

Physeptone® tablets

methadone hydrochloride 10 mg

Consumer Medicine Information

What is in this leaflet

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

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Physeptone against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Physeptone is used for

Physeptone contains methadone hydrochloride, which belongs to a group of medicines called opioid analgesics.

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

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

Your doctor may have prescribed it for another reason.

People who take Physeptone for a long time to treat their pain rarely become addicted to it. However, with time, your body will become used to taking this medicine and you may experience symptoms due to withdrawal if you suddenly stop taking this medicine. These symptoms may include body aches,

diarrhoea, nervousness, shivering, nausea, sleep disturbance, sweating, weakness and fever.

If you have not done so already, you should discuss this further with your doctor.

Before you take it

When you must not take it:

Do not take Physeptone if:

- **you have ever had an allergic reaction to methadone hydrochloride (the active ingredient in Physeptone Tablets); any other opioid drug; or any of the ingredients listed at the end of this leaflet.**
- **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**
- **the expiry date (EXP) printed on the pack has passed**

- **the packaging is torn or shows signs of tampering.**

Before you start to take 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, 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.
- **you are taking any other medicines or intend to drink alcohol while you are taking Physeptone.**

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 complete list of medicines that may cause problems when taken with Physeptone Tablets.

How to take it

How much to take

Follow all directions given to you by your doctor and pharmacist carefully.

Do not take more than the recommended dose.

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.

How to take it

Swallow the tablets with a glass of water.

How long to take it for

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

Use in children and elderly patients

Physeptone tablets are not recommended for use in children. The doctor may prescribe a smaller dose in elderly patients.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, or go to Accident and Emergency at the nearest hospital if you think you or anyone else may have taken too many Physeptone tablets. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things you must 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.

If you forget to take 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.

Things you must not do

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

Seek medical help immediately if Physeptone is accidentally taken by a child.

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

Things to be careful of

Physeptone Tablets may cause drowsiness. It is recommended that you don't drive, use machinery or undertake any activities where alertness is required.

It is unwise to drink alcohol while taking Physeptone.

Particular care should be taken when starting treatment with Physeptone or increasing the dose.

Physeptone 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

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking Physeptone tablets, even if the problem is not listed below.

Like other medicines, Physeptone may have unwanted 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:

- drowsiness
- dizziness
- light-headedness
- nausea
- vomiting
- dry mouth
- sweating
- confusion
- constipation
- problems with urine flow
- tolerance and dependence.

These 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.

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

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

You may not experience any of them.

After taking it

Storage

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

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in a car, on a window sill or in the bathroom.

Heat and dampness can destroy some medicines.

Keep Physeptone 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.

Keep it in the blister pack until it is time to take them.

Disposal

Return any unused or expired medicine to your pharmacist.

Product description

What it look like

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

Ingredients

Active ingredient:

Each Physeptone tablet contains methadone hydrochloride 10 mg.

Inactive ingredients:

- gelatin
- glycerol
- lactose monohydrate
- starch-maize
- magnesium stearate.

Sponsor

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