

PACKAGE LEAFLET: INFORMATION FOR THE USER

Physeptone 5mg Tablets

Methadone Hydrochloride

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

- Keep this leaflet. You may need to read it again
- If you have any further questions, please 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Physeptone Tablets are and what they are used for
2. What you need to know before you take Physeptone Tablets
3. How to take Physeptone Tablets
4. Possible side effects
5. How to store Physeptone Tablets
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 Tablets are and what they are used for

This medicine has been prescribed for you for treatment of moderate to severe pain. It contains methadone which belongs to a class of medicines called opioids, which are 'pain relievers'. 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 Tablets

Do not take Physeptone Tablets 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 an acquired or inherited heart condition which is characterized by irregular heartbeats.
- You have severe liver disease.
- You suffer from sudden involuntary muscle contraction of the bile ducts and kidney.

Physeptone Tablets are not suitable for children.

Warnings and precautions

Talk to your doctor or pharmacist before taking Physeptone Tablets 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.
- Are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- Have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- Feel you need to take more of methadone tablets to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

You should be aware that prolonged use of Physeptone tablets can result in tolerance of the drug and both physical and psychological addiction to Physeptone tablets. If you have any concerns speak to your doctor before you are given this medicine.

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

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

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).

Physeptone Tablets 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.

Talk to your doctor or pharmacist if you experience any of the following symptoms while taking physeptone tablets:

- 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.

Other medicines and Physeptone Tablets

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.
- Medicines used to treat epilepsy such as phenytoin and carbamazepine
- Naloxone (a medicine used to treat an overdose of opioid medicines).
- Antibiotics (medicines used to treat bacterial infections e.g. ciprofloxacin, erythromycin, telithromycin and clarithromycin).
- Antifungals (medicines used to treat fungal infections) e.g. fluconazole, itraconazole, ketoconazole
- Medicines that make urine more acidic e.g. ammonium chloride and ascorbic acid.
- Antiviral medicines including some medicines used to treat HIV e.g. nevirapine, zidovudine, delavirdine, lopinavir, saquinavir, didanosine, stavudine, efavirenz, nelfinavir, amprenavir and ritonavir.
- Medicines used to treat depression including fluvoxamine, nefazodone, paroxetine, sertraline and fluoxetine 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).
- St John's Wort - a herbal preparation for depression
- Medicines used to treat heart irregularities e.g. quinidine, mexiletine, verapamil, amiodarone, sotalol, flecainide
- Medicines that suppress the immune system e.g. ciclosporin, dexamethasone
- Medicines used to treat certain mental and emotional conditions. (anti-psychotics) e.g. thioridazine, haloperidol, sertindole, and phenothiazines
- Medicines used to treat high blood pressure e.g. spironolactone
- Medicines used to treat diarrhoea e.g. Loperamide
- Medicines used to treat allergies e.g. diphenhydramine
- Medicines used to treat tuberculosis e.g. rifampicin.

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 tablets. 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 tablets 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 tablets 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 Tablets with food and drink

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

Pregnancy, breast-feeding and fertility

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.

Pregnancy

Do not take Physeptone Tablets 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 Tablets during pregnancy, your baby may become dependent and experience

withdrawal symptoms after the birth which may need to be treated.

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.

Breast-feeding:

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

Labour:

You should not take Physeptone Tablets 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.

The 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 Tablets contain:

- **lactose:** 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 Tablets

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 Tablets.

Your prescriber should have discussed with you, how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

Adults: The recommended initial dose is 5-10mg (1 to 2 tablets) every 6 to 8 hours. The dose may be adjusted depending on the level of pain relief you need.

Elderly or ill:

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

Use in children and adolescents

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 Tablets

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 Tablets**

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 Tablets than you should

If you take too many Physeptone Tablets, you can experience the following:

- difficulty in breathing
- extreme sleepiness, fainting or coma
- pin point pupils
- swelling and/or fluid accumulation in the lungs
- low blood pressure
- low blood sugar.

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. Repeated use of Physeptone tablets can result in tolerance and addiction.

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

- 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
- 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
- Low blood platelet count. Symptoms include bleeding or bruising more easily than normal

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):

- fluid retention due to slow metabolism

- changes in your mood, feeling 'high' or over excited
- seeing or hearing things that are not there (hallucinations)
- low magnesium levels in the blood
- drowsiness or sleepiness (sedation)
- blurred vision
- small pupils
- dizziness, spinning sensation
- constipation
- rash

- sweating
- tiredness
- weight increase

Uncommon (may affect up to 1 in 100 people):

- feeling tense and restless
- addiction to medicines
- 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 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
- Unusual weakness (asthenia)

- Itching
- Hives
- Uncontrollable twitching, jerking or writhing movement of the bile duct (bile duct dyskinesia)
- Swelling of the hands, ankles or feet

Not known (frequency cannot be estimated from the available data):

- Loss of appetite
- Low potassium and magnesium levels in the blood
- High prolactin levels in the blood
- Dependence and addiction (see section "How do I know if I am addicted?")
- low blood sugar

Drug Withdrawal

When you stop taking Physeptone Tablets, 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.

How do I know if I am addicted?

If you notice any of the following signs whilst taking physeptone tablets, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the 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 Tablets

Keep this medicine out of the sight and reach of children.

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.

Do not store above 25°C.

6. Contents of the pack and other information**What Physeptone Tablets contain:**

The **active ingredient** is Methadone Hydrochloride 5mg per tablet.

The **other ingredients** are lactose, maize starch, gelatin, glycerol and magnesium stearate.

What Physeptone Tablets look like and the contents of the pack:

Physeptone Tablets are plain white uncoated tablets with break line "MART 5" marking, supplied either in amber glass bottles, each containing 100 tablets or in plastic blister packs, each containing 50 tablets.

Marketing Authorisation Holder:

Macarthy's Laboratories Ltd
T/A Martindale Pharma,
Bampton Road, Harold Hill,
Essex, RM3 8UG,
United Kingdom

Manufacturer:

Dales Pharmaceuticals Ltd,
Snaygill Industrial Estate, Skipton,
North Yorkshire, BD23 2RW
Macarthy's Laboratories Ltd
T/A Martindale Pharma,
Bampton Road, Harold Hill,
Essex, RM3 8UG,
United Kingdom

Product licence number: PL 01883/0062

This leaflet was last revised in: May 2020

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

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

Continued overleaf