

Methadone BNM

Methadone hydrochloride

Tablets 5 mg

WARNINGS

Limitations of use

Methadone BNM should only be used when your doctor decides that other treatment options are not able to effectively manage your pain, or you cannot tolerate them.

Hazardous and harmful use

Methadone BNM poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

Methadone BNM 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 Methadone BNM 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 Methadone BNM

Methadone BNM 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 Methadone BNM.

What is in this leaflet

Please read this leaflet carefully before you start taking Methadone BNM.

This leaflet answers some common questions about Methadone BNM.

It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from www.medsafe.govt.nz.

Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Methadone BNM against the benefits this medicine is expected to have for you.

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



Keep this leaflet with the medicine.

You may want to read it again.

What Methadone BNM is used for

Methadone BNM contains methadone hydrochloride, which belongs to a group of medicines called opioid analgesics.

Methadone BNM is used for the relief of severe pain, and sometimes for the relief of coughing when severe pain is present and coughing cannot be relieved by other medicines. It is also used for the treatment of dependence on opioid drugs.

Your doctor may have prescribed this medicine for another reason.

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

Methadone BNM is only available with a doctor's prescription.

People who are given Methadone for a long time to treat their pain can become addicted to it.

With time, your body will become used to taking Methadone and you may experience symptoms due to withdrawal if you stop getting this medicine.

The symptoms may include body aches, diarrhoea, nervousness, shivering, nausea, sleep disturbance, sweating, weakness and fever.

If you have not done so already, you should discuss this further with your doctor.

Methadone should not be stopped suddenly in patients who may have developed a physical dependence on the medicine.

This medicine should be given with great care to infants, especially neonates, children, the elderly and debilitated patients.

Before you take Methadone BNM

Methadone BNM is not suitable for everyone.

When you must not take it

Do not take Methadone BNM if you:

- are taking or have recently taken antidepressants of the type called monoamine oxidase inhibitors (MAOIs)
- suffer from 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
- have an addiction to alcohol
- had a recent head injury, or increased pressure in the head



- have a bowel condition known as ulcerative colitis
- have severe liver disease
- biliary tract spasm, a gall bladder or liver condition
- renal tract spasm, a kidney condition

Do not take Methadone BNM if you are allergic to any medicine containing methadone hydrochloride or any of the ingredients listed at the end of this leaflet.

Methadone BNM should not be given to you if:

- you are, or become, pregnant while on Methadone BNM. 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.

Do not take it after the expiry date ('Exp' (as per carton)) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking Methadone BNM, talk to your doctor or pharmacist.

Tolerance, dependence, and addiction

This medicine contains methadone which is an opioid medicine. Repeated use of opioids can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Methadone BNM can also lead to dependence, abuse, and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use. Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it. When used for the treatment of pain, you might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent or addicted on Methadone BNM if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety, or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking Methadone BNM, it could be a sign that you have become dependent or addicted.

- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose



- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects')

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See *How long to take it*).

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Sleep-related breathing disorders

Methadone BNM can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) 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. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

Tell your doctor if you have or have had any medical conditions, especially the following:

- certain heart conditions
- certain liver or kidney problems

Tell your doctor if you are taking certain anti-depressants

The use of certain anti-depressants with Methadone BNM can lead to serotonin syndrome, a potentially life-threatening conditions (see "Taking Other medicines")

Tell your doctor if you are pregnant, or become pregnant while taking Methadone BNM, are about to give birth, or are breastfeeding

Use with caution if you are over 65 years old.

Elderly persons are more sensitive to the effects of the medicine.

Do not give Methadone BNM to a child or adolescent aged under 18 years.

There is not enough information to recommend the use of this medicine for children or adolescents under 18 years.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Methadone BNM.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.



Tell any healthcare professional who is prescribing a new medicine for you that you are taking Methadone BNM.

Some medicines and Methadone BNM may interfere with each other. These include:

- alcohol
- medicines to help you sleep including zopiclone, chlormethiazole, benzodiazepines, barbiturates such as phenobarbitone
- medicines used to treat alcohol or drug addiction such as buprenorphine, naltrexone, naloxone
- medicines used to treat epilepsy such as carbamazepine, phenytoin
- medicines to relieve nausea and vomiting such as domperidone, metoclopramine, cyclizine
- medicines to treat allergies, other non-sedating antihistamines
- medicines used to treat a depressed mood such as desipramine, fluoxetine, fluvoxamine, tricyclic antidepressants, SSRIs, SNRIs, MAOIs. These medicines may interact with Methadone BNM and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, increase body temperature, confusion, increased heart rate, blood pressure fluctuation, nausea, vomiting, diarrhoea. Contact your doctor when experiencing such symptoms.
- medicines used to treat viral infections such as efavirenz, indinavir, nevirapine, zidovudine, protease inhibitors
- Antibiotics, medicines used to treat bacterial infections such as erythromycin, rifampicin, rifabutin
- medicines used to treat fungal infection such as fluconazole, ketoconazole
- grapefruit juice
- nifedipine, medicine used to treat high blood pressure and certain heart conditions
- omeprazole, cimetidine, cisapride, medicines to treat reflux and stomach ulcer
- vitamin C and other medicines that make the urine acidic
- urine alkalinisers such as sodium bicarbonate which make the urine less acidic
- opioids, medicines for pain relief
- drugs that depress the central nervous system
- hyoscine, a medicine to help to motion sickness or allergies
- Cannabidiol (a medicine used to treat seizures)
- Gabapentin and pregabalin (medicines used to treat epilepsy, nerve pain or anxiety), can increase the risk of opioid overdose, respiratory depression (breathing difficulties) and may be life-threatening.

