

Methatabs

Methadone Hydrochloride BP

Tablet, uncoated 5 mg

WARNINGS

Limitations of use

Methatabs 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

Methatabs 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

Methatabs 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 Methatabs 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 Methatabs

Methatabs 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 Methatabs.

What is in this leaflet

Please read this leaflet carefully before you start using Methatabs.

This leaflet answers some common questions about Methatabs.

It does not contain all the available information. It 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 using Methatabs against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Methatabs is used for

Methadone belongs to a group of medicines called opioid analgesics.

Methatabs is a medicine used for relief of severe pain.

Methatabs is also used to suppress the craving for opiate-type drugs in people who are addicted to them. Methadone, the active ingredient in Methatabs, is a synthetic opiate similar to morphine because it acts on the central nervous system to suppress withdrawal symptoms.

Your doctor may have prescribed Methatabs for another reason.

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

This medicine is available only 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 use Methatabs

When you must not use it

Methatabs should not be given to you if you have an allergy to methadone or any of the ingredients listed at the end of this leaflet.

Do not use Methatabs if:

- you are allergic to methadone.

- 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 Methatabs or that your dose level may need to be modified. Your doctor will advise you.

Methatabs should not be given to you if:

- you have problems with your central nervous system function or acute stomach conditions. Methatabs 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 Methatabs.
- 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 Methatabs. 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.

Methatabs should not be given to you after the expiry date (EXP) printed on the pack.

If this medicine is used after the expiry date has passed, it may not work as well.

Methatabs should not be given to you if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start therapy with methadone, talk to your doctor or pharmacist.

Before you start to use it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives, or dyes.

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

- asthma
- hypothyroidism or lack of thyroid hormones
- lack of adrenal hormones such as cortisol
- diabetes
- kidney problems
- liver problems
- hypertension
- prostate problems
- shock
- inflamed or obstructed bowels
- heart conduction abnormalities
- low potassium levels in the blood
- low magnesium levels in the blood.
- pheochromocytoma (a rare tumour of the adrenal gland). Symptoms include bouts of anxiety and headaches. There may be palpitations (banging of heart felt in the chest), dizziness, weakness, nausea, vomiting, diarrhoea, dilated pupils, blurry vision, stomach pains and raised blood pressure.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant while taking Methatabs.

Your doctor or pharmacist will discuss the possible risks and benefits of you being given methadone during pregnancy.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you intend to drink alcohol while you are taking Methatabs.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop, naturopath or herbalist, including St John's Wort.

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.

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

Your doctor or pharmacist will have a complete list of the medicines that may cause problems when taken with Methadone.

You should also tell any health professional who is prescribing a new medication for you that you are taking Methatabs.

Some medicines may interfere with Methatabs. These include: alcohol, benzodiazepines, buprenorphine, carbamazepine, chlormethiazole, cyclizine and other non-sedating antihistamines, indinavir, ketoconazole, naltrexone, naloxone, nevirapine, phenobarbitone, phenytoin, rifampicin, ritonavir, urine acidifiers such as ascorbic acid (vitamin C), urine alkalinisers such as sodium bicarbonate, zidovudine, zopiclone, other opioid drugs, other drugs that depress the central nervous system and antidepressants or medicines for anxiety disorders, such as: selective serotonin reuptake inhibitors (SSRIs), e.g., fluoxetine, fluvoxamine; serotonin and norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs) e.g., desipramine and monoamine oxidase inhibitors (MAOIs) e.g., selegiline and moclobemide.

These medicines may be affected by Methadone or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor has more information on medicines to be careful with or avoid while being given this medicine.

How to use Methatabs

How much to take

Your doctor will decide what dose of Methadone you will receive and explain how long your course of treatment with Methadone will continue and will advise you when the treatment is complete. This depends on your medical condition and other factors, such as your weight.

The recommended dose of Methatabs is:

Adults

For treatment of severe pain

Given orally 1 to 2 tablets, as prescribed by your doctor.

