

BIODONE FORTE™

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using Biodone Forte?

Biodone Forte contains the active ingredient methadone hydrochloride. Biodone Forte is used for treating people with a dependency on opioid analgesic drugs.

For more information, see Section [1. Why am I using Biodone Forte?](#) in the full CMI.

2. What should I know before I use Biodone Forte?

Do not use if you ever had an allergic reaction to Biodone Forte or any of the ingredients listed at the end of the CMI.

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

For more information, see Section [2. What should I know before I use Biodone Forte?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Biodone Forte 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 do I use Biodone Forte?

- Biodone Forte is to be taken by mouth only.
- Each dose, number of dose/s for each day, when to take your dose/s is calculated by your doctor or pharmacist which is appropriate for you to stop you having withdrawal symptoms.
- Follow the instructions given to you by your doctor or your pharmacist.

More instructions can be found in Section [4. How do I use Biodone Forte?](#) in the full CMI.

5. What should I know while using Biodone Forte?

Things you should do	<ul style="list-style-type: none">• Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.• Seek medical help immediately if Biodone Forte is accidentally taken by a child.
Things you should not do	<ul style="list-style-type: none">• Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
Driving or using machines	<ul style="list-style-type: none">• This medicine may cause drowsiness. It is recommended that you don't drive, use machinery or undertake any activities where alertness is required.
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol while taking Biodone Forte.
Looking after your medicine	<ul style="list-style-type: none">• Store Biodone Forte in a cool, dry place where it stays below 25°C. Protect from light. Do not freeze.• Keep this medicine where children cannot reach it.

For more information, see Section [5. What should I know while using Biodone Forte?](#) in the full CMI.

6. Are there any side effects?

Common side effects include drowsiness, dizziness, vomiting and sweating. Serious side effects include symptoms of an allergic reaction such as wheezing, swelling of the lips/mouth, difficulty in breathing and fainting

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.

WARNINGS

Hazardous and harmful use

Biodone Forte poses risks of abuse, misuse and addiction 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 and change the dose as appropriate.

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 minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using Biodone Forte.

BIODONE FORTE™

Active ingredient(s): *methadone hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Biodone Forte. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Biodone Forte.**

Where to find information in this leaflet:

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

1. Why am I using Biodone Forte?

Biodone Forte contains the active ingredient methadone hydrochloride. It belongs to a group of medicines called opioid analgesics.

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

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

Biodone Forte is only available with a doctor's prescription.

2. What should I know before I use Biodone Forte?

Warnings

Addiction

You can become addicted to Biodone Forte even if you take it exactly as prescribed. Biodone Forte may become habit forming causing mental and physical dependence. If abused, it may become less able to reduce pain.

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.

Tolerance

Tolerance to Biodone Forte may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and 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.

Do not use Biodone Forte if:

- you have ever had an allergic reaction to methadone hydrochloride, any other opioid drug or any of the ingredients listed toward the end of this leaflet.
 - Some symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or any other parts of the body; rash, itching or hives on the skin.
- you are taking or have recently taken antidepressants of the type called monoamine oxidase inhibitors (MAOIs)
- **you have any other medical condition including:**
 - a lung disorder such as asthma, or any illness causing difficulty in breathing, especially if there is excessive phlegm or skin is bluish in colour
 - recent head injury or increased pressure in the head
 - a bowel condition known as ulcerative colitis
 - certain liver or kidney conditions
 - certain heart conditions
 - alcoholism.
- biliary and renal tract spasm

Check with your doctor if you:

- are under 18 years of age
- are allergic to foods, dyes, preservatives or any other medicines
- have any other medical condition including:
 - hormone problems
 - an underactive thyroid gland
 - diabetes
 - prostate disease
 - phaeochromocytoma, a rare tumour of the adrenal gland. Symptoms include bouts of anxiety and headaches. There may be palpitations (banging of the heart felt in the chest), dizziness, weakness, nausea, vomiting, diarrhoea, dilated pupils, blurry vision, stomach pains and raised blood pressure.
- intend to drink alcohol while you are taking Biodone Forte.

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 doctor if you are or intend to become pregnant, or are about to give birth, or are breastfeeding.

Use in children

Biodone Forte is not recommended for use in children under 18 years of age.

Use in the elderly

The doctor may prescribe a smaller dose in elderly patients.

