

Equity Pharmaceuticals (Pty) Ltd
Eptadone 10 mg/mL (57/2.9/0630 – Registered)
Oral solution
Each mL contains methadone hydrochloride 10 mg

Approved Patient Information Leaflet
Approval Date: 24 June 2025

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S6

Eptadone 10 mg/mL, oral solution

Methadone hydrochloride

Contains sodium benzoate (0,05 % w/v) (preservative)

Contains glycerol 100 mg/mL

Contains sweetener (xylitol 100 mg/mL)

Read all of this leaflet carefully before you start taking Eptadone

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- Eptadone has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Eptadone is and what it is used for
2. What you need to know before you take Eptadone
3. How to take Eptadone
4. Possible side effects
5. How to store Eptadone
6. Contents of the pack and other information

1. What Eptadone is and what it is used for

Eptadone contains a medicine called methadone hydrochloride. This belongs to a group of medicines called narcotic analgesics.

Eptadone is used in the treatment of opioid drug addiction.

2. What you need to know before you take Eptadone

Do not take Eptadone:

- if you are hypersensitive (allergic) to methadone or any of the other ingredients of Eptadone (listed in section 6);
- if you have any breathing difficulties or during an asthma attack;
- if you are dependent on alcohol or any other medicines;
- if you have or have recently had a head injury;
- if you are taking monoamine oxidase inhibitors (MAOI's) which are medicines used to treat depression or if you have taken a MAOI medicine in the past two weeks (see 'other medicines and Eptadone');
- if you are in labour;
- if you have liver failure;
- if you have ulcerative colitis (inflammatory bowel disease);
- if you have biliary and renal tract spasm;
- if you have a risk of temporarily paralysation of the muscle contractions, which move food through the intestines;
- if you have a hormone-secreting tumour of the adrenal glands.

Eptadone should not be given to children.

Warnings and precautions

Tell your doctor or healthcare provider before you take Eptadone:

- if you have any breathing problems or lung conditions;
- if you have liver or kidney problems;

- if you have underactive thyroid (hypothyroidism);
- if you have an enlarged prostate gland (prostatic hypertrophy);
- if you are an elderly or very ill person. You may be sensitive to the medicine and it may cause low blood pressure and fainting.

Take special care with Eptadone:

- if you have any heart condition as this can be intensified with the use of Eptadone;
- if you have low potassium blood levels or other electrolyte imbalance;
- if you have problems with your adrenal glands (adrenocortical insufficiency);
- if you have low blood sugar levels;
- if you are currently taking any medicine that make you sleepy and relaxed;
- if you have convulsive disorders (seizures);
- if you have bowel problems;
- if you have myasthenia gravis (weakness and rapid fatigue of the muscles).

Tolerance, dependence, and addiction

Eptadone contains methadone which is an opioid medicine. Repeated use of opioids can result in the medicine being less effective (you become accustomed to it, known as tolerance). Repeated use of Eptadone can also lead to dependence, abuse, and addiction, which may result in life-threatening overdose.

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.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent or addicted on Eptadone 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 Eptadone, 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 section 3, If you stop taking Eptadone).

Withdrawal

This medicine should not be stopped suddenly, but gradually, as sudden stoppage could lead to withdrawal symptoms. Your doctor will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Sleep-related breathing disorders

Eptadone 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.

Children

Do not give Eptadone to children as it may cause breathing difficulty.

Other medicines and Eptadone

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking the following medicines:

- MAOI's (e.g. selegiline, phenelzine) used to treat depression. Eptadone should not be used with MAO inhibitors and for two weeks after treatment;
- Medicines to prevent pain during surgery and other procedures (anaesthetics);
- Medicines that make you sleepy and relaxed. (e.g. benzodiazepines including alprazolam or diazepam);
- Medicine use to treat psychosis, a mental condition where one lose touch with reality (e.g. barbiturates, phenothiazines);
- 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;
- Medicine used to treat depression. (e.g. Selective serotonin re-uptake inhibitor (SSRI), serotonin norepinephrine re-uptake inhibitor (SNRI) and tricyclic antidepressants (TCAs);
- Medicine used to reduce stomach acid production (e.g. cimetidine,);
- Medicine use to treat bacterial infections such as rifampicin (used to treat tuberculosis), ciprofloxacin, and macrolide antibiotics (e.g. erythromycin);