The above medicines may be affected by Methadone BNM, or may affect how well it works. You may need different amounts of Methadone BNM, or take it at different times, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Methadone BNM.



How to take Methadone BNM

Read the label carefully and follow all directions given to you by your doctor and pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Methadone BNM, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see *How long to take it*).

How much to take

Follow all directions given to you by your doctor and pharmacist carefully. Do not take more than the recommended dose.

Severe pain

The usual dose is 1 to 2 tablets taken 3 to 4 times a day, but this dosage may be adjusted by your doctor.

Drug addiction

Your doctor will tell you how much Methadone BNM you should take. The starting dose is 2 to 4 tablets per day. This dosage may be adjusted by your doctor, the dose may be gradually increased to a maintenance dose of 6 to 10 tablets per day. The maximum dose is 16 tablets per day.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take. This depends on your condition and whether or not you are taking any other medicines.

If you take the wrong dose, Methadone BNM may not work as well and your problem may not improve.

Swallow Methadone BNM with a full glass of water.

How long to take it

Continue taking the medicine for as long as your doctor tells you to.

Methadone BNM helps to control your condition, but does not cure it. It is important to keep taking the medicine even if you feel well.

For long term users, seek advice from the prescriber before stopping the medicine. Stopping the medicine may lead to withdrawal symptoms. Your doctor will probably want you to gradually reduce the amount of methadone you are using, before stopping it completely.

If you are unsure whether you should stop taking Methadone BNM, talk to your doctor or pharmacist.



If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Do not try to make up for missed doses by taking more than one dose at a time.
This may increase the chance of getting an unwanted side effect.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for hints.

While you are taking Methadone BNM

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Methadone BNM. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are taking this medicine.

If you are going to have surgery, tell the surgeon and anaesthetist that you are taking this medicine.
It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

See your doctor if you feel that your condition is not improving or is getting worse.

Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you.
This medicine is only intended for the person it has been prescribed for.

Do not take Methadone BNM to treat any other complaints unless your doctor tells you to.

Do not stop taking Methadone BNM or change the dosage without checking with your doctor.

If you have been using methadone for more than two weeks, you may experience unpleasant feelings if you stop it suddenly.

Your doctor will probably want you to gradually reduce the amount of methadone you are using, before stopping it completely.



Things to be careful of

Be careful driving or operating machinery until you know how Methadone BNM affects you.

In case of overdose

If you take too much

Immediately telephone your doctor, or the Poisons Information Centre telephone 0800 POISON or 0800 764 766, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Methadone BNM.

Do this even if there are no signs of discomfort or poisoning.
You may need urgent medical attention.

Symptoms of an overdose may include difficulty breathing, pin-point pupils, floppiness, coma and drowsiness. You may also experience loss of coordination, difficulty walking, facial drooping, personality changes or trouble speaking (signs of a brain disorder known as toxic leukoencephalopathy)

Side effects

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

Like all medicines, Methadone BNM may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- drowsiness
- dizziness
- light-headedness
- headache
- nausea
- vomiting
- dry mouth
- sweating
- confusion
- constipation
- problems with urine flow
- tolerance and dependence (for more information see section *Tolerance, dependence, and addiction*)
- sleep apnoea (breathing pauses during sleep)
- swelling or pain in parts of the body
- swelling or redness along a vein which is extremely tender when touched



- feeling weakness
- tummy pain
- weight gain
- (if you are female) stop getting your period
- reduced sex drive
- low blood glucose level

These side effects are usually mild.

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 withdrawal symptoms.

Tell your doctor immediately if you notice any of the following:

- wheezing
- hay fever
- lumpy rash (hives)
- fainting
- agitation
- changes in mood.

These may be serious side effects. You may need urgent medical attention.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- serious allergic reaction (swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing)
- breathing difficulties
- abnormal heart beat.

These are very serious side effects; you may need urgent medical attention or hospitalisation.

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

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking Methadone BNM

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep Methadone BNM in a cool dry place where the temperature stays below 25°C.



Do not store it or any other medicine in the bathroom, near a sink, or on a window sill. Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it and any other 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. Store this medicine in a safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.

Do not keep Methadone BNM past its expiry date.

Disposal

Return any unused medicine and any medicine past its expiry date (as shown on the labelling) to your pharmacy.

Product description

What it looks like

Methadone BNM is available in blister packs of 10 tablets. The tablets are white, or almost white, round, flat uncoated tablets, imprinted with "M5" on one side and concave with a score line on other side.

Ingredients

Active ingredient:

- methadone hydrochloride

Inactive ingredients:

- Lactose monohydrate
- Maize starch
- Povidone
- Purified water
- Colloidal anhydrous silica
- Talc
- Magnesium stearate

Methadone BNM contains lactose.

It does **not** contain sucrose, tartrazine or any other azo dyes.

Sponsor details

BNM Group
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