PACKAGE LEAFLET: INFORMATION FOR THE USER

Physeptone Mixture

Methadone Hydrochloride
(This medicine will be referred to as Physeptone Mixture in this leaflet)

Read all this leaflet carefully before you take Physeptone Mixture 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 Mixture is and what it is used for
2. What you need to know before you take Physeptone Mixture
3. How to take Physeptone Mixture
4. Possible side effects
5. How to store Physeptone Mixture
6. Contents of the pack and other information

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 Mixture 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 Mixture

Do not take Physeptone Mixture 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 have a bowel disorder known as paralytic ileus.
- 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 are a child.
- You are dependent on other non-opioid drugs.
- You have phaeochromocytoma, a tumour of the adrenal glands.

Warnings and precautions
Talk to your doctor or pharmacist before taking Physeptone Mixture 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.

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

Sleep-related breathing disorders
Physeptone Mixture 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.

Physeptone Mixture 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 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 Mixture 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 Mixture 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 Mixture, 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 Mixture).

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 (amenorrhea).

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking Physeptone Mixture:
- 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.
- Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) or the biliary tract system.
- Pain or increased sensitivity to pain (hyperalgesia) which does not respond to a higher dosage of your medicine.

Other medicines and Physeptone Mixture
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)
- drugs used to treat epilepsy (e.g. phenytoin, phenobarbital, primidone and carbamazepine)
- naloxone (a medicine used to treat difficulties with breathing)
- antibiotics (medicines used to treat bacterial infections)
- antifungals (medicines used to treat fungal infections)
- medicines that make urine more acidic e.g. ammonium chloride
- antiviral drugs including some medicines used to treat HIV e.g. nevirapine, zidovudine, efavirenz, nelfinavir, ritonavir and abacavir
- metoclopramide or domperidone (medicines used to stop you feeling and being sick)
- mexiletine (a drug used to treat heart irregularities)
- medicines used to treat depression including fluvoxamine, 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)
- other opioid type drugs e.g. morphine
- pentazocine (a pain killer)
- medicines used to help you relax (tranquillisers)
- medicines used to help you to sleep (sedatives).
- herbal medicines including St John's Wort
- medicines used to treat tuberculosis (rifampicin)
- medicines used to treat certain mental and emotional conditions (anti-psychotics)
- 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 physeptone. 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 Methadone Mixture 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 Methadone Mixture 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 Mixture with food, drink and alcohol
You must not drink alcohol whilst you are taking Physeptone Mixture as this could cause serious side effects.

You are advised not to drink grapefruit juice whilst you are being treated with Physeptone Mixture as it could cause an overdose.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast feeding, think you may be 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 Mixture 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 Mixture during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Some studies have reported birth defects or neurodevelopmental problems (problems with early childhood development in children born to mothers who used methadone during pregnancy to treat opioid addiction. However, it is not possible to determine if this is caused by methadone use or other factors such as the health of the mother and social and environmental conditions associated with opioid addiction.

Breast-feeding:
Do not take Physeptone Mixture while you are breastfeeding as methadone passes into breast milk and will affect your baby.

Labour:
You should not take Physeptone Mixture whilst you are in labour.

Driving and using machines
The ability to drive or use machinery may be severely affected during and after treatment with physeptone. 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 and operate machinery 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 Mixture contains:
- glycerol which may cause headache, stomach upset and diarrhoea

Continued overleaf

100mm MEASUREMENT VERIFICATION BAR

- Tartrazine (E102) and sunset yellow (E110) which may cause allergic reactions.
- 26.49g of demineralised liquid sucrose per maximum daily dose. This should be taken into account if you suffer from diabetes mellitus. It may also be harmful to your teeth.

3. How to take Physeptone Mixture

You must only take Physeptone Mixture 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.

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 dependant on Physeptone Mixture.

Your prescriber should discuss your treatment and whether you need to continue taking Physeptone Mixture 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:

For the treatment of drug addiction:
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/day. Your doctor will decide what dose you need and when to reduce the dose.

