

BIODONE FORTE™

methadone hydrochloride 5 mg/mL

Consumer Medicine Information

WARNINGS

Hazardous and harmful use

BIODONE FORTE poses risks of abuse and misuse which can lead to overdose and death. Your doctor will monitor you regularly during your treatment.

Life threatening respiratory depression

BIODONE FORTE can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting BIODONE FORTE and after a dose increase, if you are older, or have an existing problem with your lungs.

Your doctor will monitor you.

Use of other medicines while using BIODONE FORTE

Using BIODONE FORTE with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using BIODONE FORTE.

What is in this leaflet

This leaflet provides a summary of information about BIODONE FORTE. Please read it carefully before you use this product. Keep this leaflet. You may need to read it again.

Where to go for further information:

This information has been provided to help you understand how BIODONE FORTE works. If you have any questions or are not sure about anything please ask your doctor or pharmacist. More detailed technical information is included in the Product Information available to the medical profession.

What it is used for

BIODONE FORTE has been approved for use in treating people with a dependency on opioid analgesic drugs.

The active ingredient in BIODONE FORTE is methadone

hydrochloride. This belongs to the class of drugs known as opioid analgesics.

Dependence

As with all other opioid containing products, your body may become used to you taking this medicine. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking BIODONE FORTE suddenly, so it is important to take it exactly as directed by your doctor.

Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea

- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

BIODONE FORTE given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

BIODONE FORTE works like other opioid analgesic drugs and so it may be used to replace heroin or other morphine-like drugs. Because BIODONE FORTE tends to stay in the body longer, it helps stop the withdrawal symptoms that are experienced by people who are dependent on opioid drugs. The withdrawal symptoms are less intense but more prolonged than those produced by morphine or diamorphine. They develop more slowly and do not usually appear until 24 to 48 hours after the last dose.

Before you take it

BIODONE FORTE is not suitable for everyone. Your doctor will take a full assessment of your condition before prescribing BIODONE FORTE.

You should not use BIODONE FORTE if you:

- Know or suspect you are allergic to methadone hydrochloride, any other opioid drug or any of the ingredients listed toward the end of the leaflet.
- Have any type of breathing problems especially if you suffer from blue discolouration of the skin, or plenty of mucus in your airways.
- Are suffering from or have repeatedly suffered from ulcerative colitis (an ulcer or inflammation of the large bowel).
- Have been drinking or are currently drinking alcohol.
- Have head injuries or are in a condition where you have increased pressure within your head.
- Have a history of problems related to the biliary or renal tract.
- Are suffering from an asthma attack.
- Are suffering from heart failure as a result of chronic lung disease.
- Are under 18 years of age.

You should be under the care of your doctor or pharmacist throughout your treatment with BIODONE FORTE.

Tell your doctor or pharmacist if you:

- Have recently lost a significant amount of blood. You may be more susceptible to the low blood pressure effects of BIODONE FORTE.
- Have any abdominal conditions as taking BIODONE FORTE

may block the diagnosis of these conditions.

- Suffer from an enlarged prostate or narrowing of the urethra as taking BIODONE FORTE may increase your chances of urinary retention and oliguria (low urine production).
- Have liver or kidney disease.
- Have a history of underactivity of the thyroid gland, pituitary gland or a history of diabetes mellitus.
- Are pregnant or suspect that you may be pregnant.
- Are currently nursing a baby as caution should be exercised when methadone is given due to the risks of sedation and respiratory depression in the infant.

BIODONE FORTE may interact with other medicinal products.

Be sure to let your doctor or pharmacist know if you are taking any other medicine no matter where you got it from.

Some interactions between BIODONE FORTE and other medicines include:

Rifampicin, monoamine oxidase inhibitors (MAOIs), barbiturates, neuromuscular blocking agents, phenothiazines, tranquillisers, psychotropic drugs, anticholinergics, antihypertensives, domperidone, metoclopramide, phenytoin, propranolol and cisapride, mexiletine and fluvoxamine.