For treatment of dependence on opioid drugs

Given orally 2 to 4 tablets initially, gradually increased as necessary up to a maximum of 80 mg daily.

The dose of Methadone is then gradually decreased until total withdrawal is achieved.

Opioid dependence involves prolonged maintenance therapy with Methadone where

the daily dose is adjusted carefully for the individual.

Children

Not recommended for use in children.

Elderly patients

The doctor may prescribe a smaller dose.

When to take it

Every 6 to 8 hours, or as prescribed by your doctor,

How long to take it

Continue taking Methatabs for as long as your doctor tells you.

If symptoms persist, see your doctor.

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 forget to take it

Take your dose as soon as you remember and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.

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

The medicine is only intended for the use of the person it has been prescribed for.

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

While you are using Methatabs

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given Methatabs.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given Methatabs.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are undergoing therapy with Methatabs.

If you become pregnant while you are undergoing therapy with methadone, tell your doctor or pharmacist.

Things you must not do

Do not give Methatabs to anyone else, even if they have the same condition as you.

Do not use Methatabs to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop using Methatabs, or lower the dosage, without checking with your doctor or pharmacist.

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.

Do not take any other medicines, whether they are prescription or over-the-counter medicines, unless they have been approved or recommended by a doctor or pharmacist that knows you are being given methadone.

Things to be careful of

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

If you are well stabilised on Methatabs, you may continue to drive and operate machinery as part of normal activities. If your Methatabs 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.

Tell your doctor, pharmacist or nurse if you have any concerns about this.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons 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 Methatabs.

Do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include:

- rapid shallow breathing, which may be very severe and worsen when lying down
- temporary paralysis or weakness of muscles
- little or no urine
- drowsiness
- nausea, vomiting
- symptoms of shock
 - cold clammy skin
 - rapid weak pulse
 - dizziness
 - weakness and fainting

Low blood sugar level (hypoglycaemia) has been reported.

A condition called serotonin syndrome may occur with high fever, fast heart rate, agitation, confusion, hallucinations, trembling and abrupt contractions of the muscles.

Side Effects

Tell your doctor or nurse as soon as possible if you do not feel well or think you are experiencing any side effects or allergic reaction while being given Methadone, even if the problem is not listed below.

This medicine helps most people with pain, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, but most of the time they are minor and temporary. You may need medical attention if you get some of the side effects.

If you are over 65 years of age, debilitated, a neonate, infant or child you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

Common side effects are:

- nausea
- vomiting
- constipation
- drowsiness

- confusion
- pain, irritation or hardening of the skin at the injection site.
- dizziness
- light-headedness
- dry mouth
- sweating
- problems with urine flow
- tolerance and dependence

Low blood sugar level (hypoglycaemia) may also occur.

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.

If any of the following happen, tell your doctor immediately or go to the Emergency Department at your nearest hospital:

- wheezing
- swelling of lips/mouth
- difficulty in breathing
- hay fever
- lump rash (hives)
- fainting

These could be a symptom of an allergic reaction.

- agitation, confusion, hallucinations
- high fever, fast heart rate
- trembling and abrupt contractions of the muscles

These symptoms could be signs of a rare condition called serotonin syndrome.

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

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

After using Methatabs

Storage

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

Methatabs should be stored in a cool, dark place where the temperature stays below 25°C. It should be kept out of reach of children.

Do not store it, or any other medicines, in a bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

The tablets should not be taken if they show visible signs of deterioration.

Do not take Methatabs if the tablets do not look quite right.

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

Disposal

If your doctor tells you to stop taking this medication OR it has passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

Methatabs are white, 7 mm, normal convex tablets.

Ingredients

Active ingredient:

Each tablet contains 5 mg of Methadone hydrochloride

Inactive ingredients:

The product contains lactose.

Also, Magnesium stearate and Maize starch

Sponsor Details

Noumed Pharmaceuticals Limited
Auckland, New Zealand

Freephone 0800 5275459

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