- Medicine use to treat fungus infections (azole e.g. ketoconazole, fluconazole);
- Medicines used to treat epilepsy (e.g. phenytoin, carbamazepine);
- Medicines that make the urine acidic (e.g., ascorbic acid –vitamin C);
- Strong painkillers (opioid agonist analgesics e.g. codeine, pethidine, pentazocine);
- Medicines used to block or reverse the effects of opioids (e.g. naloxone, naltrexone, buprenorphine);
- Medicine use to treat HIV infection (e.g. nelfinavir, nevirapine, efavirenz). Your doctor may consider Eptadone dosage adjustments if you are taking these medicines;
- Medicine used to treat nausea, vomiting and dizziness (e.g. cyclizine);
- Medicines for heart problems (e.g. verapamil, enalapril);
- Medicines which affect the electrolyte balance such as diuretics (water tablets) or lithium;
- Herbal preparation used for depression (St. John's wort);
- Medicine use to treat pain and fever (metamizole);
- Medicine that can be used to treat high blood pressure (centrally acting alpha-adrenergic blocker e.g., lofexidine and clonidine);
- Medicine use to treat irregular heartbeat (mexiletine);
- Medicine use to treat nausea and promote the passage of ingested material in the gastrointestinal tract (domperidone and metoclopramide);
- Cannabidiol (a medicine used to treat seizures).

Eptadone with drink and alcohol

Do not consume alcohol during treatment with Eptadone, as this may increase the sleepiness caused by Eptadone. Grapefruit juice may affect how Eptadone works and should not be taken with Eptadone.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Eptadone should not be used during pregnancy. Withdrawal symptoms, difficulty breathing, and a low birth weight may occur in babies after treatment with Eptadone during pregnancy.

Eptadone is distributed into the breastmilk. You should therefore not use Eptadone while breastfeeding your baby.

Driving and using machines

Your ability to drive or use machinery may be severely affected during and after treatment with Eptadone. This medicine can affect your ability to drive as it may make you sleepy or dizzy. You must not drive or use machinery until you are told that you can do so by your doctor.

It is not always possible to predict to what extent Eptadone may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which Eptadone affects you.

Eptadone contains glycerol

This medicine contains 100 mg glycerol per mL.

Glycerol may cause headache, stomach upset and diarrhoea.

Eptadone contains sodium benzoate (as preservative)

This medicine contains 500 µg sodium benzoate per mL (0,05 % w/v).

This medicine contains less than 1 mmol sodium (23 mg) per 1 mL, that is to say essentially 'sodium-free'.

Benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Eptadone contains xylitol (as sweetener)

This medicine contains 100 mg xylitol per mL.

Xylitol may have a laxative effect.

3. How to take Eptadone

Do not share medicines prescribed for you with any other person.

Always take Eptadone exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Eptadone is to be taken by mouth.

Eptadone is normally administered once daily.

The correct dosage should be extracted from the bottle by using a dispenser, measuring cylinder or syringe.

Treatment with Eptadone assumes that you are taking part in a programme including medicine-assisted rehabilitation for narcotics abuse, approved by a relevant authority.

The dose will be determined by your doctor and is tailored for each individual patient.

Adults

The usual dose for addiction is initially 20 mg once daily. Your doctor will increase the dose over three weeks until you feel well and do not have withdrawal symptoms. The final dose is usually between 60 mg and 120 mg in 24 hours.

Special population

If you are elderly or very ill, you should be careful when taking repeated doses.

If you suffer from impaired liver function, hypothyroidism or prostatic hypertrophy, your doctor may prescribe a lower initial dose.

Children

Eptadone must not be used in children.

Your doctor will tell you how long your treatment with Eptadone will last. If you have the impression that the effect of Eptadone is too strong or too weak, tell your doctor or pharmacist.

If you take more Eptadone than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Signs of severe overdosage include:

- apnoea (breathing stop and starts repeatedly);
- heart problems or heart stops beating;
- a brain disorder (known as toxic leukoencephalopathy);
- death may occur.

Signs of or taking too much Eptadone:

- inability to breath properly;
- extreme drowsiness that can leads to unconsciousness or coma;
- constriction of the pupils – pupils become smaller;
- muscle slack (which is represented by the delay between muscular contraction and recoil of the series);
- cold and clammy skin;
- slow heart rate;
- low blood pressure;
- low blood sugar.

If you forget to take Eptadone

Do not take / receive a double dose to make up for forgotten individual doses.

