

Package leaflet: Information for the user

Physeptone 1mg/1ml Oral Solution sugar-free

Methadone Hydrochloride

(This medicine will be referred to as Physeptone Oral Solution in this leaflet)

Read all of this leaflet carefully before you start taking Physeptone Oral Solution because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

This leaflet contains a summary of the information available for this medicine. You should ask your doctor or pharmacist if you are unsure about any aspect of this medicine.

This medicine contains methadone, which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

1. What Physeptone Oral Solution is and what it is used for

This medicine has been prescribed for you for the treatment of addiction in order to reduce withdrawal symptoms.

It contains the methadone which belongs to a class of medicines called opioids.

This medicine has been prescribed to you and should not be given to anyone else.

Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you take Physeptone Oral Solution

Do not take Physeptone Oral Solution if:

- You are allergic to methadone or any of the ingredients of this medicine (listed in section 6).
- You have any problem with your breathing, any chronic lung disease or have an asthma attack.
- You are addicted to alcohol.
- 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.
- You are taking, or have recently stopped taking, a type of medicine called Monoamine Oxidase Inhibitors (MAOIs), including moclobemide which are used to treat depression, within the past two weeks.
- You are in labour.
- You have a bowel problem called ulcerative colitis.
- You are dependent on other non-opioid drugs.
- You have severe liver disease.
- You suffer from sudden involuntary muscle contraction of the bile ducts and kidney.

Physeptone Oral Solution is not suitable for children.

Warnings and precautions

Talk to your doctor or pharmacist before taking Physeptone Oral Solution if:

- You are extremely ill or an older person. You may be more sensitive to the medicine.

- You have history of asthma or breathing difficulties.
- You have bowel problems.
- You have liver or kidney problems.
- You have a history of convulsions, fits or epilepsy.
- You have a history of low blood pressure.
- You have a history of under-active thyroid gland, or problems with your adrenal glands.
- You have a history of enlarged prostate gland.
- You have a condition that causes severe muscle weakness and fatigue (myasthenia gravis).
- You are in shock.
- You are taking medicines called CNS depressants to treat anxiety, acute stress and panic attacks.

Sleep-related breathing disorders

Physeptone oral solution 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.

Methadone may affect the electrical signals which control your heart contractions, particularly at high doses.

Tell your doctor you have recognised risk factors for the heart condition 'QT prolongation' that include if

- you have a history of heart problems
- you have liver disease
- you have any blood abnormalities such as low levels of potassium or magnesium
- you have a history of sudden death in the family.

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 Physeptone oral solution 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 Physeptone oral solution 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 Physeptone oral solution, 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 Physeptone oral solution).

Taking this medicine regularly, particularly for a long time, can lead to addiction

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness,

difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber 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.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Long-term use may cause decreased sex hormone levels and increased levels of the hormone prolactin. Contact your doctor if you experience symptoms such as decreased libido, impotence or absence of menstruation (amenorrhoea).

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking Physeptone Oral Solution:

- Weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. This may be a symptom of the adrenals producing too little of the hormone cortisol, and you may need to take hormone supplement.

During treatment, this medicine should not be stopped suddenly, but gradually, as sudden stoppage could lead to withdrawal symptoms.

Children and adolescents

Physeptone Oral Solution is not suitable for children.

Other medicines and Physeptone Oral Solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Medicines used to treat addiction e.g. naltrexone and buprenorphine.
- Cimetidine (a medicine used to treat stomach ulcers).
- Medicines used to treat epilepsy such as phenytoin, carbamazepine, phenobarbital and primidone.
- Naloxone (a medicine used to treat an overdose of opioid medicines).
- Antibiotics (medicines used to treat bacterial infections e.g. ciprofloxacin).
- Antifungals (medicines used to treat fungal infections).
- Medicines that make urine more acidic e.g. ammonium chloride.
- Antiviral medicines including some medicines used to treat HIV e.g. nevirapine, zidovudine, efavirenz, nelfinavir and ritonavir.
- Medicines used to treat depression including fluvoxamine and fluoxetine, tricyclic antidepressants such as amitriptyline and imipramine, or MAOIs including moclobemide, must not be taken at the same time or within 2 weeks of taking MAOIs.
- CNS depressants (medicines that act on the brain and cause drowsiness or sleepiness).
- Pentazocine (a pain killer).
- Medicines used to help you relax (tranquillisers)
- Medicines used to help you to sleep (sedatives).
- St John's Wort.
- Medicines used to treat tuberculosis (rifampicin).
- Medicines used to treat pain and fever such as metamizole.
- fluconazole (used for treating infections)
- 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 risk of side effects increases, if you use methadone concomitantly with antidepressants (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine, amitriptyline, clomipramine, imipramine, nortriptyline). Contact your doctor if you experience symptoms such as:

- mental-status changes (e.g. agitation, hallucinations, coma)
- fast heartbeat, unstable blood pressure, fever
- exaggeration of reflexes, impaired coordination, muscle stiffness
- gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea)

Other medicines you may be taking can also affect the heart. You must tell your doctor about any other medicines that you are taking as they may be dangerous if they are taken with methadone. In these situations your doctor may decide that it is necessary to monitor your heart with an electrocardiogram (ECG) at the start of treatment to ensure that these effects do not occur.

Concomitant use of Physeptone Oral Solution and sedative medicines such as benzodiazepines or related drugs 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 Physeptone Oral Solution 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.

