

PHYSEPTONE tablets

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 using PHYSEPTONE tablets?

PHYSEPTONE tablets contain the active ingredient methadone (as methadone hydrochloride). PHYSEPTONE is used for the relief of chronic, moderate to severe pain.

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

2. What should I know before I use PHYSEPTONE tablets?

Do not use if you have ever had an allergic reaction to methadone, any other opioids, or any of the ingredients listed at the end of the CMI.

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 use PHYSEPTONE tablets?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PHYSEPTONE tablets 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 do I use PHYSEPTONE tablets?

- The usual dose for adults is half to one tablet taken 2 to 3 times a day, but this dosage may be adjusted by your doctor.
- Swallow the tablets with a glass of water.
- Do not stop taking PHYSEPTONE or change the dose without first checking with your doctor.

More instructions can be found in Section [4. How do I use PHYSEPTONE tablets?](#) in the full CMI.

5. What should I know while using PHYSEPTONE tablets?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using PHYSEPTONE tablets.• Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.
Things you should not do	<ul style="list-style-type: none">• Do not give this medicine to anyone else, even if their symptoms seem similar to yours.• Do not use PHYSEPTONE to treat any other complaints unless your doctor says to.
Driving or using machines	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol. It is unwise to drink alcohol while being given PHYSEPTONE tablets.
Looking after your medicine	<ul style="list-style-type: none">• Keep this medicine in the original container protected from light, where the temperature stays below 25°C.

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

6. Are there any side effects?

Common side effects of PHYSEPTONE tablets include 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 are associated with an 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 tablets

Active ingredient: *methadone hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PHYSEPTONE tablets.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PHYSEPTONE tablets.

Where to find information in this leaflet:

- [1. Why am I using PHYSEPTONE tablets?](#)
- [2. What should I know before I use PHYSEPTONE tablets?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use PHYSEPTONE tablets?](#)
- [5. What should I know while using PHYSEPTONE tablets?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using PHYSEPTONE tablets?

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

PHYSEPTONE tablets are used for the relief of chronic, moderate to severe pain.

Ask your doctor if you have any questions about why PHYSEPTONE tablets have been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I use PHYSEPTONE tablets?

Warnings

Addiction

You can become addicted to PHYSEPTONE tablets even if you are given it exactly as prescribed. PHYSEPTONE tablets 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 tablets suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to PHYSEPTONE tablets 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 taking 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 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.

Do not take PHYSEPTONE tablets if:

- you are allergic to methadone hydrochloride, any other opioid drug, or any of the ingredients listed at the end of this leaflet.
 - 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.
 - 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.
 - 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 other 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 tablets are 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 tablets 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 tablets.

4. How do I use PHYSEPTONE tablets?

How much to take

- The usual dose for adults is half to one tablet taken 2 to 3 times a day, but this dosage may be adjusted by your doctor.
- **Do not take more than the recommended dose.** It can result in low blood sugar and other side effects.

How to take it

Swallow the tablets with a glass of water.

How long to take it for

Do not stop taking PHYSEPTONE tablets or change the dose without first checking with your doctor.

If you forget to use it

If you forget to take a dose, take it as soon as you remember and then go on as before, but remember not to take the tablets more often than recommended by your doctor.

If you take too much (overdose)

If you know that you or someone else have taken too many PHYSEPTONE tablets, urgent medical attention may be needed.

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

Symptoms of overdose include:

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

You should immediately:

- phone triple zero (000) for an ambulance, or
- 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.

Report any other medicine or alcohol which has been taken.

5. What should I know while using PHYSEPTONE tablets?

Things you should do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

Remind any other doctor, dentist, or pharmacist you visit that you are using PHYSEPTONE tablets.

Things you should not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use PHYSEPTONE to treat any other complaints unless your doctor says to.

Things to be careful of

Particular care should be taken when starting on treatment with PHYSEPTONE tablets 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 tablets affect you.

As this medicine 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 using PHYSEPTONE tablets.

Looking after your medicine

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

Keep this medicine in the original container protected from light, where the temperature stays below 25°C.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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">• drowsiness• fatigue• lack of appetite• sleep disturbances such as a sudden awakening from sleep with shortness of breath• trouble with sleeping (either not enough or too much)• snoring• dizziness• light-headedness• nausea and vomiting	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> • severe stomach pain that may be felt in the back • fever and chills • change in bowel habits • dry mouth • sweating • confusion • problems with urine flow • tolerance and dependence. 	
<ul style="list-style-type: none"> • decreased libido • impotence • absence of menstruation • trouble swallowing • chest discomfort such as pressure, heartburn or tightness. 	<p>Speak to your doctor if you have any of these side effects that may be associated with long-term use.</p>

Serious side effects

Serious side effects	What to do
<p>Allergic reaction including:</p> <ul style="list-style-type: none"> • wheezing • swelling of the lips/mouth • difficulty in breathing • hayfever • lumpy rash (hives) • fainting. 	<p>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.</p>

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. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What PHYSEPTONE tablets contain

Active ingredient (main ingredient)	<ul style="list-style-type: none"> • methadone hydrochloride 10 mg/tablet
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • gelatin • glycerol • lactose monohydrate • maize starch • magnesium stearate.
Potential allergens	<ul style="list-style-type: none"> • lactose monohydrate

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

What PHYSEPTONE tablets look like

PHYSEPTONE tablets are white, uncoated, round, biconvex tablets, scored on one side. Available in blister packs of 20 tablets.

Australian Registration number: AUST R 76083.

Who distributes PHYSEPTONE tablets

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

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