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

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 Mixture
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.

If you stop taking Physeptone Mixture
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.

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

If you take more Physeptone Mixture than you should
If you take too much Physeptone Mixture, you can experience the following:
- difficulty in breathing
- extreme sleepiness, fainting or coma
- pin point pupils
- muscle weakness
- cold and clammy skin
- low blood sugar
- 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 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, Physeptone Mixture can cause side effects, although not everybody gets them.

Stop taking this medicine and see a doctor straightaway if you have any of the following:
- 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.
- Severe itching of your skin with raised lumps

Frequency not known:
You can become dependent on Physeptone Mixture (for m
information see section 2 Warnings and Precautions)

Other possible side effects

Very common (may affect more than 1 in 10 people):
- Feeling sick (nausea) or being sick (vomiting)

Common (may affect up to 1 in 10 people):
- changes in your mood, feeling 'high' or over excited
- seeing or hearing things that are not there (hallucination
- drowsiness or sleepiness (sedation)
- blurred vision
- dry eyes
- small pupils
- dizziness, spinning sensation
- constipation
- rash
- sweating
- tiredness
- drowsiness
- weight increase

Uncommon (may affect up to 1 in 100 people):
- feeling tense and restless
- addiction to this medicine
- agitation
- inability to sleep
- reduced sexual drive
- disorientation
- facial flushing
- feeling dizzy, particularly when standing up. This may be a sign that you have low blood pressure
- headache
- fainting
- build-up of fluid in the lungs
- dry nose
- dry mouth
- swollen, red, sore tongue
- swelling of the hip, knee, feet and ankle joints
- difficulty in passing water(urine), pain in the lower back and abdomen caused by muscle spasms
- lower sexual urge or desire
- painful periods or lack of periods
- low body heat(hypothermia)
- unusual weakness (asthenia)
- disorder of the biliary part of the digestive system (bile duct dyskinesia)

Not known (frequency cannot be estimated from the available data):
- High prolactin levels in the blood
- Rapid, uncontrollable movements of the eyes
- dependence and addiction
- low blood sugar
- Sleep apnoea (breathing pauses during sleep)
- Symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system (a problem affecting a valve in the intestines known as sphincter of Oddi dysfunction), e.g. severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever.

The following side effects have also been reported:
Eye and eyesight problems in babies and young children born to mothers who used methadone during pregnancy. This may mean your child needs more frequent eye-tests.

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

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 Mixture

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.

Store below 25°C and protect from light.

6. Contents of the pack and other information

What Physeptone Mixture contains
The active ingredient is Methadone Hydrochloride 1mg in 1ml.

The other ingredients are, demineralised liquid sucrose, glycerol (E422), hydrochloric acid (E507), sodium hydroxide (for pH adjustment), sodium benzoate (E211), purified water and colours tartrazine (E102), sunset yellow (E110), green S (E142).

What Physeptone Mixture looks like and the contents of the pack
Physeptone Mixture is a bright green liquid, supplied in amber glass bottles, each containing 500, 100, 50 or 30ml of the liquid, or it is supplied in HDPE plastic bottles, each containing 5l, 2.5l, 1l or 500ml of the liquid.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Macarthys Laboratories Ltd T/A Martindale Pharma,
Bampton Road, Harold Hill, Romford, Essex, RM3 8UG,
United kingdom

Manufacturers:
Macarthys Laboratories Limited T/A Martindale Pharma,
Bampton Road, Romford, Essex, RM3 8UG, United Kingdom

If this leaflet is difficult to see or read, please contact the marketing authorisation holder for help.
Product licence number: PLGB 01883/0047
This leaflet was last approved in May 2026
© Martindale Pharmaceuticals

MARTINDALE PHARMA
Bampton Road, Harold Hill, Romford, RM3 8UG, UK

D06654 0.0.0.0

100mm MEASUREMENT VERIFICATION BAR

6654-A