

# Physeptone injection

methadone hydrochloride 10 mg/1 mL

## Consumer Medicine Information

### WARNING

#### Limitations of use

Physeptone should only be given when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

#### Hazardous and harmful use

Physeptone poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

#### Life threatening respiratory depression

Physeptone can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting Physeptone and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

#### Use of other medicines while being given Physeptone

Using Physeptone with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while being given Physeptone.

## What is in this leaflet

This leaflet answers some common questions about Physeptone injection. It does not contain all of the available information.

It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of giving you Physeptone injection against the benefits they expect it will have for you.

**If you have any concerns about being given this medicine, ask your doctor.**

**Keep this leaflet while being treated.**

You may need to read it again.

## What is Physeptone injection used for

Physeptone injection contains methadone hydrochloride as the active ingredient, which belongs to

a group of medicines called opioid analgesics.

Physeptone injection is used for the relief of moderate to severe pain.

### Addiction

You can become addicted to Physeptone even if you are given it exactly as prescribed. Physeptone may become habit forming causing mental and physical dependence. If abused, it may become less able to reduce pain.

### Dependence

As with all other opioid containing products, your body may become used to you being given this medicine. Using it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop using Physeptone suddenly, so it is important to take it exactly as directed by your doctor.

### Tolerance

Tolerance to Physeptone may develop, which means that the effect of the medicine may

decrease. If this happens, more may be needed to maintain the same effect.

### Withdrawal

**Continue using your medicine for as long as your doctor tells you.**

If you stop using this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

Physeptone given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

**Ask your doctor if you have any questions about why Physeptone injection has been prescribed for you.**

Your doctor may have prescribed it for another reason.

This medicine is only available with a doctor's prescription.

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## Before you are given it

### *When you must not be given it:*

**You must not be given Physeptone injection if:**

- you have ever had an allergic reaction to methadone hydrochloride or any other opioid drug
- you have any other medical condition including:
  - suffering from a lung disorder such as asthma, or any illness causing difficulty in breathing, especially if there is excessive phlegm or skin is bluish in colour
  - a recent head injury, or increased pressure in the head
  - a bowel condition known as ulcerative colitis
  - certain liver or kidney conditions
  - certain heart conditions
  - alcoholism.
- you are taking or have recently taken antidepressants of the type called monoamine oxidase inhibitors (MAOIs)
- you suffer from biliary and renal tract spasm.

### *Before you are given it*

**Tell your doctor if:**

- you are allergic to foods, dyes, preservatives or any other medicines
- you are pregnant, or become pregnant while taking Physeptone Injection, are about to give birth, or are breastfeeding

- you have any other medical condition including:
  - hormone problems
  - diabetes
  - prostate disease
  - pheochromocytoma (a rare tumour of the adrenal gland).Symptoms include bouts of anxiety and headaches. There may be palpitations (banging of the heart felt in the chest), dizziness, weakness, nausea, vomiting, diarrhoea, dilated pupils, blurry vision, stomach pains and raised blood pressure.

### *Taking other medicines*

**Tell your doctor if you are taking any other medicines or intend to drink alcohol while you are being given Physeptone injection.**

These include medicines that you buy without a prescription from a pharmacy, supermarket or health food shop, including St John's Wort.

Your doctor or pharmacist will have a more complete list of the medicines that may cause problems when being treated with Physeptone injection.

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## How it is given

Physeptone Injection will be administered under the supervision of a doctor.

It is administered by injection into a muscle or just under the skin.

Your doctor will explain to you how long your course of treatment with Physeptone injection will be and will advise you when the treatment is complete.

### *Use in children and elderly patients*

Physeptone injection is not recommended for use in children.

The doctor may prescribe a smaller dose in elderly patients.

### *If you are given too much (overdose)*

As this medicine is given to you under the supervision of your doctor, it is extremely unlikely that you will be given too much.

However, if you or someone else receive too much (overdose) and experience one or more of the symptoms below, immediately call triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally been given Physeptone that was prescribed for you. If someone takes an overdose they may experience one or more of the following symptoms:

- slow, unusual or difficult breathing
- drowsiness, dizziness or unconsciousness
- slow or weak heartbeat
- nausea or vomiting
- convulsions or fits.

If you think you or someone else may have been given too much Physeptone, you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

When seeking medical attention, take this information to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

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## While you are having it

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### *Things to be careful of*

As Physeptone injection may cause drowsiness, it is recommended that you do not drive, use machinery or undertake any activities where alertness is required.

It is unwise to drink alcohol while being given Physeptone injection.

Particular care should be taken when starting on treatment with Physeptone injection or increasing the dose. This medicine can decrease heart and breathing rates, which if severe may lead to death.

**Speak to your doctor immediately if you have any concerns.**

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## Side effects

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**Tell your doctor as soon as possible if you do not feel well while you are being given Physeptone injection.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

With prolonged use, the dose may have to be increased to achieve the same benefit, whilst a sudden decrease in dose or interruption of therapy may give rise to withdrawal symptoms.

**Tell your doctor if you notice any of the following and they worry you.**

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• soreness at the site of injection</li><li>• drowsiness</li><li>• dizziness</li><li>• light-headedness</li><li>• nausea</li><li>• vomiting</li><li>• dry mouth</li><li>• sweating</li><li>• confusion</li><li>• constipation</li><li>• problems with urine flow</li><li>• tolerance and dependence.</li></ul>	Speak to your doctor or pharmacist if you have any of these less serious, common side effects and they worry you.
<ul style="list-style-type: none"><li>• decreased libido</li><li>• impotence</li><li>• absence of menstruation</li></ul>	Speak to your doctor if you have any of these side effects that may be associated with long term use.

Serious side effects	What to do
Allergic reaction including: <ul style="list-style-type: none"><li>• wheezing</li><li>• swelling of the lips/ mouth</li><li>• difficulty in breathing</li><li>• hayfever</li><li>• lumpy rash (hives)</li><li>• fainting.</li></ul>	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

**Tell your doctor if you notice anything else that is making you feel unwell, even if you think the problems are not connected with this medicine and are not referred to in this leaflet.**

Other side effects not listed above may also occur in some people.

**Do not be alarmed by this of possible side effects.**

You may not experience any of them.

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## After using it

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### *Storage*

**Keep Physeptone injection in its carton protected from light, in a cool, dry place where the temperature stays below 25°C.**

**Keep this medicine where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

**Return any unused or expired medicine to your pharmacist.**

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## Product description

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### *What it looks like*

Physeptone injection is a clear, colourless solution in a clear 1 mL glass vial. Available in packs of 5 single-use vials.

### *Ingredients*

Each 1 mL vial contains methadone hydrochloride 10 mg and water for injections.

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## Sponsor

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Australian Registration Number:  
AUST R 159750

This leaflet was revised in  
December 2024.