

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S6**

EQUITY METHADONE, 2 mg/ml, oral solution

Methadone hydrochloride

Contains sodium benzoate 0,12 % *m/v* as preservative

Contains sunset yellow (E110) 0,008 mg/ml

Contains sweetener (Saccharine sodium 0,25 mg/ml and sodium cyclamate 2,5 mg/ml)

EQUITY METHADONE is a sugar free oral solution

Read all of this leaflet carefully before you start taking EQUITY METHADONE

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- EQUITY METHADONE 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 EQUITY METHADONE is and what it is used for
2. What you need to know before you take EQUITY METHADONE
3. How to take EQUITY METHADONE
4. Possible side effects
5. How to store EQUITY METHADONE
6. Contents of the pack and other information

- 1. What EQUITY METHADONE is and what it is used for**

EQUITY METHADONE is a synthetic opiate (a morphine-like medicine) used in the treatment of opioid drug addiction. The treatment should be given at the same time as medical and psychological treatment and social rehabilitation.

2. What you need to know before you take EQUITY METHADONE

Do not take EQUITY METHADONE:

- If you are hypersensitive (allergic) to methadone or to any of the other ingredients of EQUITY METHADONE (listed in section 6).
- If you have any breathing difficulties or a history of asthma. You must not use EQUITY METHADONE during an asthma attack. Wait until the asthma attack has passed and you are fully recovered before taking EQUITY METHADONE.
- If you use or have used monoamine oxidase inhibitors (MAOIs - medicines used in the treatment of depression, Parkinson's disease) within the last two weeks.

EQUITY METHADONE should not be given to children.

Warnings and precautions

Take special care with EQUITY METHADONE.

Tolerance, dependence, and addiction

This medicine 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 EQUITY METHADONE 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 EQUITY METHADONE if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal medicines (“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 EQUITY METHADONE 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 to 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).

Sleep-related breathing disorders

EQUITY METHADONE 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.

Before taking EQUITY METHADONE, tell your doctor:

- EQUITY METHADONE may affect the electrical signals which control your heart contractions, particularly at high doses. Tell your doctor if you have a history of heart problems or have had a heart disease or irregular heartbeat.
- If you have a family history of sudden deaths.
- If you have low sodium or potassium levels in your blood.
- If your liver or kidneys are not functioning properly (including kidney calculi and gallstones).
- If you have an under-active thyroid gland or skin and tissues disorders.
- If you have prostate problems (an enlarged prostate gland) or narrowed urethra, and you have difficulty in passing urine.
- If you have a head injury and the pressure inside your brain is higher than it should be. Check this with your doctor - you might be getting bad headaches.
- If you are an elderly or very ill person. You may be sensitive to the medicine and may cause low blood pressure and fainting.
- If you have abdominal pain, diarrhoea or constipation.
- If you have acute asthma attacks.
- If you are suffering from lung disease or breathing difficulties.
- If you have low oxygen level or high carbon dioxide level in the blood.
- If you are taking other opioid type (painkiller) medicines such as morphine and pentazocine.
- If you are being treated for medicine addiction or opioid overdose
- You are taking medicines that relax you and help you to sleep (barbiturates and benzodiazepines).

Some medicines can increase the risk of heart problems when used with EQUITY METHADONE. Tell your doctor if you are taking any of the following:

- Medicines for heart problems (e.g. verapamil, enalapril)
- Medicines which affect the electrolyte balance such as diuretics (water tablets) or lithium.

Tell your doctor if you are taking or have taken in the last two weeks monoamine oxidase inhibitors (MAOIs) for depression.

Tell your doctor also if you are taking other antidepressants, central nervous system (CNS) depressants, H₂ antagonists, antibacterial-, antiretroviral- and antifungal medicines, anti-epileptic medicines, medicines that make the urine acidic, opioid agonist analgesics, medicines used to block or reverse the effects of opioids or St. John's Wort. See also 'Using other medicines with EQUITY METHADONE' below.

Children

Children are more sensitive to methadone than adults; that is why poisoning may occur at very low doses. To avoid unintentional intake of EQUITY METHADONE by children when it is taken home, keep it in a safe place where children cannot reach it.

Other medicines and EQUITY METHADONE

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:

- Medicines used to treat depression known as monoamine oxidase inhibitors (MAOIs), particularly if you have taken them within the last two weeks. Also tell your doctor if you use other medicines to treat depression (e.g. fluvoxamine, fluoxetine, imipramine, desipramine, nefazodone, paroxetine and sertraline).
- Anti-inflammatory and immunosuppressants (e.g. dexamethasone and ciclosporin).
- CNS depressants or medicines that make you feel sleepy (e.g. medicines such as sedatives, tranquilisers, hypnotics, anaesthetics).
- H₂ antagonists (e.g. cimetidine, used to reduce stomach acid production).
- Medicines used to treat diarrhoea (loperamide, diphenoxylate).

