

Physeptone® injection

methadone hydrochloride 10 mg/1 mL

Consumer Medicine Information

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.

People who are given Physeptone for a long time to treat their pain rarely become addicted to it.

However, with time, your body will become used to being given Physeptone injection and you may experience symptoms due to withdrawal if you suddenly stop getting this medicine. These symptoms may include body aches, diarrhoea, nervousness, shivering, nausea, sleep disturbance, sweating, weakness and fever.

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.

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
 - phaeochromocytoma (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.

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 experience any side effects after being given Physeptone injection, tell your doctor immediately.

You may need urgent medical attention.

While you are having it

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.

Side effects

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.

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

- soreness at the site of injection
- drowsiness
- dizziness
- light-headedness
- nausea
- vomiting
- dry mouth
- sweating
- confusion
- constipation
- problems with urine flow
- tolerance and dependence.

The above side effects are common.

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 immediately if you notice any of the following:

- wheezing
- swelling of the lips/mouth
- difficulty in breathing
- hayfever
- lumpy rash (hives)
- fainting.

These could be a symptom of an allergic reaction.

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.

After using it

Storage

Keep this medicine where children cannot reach it, such as in a locked cupboard.

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

Do not leave in a car, on a window sill or in the bathroom.

Return any unused or expired medicine to your pharmacist.

Product description

What it looks like

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

Ingredients

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

Sponsor

Aspen Pharma Pty Ltd

34-36 Chandos Street
St Leonards NSW 2065
Australia

Australian Registration Number:
AUST R 159750

This leaflet was revised in February 2012.