

# PHYSEPTONE injection

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

**WARNING:** Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

### 1. Why am I being given PHYSEPTONE injection?

PHYSEPTONE injection contains the active ingredient methadone, as methadone hydrochloride. PHYSEPTONE injection is used for the relief of moderate to severe pain.

For more information, see Section [1. Why am I being given PHYSEPTONE injection?](#) in the full CMI.

### 2. What should I know before I receive PHYSEPTONE INJECTION?

You should not be given PHYSEPTONE injection if you have ever had an allergic reaction to methadone or any other opioid analgesic.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I receive PHYSEPTONE injection?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with PHYSEPTONE injection and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How is PHYSEPTONE injection 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.

More instructions can be found in Section [4. How is PHYSEPTONE injection given?](#) in the full CMI.

### 5. What should I know while receiving PHYSEPTONE injection?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using PHYSEPTONE injection.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• As PHYSEPTONE injection may cause drowsiness, it is recommended that you do not drive, use machinery or undertake any activities where alertness is required.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol. It is unwise to drink alcohol while being given PHYSEPTONE injection.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep this medicine in its carton protected from light, in a cool, dry place where the temperature stays below 25°C.</li></ul>

For more information, see Section [5. What should I know while receiving PHYSEPTONE injection?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects of PHYSEPTONE injection include soreness at the injection site, drowsiness, dizziness, light-headedness, nausea, vomiting, dry mouth, sweating, confusion, constipation, problems with urine flow, and tolerance and dependence. With prolonged use, a sudden decrease in dose or interruption of therapy may result in withdrawal symptoms.

Serious side effects of PHYSEPTONE injection are associated with allergic reaction. Symptoms of this include wheezing, swelling of the lips/mouth, difficulty breathing, hay fever, lumpy rash (hives), and fainting.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

## 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.

# PHYSEPTONE injection

Active ingredient: *methadone hydrochloride*

## Consumer Medicine Information (CMI)

This leaflet provides important information about being given PHYSEPTONE injection.

**You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being given PHYSEPTONE injection.**

Where to find information in this leaflet:

- [1. Why am I being given PHYSEPTONE injection?](#)
- [2. What should I know before I receive PHYSEPTONE injection?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is PHYSEPTONE injection given?](#)
- [5. What should I know while receiving PHYSEPTONE injection?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I being given PHYSEPTONE injection?

PHYSEPTONE injection contains the active ingredient methadone, as methadone hydrochloride. Methadone belongs to a group of medicines called opioid analgesics.

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

**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.

## 2. What should I know before I receive PHYSEPTONE injection?

### Warnings

#### 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 being given PHYSEPTONE suddenly, so it is important to be 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.

**You should not be given PHYSEPTONE injection if:**

- you are allergic to methadone hydrochloride or any other opioid drug.
  - Some symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue, or any other parts of the body; rash, itching or hives on the skin.
- you are taking or have recently taken antidepressants of the type called monoamine oxidase inhibitors (MAOIs)
- the expiry date printed on the pack has passed.
- the packaging is torn or shows signs of tampering.
- you have any of the following medical conditions:
  - 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
  - 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
  - biliary and renal tract spasm.

**Check with your doctor if you:**

- are allergic to any other medicines, or any other substances, such as foods, preservatives, or dyes.
- have any other medical conditions, especially the following:
  - 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.
- take any medicines for any other conditions or intend to drink alcohol.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

**Pregnancy and breastfeeding**

**Check with your doctor if you are or intend to become pregnant, are about to give birth, or are breastfeeding.**

**Use in children**

PHYSEPTONE is not recommended for use in children less than 18 years of age.

**Use in the elderly**

The doctor may prescribe a smaller dose in elderly patients.

**3. What if I am taking other medicines?**

**Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines may interfere with PHYSEPTONE injection and affect how it works. These include:

- some antidepressant medicines (including some SSRIs, MAOIs, and tricyclic antidepressants)
- some antiviral medicines
- other drugs that may have a sedative effect
- diuretics
- laxatives
- fluconazole
- rifampicin
- phenytoin
- carbamazepine
- St John's Wort.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PHYSEPTONE injection.**

**4. How is PHYSEPTONE injection given?**

**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.

**If you are given too much**

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.**

Symptoms of an overdose include:

- slow, unusual or difficult breathing
- drowsiness, dizziness or unconsciousness
- slow or weak heartbeat
- nausea or vomiting
- convulsions or fits
- confusion, memory loss
- difficulty walking
- changes in behaviour or personality.

Keep the person awake by talking to them or gently shaking them every now and then.

If you think that you or someone else have been given too much PHYSEPTONE or if you are particularly sensitive to it, medical attention may be urgently needed.

**If any overdose occurs, 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.**

Be sure to report any other medicine or alcohol which has been taken.

## 5. What should I know while receiving PHYSEPTONE injection?

### Things you should do

**Remind any doctor, dentist or pharmacist you visit that you are using PHYSEPTONE injection.**

### Things to be careful of

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

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

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how PHYSEPTONE affects you.**

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

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

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

### Looking after your medicine

Due to the high potential for abuse, misuse and addiction, this medicine is kept in a safe place, preferably locked.

**PHYSEPTONE injection should be kept 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.**

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

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 and vomiting</li> <li>• sleep disturbances such as a sudden awakening from sleep with shortness of breath</li> <li>• trouble with sleeping (either not enough or too much)</li> <li>• snoring</li> <li>• severe stomach pain that may be felt in the back</li> <li>• fever and chills</li> <li>• change in bowel habits</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>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>
<ul style="list-style-type: none"> <li>• decreased libido</li> <li>• impotence</li> <li>• absence of menstruation</li> <li>• trouble swallowing</li> <li>• chest discomfort such as pressure, heartburn or tightness.</li> </ul>	<p><b>Speak to your doctor if you have any of these side effects that may be associated with long-term use.</b></p>

## Serious side effects

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>	<b>Phone triple zero (000) for an ambulance, call your doctor straight away or go to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

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

### What PHYSEPTONE injection contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"><li>• methadone hydrochloride 10 mg/mL</li></ul>
<b>Other ingredient (inactive ingredient)</b>	<ul style="list-style-type: none"><li>• water for injections to 1 mL.</li></ul>

PHYSEPTONE injection is preservative free.

**Do not take this medicine if you are allergic to any of these ingredients.**

### What PHYSEPTONE injection looks like

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

Australian Registration number: AUST R 159750.

## Who distributes PHYSEPTONE injection

Aspen Pharmacare Australia Pty Ltd  
34-36 Chandos St  
St Leonards NSW 2065  
Australia

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