- Any medicines that have an effect on your mental state (e.g. thioridazine, phenothiazines, haloperidol and sertindole).
- Antibacterial medicines such as rifampicin (used to treat tuberculosis), ciprofloxacin, and macrolide antibiotics (e.g. erythromycin, clarithromycin).
- Medicines used to treat epilepsy (e.g. phenytoin, carbamazepine).
- Medicines that make the urine more acidic (e.g. ascorbic acid - vitamin C, ammonium chloride).
- Opioid agonist analgesics (e.g. strong painkillers such as codeine, pentazocine).
- Medicines used to block or reverse the effects of opioids e.g. naloxone (used to treat breathing difficulties) and naltrexone or buprenorphine (used to treat addiction).
- Antiretroviral medicines (e.g. nelfinavir, nevirapine, efavirenz, zidovudine, ritonavir, abacavir, didanosine and stavudine) - may affect blood concentrations of methadone and therefore, your doctor may consider EQUITY METHADONE dosage adjustments if you are taking these medicines.
- Azole antifungal medicines (e.g. ketoconazole, fluconazole, itraconazole).
- St John's Wort (a herbal preparation).
- Medicines for heart problems (e.g. verapamil, enalapril, quinidine).
- Medicines which affect the electrolyte balance such as diuretics (water tablets e.g. (spironolactone)) or lithium.
- 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.
- Concomitant use of EQUITY METHADONE and sedative medicines such as benzodiazepines or related medicines increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if your doctor does prescribe EQUITY METHADONE together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Other medicines you may be taking can also affect the heart (e.g. sotalol, amiodarone and flecainide).

Please consult your doctor, pharmacist or other healthcare provider for advice.

Taking EQUITY METHADONE with food or drink

You should not drink alcohol while taking EQUITY METHADONE.

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 EQUITY METHADONE.

EQUITY METHADONE is distributed into breast milk. You should therefore not use EQUITY METHADONE while breastfeeding your baby.

No fertility data are available.

Driving and using machines

EQUITY METHADONE will severely affect your ability to drive or use machines, whilst taking it and afterwards. You should only resume these activities with the permission of your doctor.

EQUITY METHADONE contains the following excipients

EQUITY METHADONE contains Sunset Yellow (E110), which may cause allergic reactions, and blood orange flavour (including propylene glycol) which may cause alcohol-like symptoms.

EQUITY METHADONE is sugar free.

EQUITY METHADONE contains 1,20 mg Sodium benzoate in each 1 ml solution, which is equivalent to 0,12 % *m/v*. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

EQUITY METHADONE contains less than 1 mmol sodium (23 mg) per 1 ml solution solution, i.e., essentially 'sodium-free'.

3. How to take EQUITY METHADONE

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

Always take EQUITY METHADONE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

EQUITY METHADONE is to be taken by mouth.

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.

Children: EQUITY METHADONE must not be used in children.

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.

If you have the impression that the effect of EQUITY METHADONE is too strong or too weak, talk to your doctor or pharmacist.

If you take more EQUITY METHADONE than you should

If you take too much EQUITY METHADONE you can experience the following:

- difficulty breathing
- extreme sleepiness, fainting or coma
- pinpoint pupils
- muscle weakness
- cold and clammy skin
- slow heartbeat, low blood pressure, heart attack or shock
- in severe cases death may occur
- a brain disorder (known as toxic leukoencephalopathy).

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

If you forget to take EQUITY METHADONE

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

Effects when treatment with EQUITY METHADONE is stopped

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

4. Possible side effects

EQUITY METHADONE can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to EQUITY METHADONE. 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 or irregular heartbeat
- breathing difficulties (including with cough) and dizziness.

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

- weight increase
- water retention
- nausea (feeling sick)
- vomiting (being sick)
- constipation (obstipation)
- seeing or hearing things that are not real (hallucinations)

- blurred vision
- pinpoint, small pupils
- sweating
- drowsiness or feeling sleepy (sedation)
- confusion
- headache
- sleep disturbances
- feeling elated or high (euphoria)
- feeling tired (fatigue).

Less frequent side effects

- if you have an under-active thyroid gland or low thyroid function (hypothyroidism)
- loss of appetite
- dry mouth
- inflammation of tongue
- feeling down (dysphoria)
- agitation
- difficulty sleeping
- worsening of existing asthma
- visual disturbances
- fainting
- bile duct spasm (abdominal pain)
- facial flush
- low blood pressure
- itching skin
- problems passing urine
- reduced sexual urge

- difficulty achieving or maintaining an erection
- disturbances in menstruation
- weakness (asthenia).

Frequency unknown

- deficiency of potassium or magnesium in blood
- lower levels of platelets in blood
- you can become dependent on EQUITY METHADONE (for more information see section 2)
- sleep apnoea (breathing pauses during sleep).

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

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

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 “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of EQUITY METHADONE.

5. How to store EQUITY METHADONE

- Store at or below 25 °C.
- Keep the bottle in the outer carton to protect it from light.
- Store all medicines out of reach of children.
- 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 use the medicine after the expiry date printed on the carton and bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What EQUITY METHADONE contains

The active substance is: methadone hydrochloride.

The other ingredients are: blood orange flavouring, purified water, saccharin sodium, sodium benzoate (0,12 % *m/v* as preservative), sodium cyclamate, and sunset yellow FCF (E110).

What EQUITY METHADONE looks like and contents of the pack

Clear, pale orange solution, practically free from particles.

EQUITY METHADONE is available in 60 ml and 500 ml pack sizes. The solution is filled into an amber glass bottle with a plastic child-proof cap, with opaque tamper evident plastic band, clean printed black text on top.

Holder of Certificate of Registration

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