, fall in blood pressure on standing, low body temperature, restlessness and contraction of the pupils. Itching, rash and contact dermatitis may also occur.

Other side effects not listed above may occur in some patients, so you should discuss any unusual effects you experience while on Biodone treatment with your doctor. But do not be alarmed by the list of side effects. You may not experience any of them.

In case of overdose

Immediately telephone your doctor or National Poisons Information Centre (New Zealand: telephone 0800 POISON or 0800 764 766) for advice or go to your nearest Accident and Emergency Department if you think that you or anyone else may have taken too much Biodone. Do this even if there are no signs of discomfort or poisoning.

Storage conditions

Store takeaway doses of Biodone at room temperature, away from sunlight and sources of heat, but not in the refrigerator.

Always store Biodone out of sight from, and out of the reach of, children. Lock it away if possible.

Return any remaining Biodone along with its container to your pharmacist if it has expired.

Never leave Biodone lying around.

List of other ingredients

In addition to methadone hydrochloride and highly purified water, the only other ingredients in Biodone are the colouring.

Biodone is sugar free.

Biodone (2mg/ml) contains sunset yellow and is a clear yellow solution.

Biodone Forte (5 mg/ml) is a clear, colourless solution.

Biodone Extra Forte (10 mg/ml) contains permicol red, a diluted form of amaranth, and is a clear, pink solution.

If you want to know more

If you have concerns relating to any aspect of your treatment with Biodone, you should discuss them your doctor or pharmacist.

Manufacturer

Biodone is manufactured by:
Biomed Limited
P O Box 44 069
Point Chevalier
Auckland

Date of information

Prepared 23 December 2004