3. What if I am taking other medicines?

Tell your doctor or pharmacist 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 of the medicines that may interfere with this medicine include:

- St John's wort
- rifampicin, an antibiotic
- medicines to treat epilepsy
- medicines to treat HIV infections
- fluconazole, an antifungal
- selective serotonin re-uptake inhibitors (SSRIs) which are medicines to treat depression or obsessive-compulsive disorders e.g. fluvoxamine
- any other medicines to treat depression
- medicines to treat mental illness
- medicines to treat heart conditions
- other pain relievers, muscle relaxants or tranquilisers
- fluid or water tablets
- laxatives
- fludrocortisone, a medicine used in certain hormone conditions.

You may need to take different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist has a more complete list of medicines to avoid while taking this medicine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Biodone Forte.

4. How do I use Biodone Forte?

How much to take

Take this medicine as directed by your doctor or pharmacist.

- Your doctor will tell you how much to take each day.
- Follow the instructions provided and take Biodone Forte until your doctor tells you to stop.
- Your doctor 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 your dose has increased from the last one you took, you may experience some intolerance to the higher dosage for a few days.

Do not take more than the recommended dose.

It can result in low blood sugar.

How to take Biodone Forte

Biodone Forte is designed specifically to be taken by mouth only.

It is NOT SUITABLE for injection. Injecting this medicine can be extremely hazardous.

How long to take it for

Do not stop taking this medicine or change the dose without first checking with your doctor.

Your doctor may want to gradually reduce the amount you are taking before stopping completely in order to lessen the chance of possible withdrawal side effects.

If you use too much Biodone Forte

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

If you or someone else receive too much (overdose) and experience one or more of the symptoms below, 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

Other signs of overdose can also include problems with the 'nervous system' caused by damage to the white matter of the brain (known as toxic leukoencephalopathy).

If you think that you have used too much Biodone Forte, 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 using Biodone Forte?

Things you should do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise your doctor may think that it was not working as it should and change your treatment unnecessarily.

If you forget to take a dose, take it as soon as you remember and then go on as before, but remember not to take the medicine more often than recommended by your doctor.

Seek medical help immediately if Biodone Forte is accidentally taken by a child.

Things you should not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use it to treat any other complaints unless your doctor says to.

Things to be careful of

Particular care should be taken when starting this medicine or increasing the dose. Methadone can decrease heart and breathing rates, which if severe, may lead to death.

Speak to your doctor immediately if you have any concerns.

Driving or using machines

Biodone Forte may cause dizziness in some people. It is recommended that you don't drive, use machinery or undertake any activities where alertness is required.

Drinking alcohol

Do not drink alcohol while taking Biodone Forte.

Looking after your medicine

Store Biodone Forte in a cool, dry place where it stays below 25 °C. Protect from light. Do not freeze.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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.

With prolonged use, the dose may have to be increased to achieve the same benefit, whilst a sudden decrease in dose or interruption of therapy may give rise to possible withdrawal symptoms.

See the information below and, if you need to, ask your doctor or pharmacist 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"> • Adrenal insufficiency symptoms such as weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure • drowsiness • dizziness • light-headedness • dry mouth • sweating • confusion • constipation • problems with urine flow • tolerance and dependence • central sleep apnoea • anorexia • spasm of the sphincter of Oddi 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>
<ul style="list-style-type: none"> • Androgen deficiency symptoms such as loss of libido, impotence, (erectile dysfunction) or your menstrual cycle stops • have difficulty swallowing, regurgitation, chest pain that is not related to your heart, especially if you have been using the medicine for a long time. 	<p>Speak to your doctor if you have any of these side effects that may be associated with long-term use.</p>

Serious side effects

Serious side effects	What to do
<p>Allergic reaction including:</p> <ul style="list-style-type: none"> • wheezing • swelling of the lips/mouth • difficulty in breathing • hayfever • lumpy rash (hives) • fainting 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these side effects.</p>

Biodone Forte can cause sleep-related breathing disorders such as sleep apnoea and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated

with inflammation of the pancreas (pancreatitis) and the biliary tract system.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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 doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Biodone Forte contains

Active ingredient (main ingredient)	<ul style="list-style-type: none"> • Methadone hydrochloride 5 mg/mL
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • Permicol red • Water for injections

Do not take this medicine if you are allergic to any of these ingredients.

Biodone Forte is preservative free.

What Biodone Forte looks like

Biodone Forte is a clear, clean and pink coloured solution (Aust R 64800).

Who distributes Biodone Forte

Biomed Aust Pty Ltd
Suite 5, Level 1
24 Hickson Road
Millers Point
NSW 2000
AUSTRALIA

This leaflet was revised in July 2025.