

## BIODONE FORTE™

Methadone hydrochloride

### Consumer Medicine Information

#### What is in this leaflet?

**This leaflet provides a summary of information about Biodone Forte. Please read it carefully before you use this product.**

#### 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.

#### Identification

Each 200 mL or 1000 mL glass bottle of Biodone Forte solution (AUST R64800) contains: Methadone hydrochloride 5 mg/mL.

Other ingredients in Biodone Forte are: Purified water, colour (permicoll red).

#### What Biodone Forte is used for and how it works:

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. Other well-known drugs that belong to this group include codeine, morphine and heroin.

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.

#### Advice before using Biodone Forte

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.
- 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.

**Before taking this product, be sure to 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, or if you are currently nursing a baby.

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 use Biodone Forte properly

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 concerns 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.**

#### Further Information

Biodone Forte is an addictive drug. It can only be prescribed by a doctor and requires you to be under the regular supervision of a doctor or pharmacist throughout your treatment.

#### 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 pupil 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.

**However, if you believe you have taken too much or someone else has taken your dose, seek the advice of your doctor immediately or contact the Poisons Information Centre (Telephone 13 11 26) or Hospital. Even if you do not feel any symptoms it is extremely important to get medical attention.**

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.

#### Storage Conditions

**Store Biodone Forte in a cool, dry place below 25°C but do not refrigerate.**

**Be sure to keep Biodone Forte in a safe and secure place out of the reach of children.**

**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.**

*Sponsor*

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