If you stop taking Eptadone

Do not stop taking Eptadone unless your doctor tells you to. If you stop this medicine abruptly, you will experience withdrawal effects. Your doctor will reduce your dose gradually.

Signs of medicine withdrawal include:

- feeling your heartbeat;
- increased blood pressure, breathing and heart rate;
- restlessness, irritability, agitation (sense of inner tension and restlessness), anxiety;
- flow of tears, runny nose;
- yawning;
- sweating, chills;
- shaking, muscle pain, muscle spasm, weakness;
- enlarged pupil;
- stomach cramps, nausea, vomiting, diarrhoea;
- difficulty in sleeping;
- loss of appetite.

4. Possible side effects

Eptadone can have side effects.

Not all side effects reported for Eptadone are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Eptadone, please consult your healthcare provider for advice.

If any of the following happens, stop taking Eptadone and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Severe itching of your skin with raised lumps.

These are all very serious side effects. If you have them, you may have had a serious reaction to Eptadone.

You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- changes in the way your heart beats, for example if you notice it beating faster;
- breathing difficulties and worsening of existing asthma;
- if your breathing becomes slow and shallow;
- confusion and disorientation;
- sleep disturbances;
- feeling elated (very happy); feeling down (dysphoria);
- agitation (annoyance);
- blurred vision, small pupils, dry eyes, visual disturbances;
- seeing or hearing things that are not there (hallucinations);
- breast growth and production of breast milk.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea (feeling sick);
- vomiting;
- constipation;
- sweating;
- dizziness;
- drowsiness;
- feeling weak, tired;

- weight gain;
- fluid retention (swollen ankles, feet or legs);
- headaches;
- reduced sexual urge.

Less frequent side effects:

- fainting or passing out;
- dry mouth and nose;
- low blood pressure;
- itching skin;
- problems passing urine;
- inflammation of the tongue;
- facial flushing;
- low body heat (hypothermia);
- painful periods or lack of periods;
- underactive thyroid gland;
- biliary dyskinesia (a functional gallbladder disorder);
- you can become dependent of Eptadone (for more information see section 2 Warnings and precautions).

Side effects with unknown frequencies:

- reversible thrombocytopenia (low number of platelets in the blood) in opioid dependent patients with chronic hepatitis (inflammation of the liver).
- increased prolactin levels;
- decreased activity of the adrenal glands;
- hypogonadism (body's sex glands produce little or no hormones);

- anorexia (eating disorder causing people to obsess about weight and what they eat);
- low blood levels of potassium;
- low blood levels of magnesium;
- low blood sugar;
- increase intracranial pressure;
- nystagmus (involuntary rhythmic side-to-side, up and down or circular motion of the eyes), strabismus (eyes that look in different directions from each other), vision loss;
- sleep apnoea (breathing pauses during sleep).

You may develop tolerance to the effects Eptadone; this means you may notice that your medicine is less effective at relieving your symptoms.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Eptadone.

5. How to store Eptadone

Store all medicines out of reach of children.

Store Eptadone 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.

Store at or below 25 °C.

Store in the original packaging to protect from light.

Keep the container tightly closed.

Do not use after the expiry date stated on the label / carton / bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What Eptadone contains

- The active substance is methadone hydrochloride.
- The other ingredients are xylitol, glycerol, sodium benzoate, citric acid monohydrate, cherry flavour, hydroxyethylcellulose, brilliant blue FCF (E133) and purified water.

What Eptadone looks like and contents of the pack

Eptadone is a clear, blue coloured syrup liquid with cherry taste.

100 mL

An amber transparent glass bottle, closed with a child resistant, tamper evident polyethylene (LDPE/HDPE) screw cap, with a polyethylene (LDPE) insert. A measuring pipette is provided in the final package of the 100 mL bottle.

500 mL

An amber non-plasticised PVC (Poly Vinyl Chloride) 500 mL bottle with 28 mm treaded neck, closed with a polypropylene child-proof screw cap fitted with a polyethylene (EPE) liner. A graduated measuring cup is provided in the final package

1 000 mL

An amber non-plasticised PVC (Poly Vinyl Chloride) 1000 mL bottle with brim-full capacity of 1375 ± 30 mL, closed with a polypropylene child-proof screw cap fitted with a polyethylene (EPE) liner and a one-piece top tabbed multistrata induction inner seal. A graduated measuring cup is provided in the final package

Holder of Certificate of Registration

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Oral solution
Each mL contains methadone hydrochloride 10 mg

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