Physeptone Oral Solution with food and drink

You must not drink alcohol whilst you are taking Physeptone Oral Solution as this could cause serious side effects. You are advised not to drink grapefruit juice whilst you are being treated with this medicine as it could cause an overdose

Pregnancy, breast-feeding and labour

If you are pregnant or breast feeding, think you maybe pregnant or are planning to have a baby, ask your doctor or pharmacist before taking this medicine.

Talk to your doctor if you are breastfeeding or thinking of breast-feeding while you are taking methadone as it may affect your baby. Monitor your baby for abnormal signs and symptoms such as increased drowsiness (more than usual), breathing difficulties or limpness. Consult your doctor immediately if you notice any of these symptoms.

Pregnancy:

Do not take Physeptone Oral Solution if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Physeptone Oral Solution during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Breast-feeding:

Do not take Physeptone Oral Solution while you are breastfeeding as methadone passes into breast milk and will affect your baby.

Labour:

You should not take Physeptone Oral Solution whilst you are in labour.

Driving and using machinery

The ability to drive or use machinery may be severely affected during and after treatment with methadone. You must not drive or use machinery until you are told that you can do so by your doctor.

This medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Important information about some of the ingredients

Physeptone Oral Solution contains:

- Colouring agent E110 (sunset yellow) which may cause an allergic reaction.
- liquid maltitol - If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Physeptone Oral Solution

You must only take Physeptone Oral Solution by mouth. Under no circumstances should you inject this product as injection may cause serious and permanent damage to your body with possibly fatal consequences.

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Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. It is important that you do not take more than the dose agreed with your doctor. You can become dependent on Physeptone Oral Solution.

Your prescriber should discuss your treatment and whether you need to continue taking Physeptone Oral Solution at regular intervals. If you and your prescriber decide to stop treatment a plan will be put in place to gradually reduce the dose and stop taking the medicine to minimise the risk of withdrawal effects.

Adults:

The recommended initial dose is 10-20mg a day. The dose will be slowly increased until you show no signs of withdrawal or intoxication. The usual dose is 60-120mg per day.

Elderly or ill:

If you are elderly or ill, your doctor will only prescribe repeated doses with caution.

Use in children

Not recommended. There is a serious risk of poisoning. Remember to keep your medicine safely where children can not get it.

If you forget to take Physeptone Oral Solution

During a course of treatment it is important that, should you miss a dose, you take the dose as soon as you remember. However, if it is almost time for you to take your next dose, miss the dose and wait until the next scheduled dose.

DO NOT TAKE A DOUBLE DOSE TO MAKE UP FOR A FORGOTTEN DOSE.

If you stop taking Physeptone Oral Solution

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

If you take more Physeptone Oral Solution than you should

If you take too much Physeptone Oral Solution, you can experience the following:

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

In the event of overdose you should seek medical assistance immediately even if you feel well as you may be suffering methadone poisoning.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking this medicine and see a doctor straight away if you have an allergic reaction to Physeptone Oral Solution.

An allergic reaction may include:

- swelling of your face, lips, tongue or throat or difficulty breathing or swallowing
- severe itching of your skin with raised lumps.

Stop taking this medicine and see a doctor straight away if you have any of the following:

- heart problems. The signs of this may include changes in the way your heart beats, such as it beating faster or missed heart beats, breathing difficulties and dizziness
- if your breathing become slow and shallow.

Keep taking the medicine but tell your doctor straight away if you get any of the following side effects:

- if you have asthma and it gets worse
- worsening of the pressure inside your head if you already have this condition following an injury to your brain or brain disease.

Frequency not known:

You can become dependent on Physeptone Oral Solution (for more information see section 2 Warnings and Precautions)

Other side effects:

- feeling sick (nausea) or being sick (vomiting)
- constipation
- sweating a lot more than usual
- feeling dizzy, particularly when standing up. This may be a sign that you have low blood pressure
- small pupils
- breast growth and excessive production of breast milk
- difficulty in passing water (urine), pain in the lower back and abdomen caused by muscle spasms
- dry mouth, eyes or nose, facial flushing
- feeling drowsy, confused or restless
- changes in your mood, feeling "high" or over excited
- seeing or hearing things that are not there (hallucinations)
- headache, rashes
- low body heat (hypothermia)
- painful periods or lack of periods
- high prolactin level in the blood
- dependence and addiction
- low blood sugar
- Sleep apnoea (breathing pauses during sleep)

Drug Withdrawal

When you stop taking Physeptone Oral Solution, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

You may notice that some of the side effects become less severe with time as you get used to the methadone.

When taken for a long period of time, it is possible that you may become dependent on Physeptone Oral Solution.

This product contains sunset yellow which may cause allergic reaction.

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Physeptone Oral Solution

Keep this medicine out of the sight and 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 this medicine after the expiry date which is stated on the bottle. The expiry date refers to the last date of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment. Once you have opened the bottle you are advised to dispose of it after 4 weeks.

Do not store above 25°C.

6. Contents of the pack and other information

What Physeptone Oral Solution contains:

The **active ingredient** is Methadone Hydrochloride 1mg/1ml. The **other ingredients** are Maltitol liquid, Hydrochloric acid, sodium benzoate (E211), purified water and colours E110 (sunset yellow FCF), E142 (green 5) and quinoline yellow (E104).

What Physeptone Oral Solution looks like and the contents of the pack:

Physeptone Oral Solution is a bright green liquid, supplied in amber glass bottles, each containing 500, 100, 50 or 30ml of the solution, or it is supplied in HDPE plastic bottles, each containing 5L, 2.5L, 1L or 500ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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If this leaflet is difficult to see or read, please contact the marketing authorisation holder for help.

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