Methadone should not be combined with alcohol.

Taking BIODONE FORTE may cause drowsiness; therefore you should not drive a motor vehicle or operate machinery.

The dose given to you by your doctor or pharmacist is specifically calculated for you only. **NEVER** give your dose to anyone else for any reason, as this may result in a dangerous or even fatal reaction.

NEVER give your dose to children as this can result in death.

How to take it

BIODONE FORTE has been specially formulated to be taken by mouth only.

BIODONE FORTE IS NOT INTENDED FOR INJECTION.

Make sure you carefully follow the directions of your doctor or pharmacist when taking BIODONE FORTE. Your doctor or pharmacist will calculate the appropriate dose for you. They will instruct you on:

- How much BIODONE FORTE to take at each dose.
- The number or dose/s to take each day.
- When to take your dose/s each day.

Your doctor or pharmacist will review your dosage regularly and change it as needed. Each dose is worked out specifically for you to stop you having withdrawal symptoms. If you have any questions regarding the dose you have been given, talk to your doctor or pharmacist.

If your dose has increased from the last one you took, your co-ordination may be affected or you may experience some intolerance to the higher dosage for a few days. If you feel any effects that concern you, make sure you see your doctor or pharmacist.

If you forget to take your dose:

If you forget to take one or more of your doses, consult your doctor or pharmacist. **DO NOT** take a double dose if you have missed your regular dose.

When to stop taking Biodone Forte:

You should not stop taking BIODONE FORTE unless directed by your doctor or pharmacist, otherwise you may experience withdrawal symptoms. If you are undergoing detoxification treatment discuss this with your doctor.

Unwanted Effects:

When taking BIODONE FORTE, you may experience the following unwanted effects:

Nausea, vomiting, constipation, rapid heart beat, drowsiness and confusion. Other effects include sweating, facial flushing, vertigo (a spinning sensation affecting your balance), slow heart beat, palpitations, low blood pressure when standing up which can lead to fainting, hypothermia (low body temperature), restlessness, constriction of pupils, abdominal pain and blurred vision. Itchy rash, and contact dermatitis may occur, but are uncommon.

If you experience any of these unwanted effects or any other effects not mentioned above, please tell your doctor or pharmacist immediately.

In case of Overdosage:

You will usually take your dose under the supervision of your pharmacist or doctor who has calculated the appropriate amount for you. Therefore, overdosage should not normally occur. Take home doses have also been calculated specifically for you and should not result in an overdosage.

If you take too much (overdose)

If you or someone else receive too much (overdose), and experience one or more of the symptoms below, immediately call triple zero (000) for an ambulance. Keep the person awake by talking to them or

gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally used BIODONE FORTE that was prescribed for you. If someone takes an overdose they may experience one or more of the following symptoms:

- Slow, unusual or difficult breathing
- Drowsiness, dizziness or unconsciousness
- Slow or weak heartbeat
- Nausea or vomiting
- Convulsions or fits

If you think you or someone else may have used too much BIODONE FORTE, 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.

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

Some of the symptoms that you may experience as a result of an overdosage are:

Difficulty breathing, low blood pressure, circulatory failure and deep coma. Convulsions may occur in infants and children. In case of severe overdosage, circulatory collapse, heart attack, stopping breathing and death may occur.

Be sure to keep BIODONE FORTE in a safe and secure place out of the reach of children. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Always keep BIODONE FORTE in the original container and do not use it if the expiry date on the container has run out.

Return any remaining BIODONE FORTE along with its container to your pharmacist if it has expired. Do not leave lying around.

Product description

Each 200 mL or 1000 mL bottle of BIODONE FORTE solution (AUST R64800) contains methadone hydrochloride 5 mg/mL.

It also contains the following inactive ingredients:

Purified water
Permicol red (colour)

Sponsor

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This leaflet was revised in November 2020.

After taking it

Store BIODONE FORTE in a cool, dry place below 25°C but do not refrigerate.