

PACKAGE LEAFLET: INFORMATION FOR THE USER

Meptid 100 mg/ml Solution for Injection

Meptazinol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Meptid Injection is and what it is used for
2. What you need to know before you use Meptid Injection
3. How to use Meptid Injection
4. Possible side effects
5. How to store Meptid Injection
6. Contents of the pack and other information

This medicine contains meptazinol which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop using it suddenly.

1. What Meptid Injection is and what it is used for

This medicine has been prescribed for you for the treatment of moderate to severe pain, including post-operative pain and the pain of renal colic. It contains meptazinol which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop using it suddenly. Your prescriber should have explained how long you will be using it for and when it is appropriate to stop, how to do this safely.

The name of this medicine is Meptid 100 mg/ml Solution for Injection but will be referred to as Meptid Injection throughout the remainder of the leaflet.

2. What you need to know before you use Meptid Injection

Do not use Meptid Injection if you

- are allergic to Meptazinol or any of the other ingredients of this medicine (listed in Section 6)
- have any alcohol-related problems
- have or you are at risk of getting the condition known as paralytic ileus
- have a head injury, or build-up of pressure in the head (raised intracranial pressure)
- are having problems breathing
- are suffering from a tumour of the adrenal gland (phaeochromocytoma)
- are having an asthma attack
- are taking medicines known as monoamine-oxidase inhibitors(MAOIs) or have stopped taking MAOIs less than 14 days ago

Warnings and precautions

Talk to your prescriber before using this medicine if you:

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to use more of Meptid to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

Using this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be using it for and when it is appropriate to stop, how to do this safely. Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop using this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop using the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Using higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Take special care with Meptid Injection if you

- have any liver or kidney problems
- have any severe breathing problems such as asthma (do not use this medicine during an asthma attack)
- have low blood pressure
- have an under-active thyroid gland (hypothyroidism)
- have an enlarged prostate gland
- suffer from fits or seizures (convulsive disorder)
- think your pain is due to a heart attack

If any of these apply to you, tell your doctor or pharmacist before you are given a Meptid Injection.

Other medicines and Meptid Injection

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including medicines obtained without a prescription.

If you are taking any medicines known as monoamine-oxidase inhibitors (MAOIs) including moclobemide to treat, for example, depression, or if you have taken this type of medicine during the past two weeks, you should also talk to your doctor.

In particular, tell your doctor if you are taking, or have recently taken, any of the following medicines which are known to interact with Meptid Injection:

- medicines for treatment of depression known as monoamine-oxidase inhibitors (MAOIs) including moclobemide, and those called tricyclic antidepressants such as amitriptyline or mirtazapine
- medicines for certain mental disorders, such as chlorpromazine
- ritonavir (for HIV infection)

- ciprofloxacin (for bacterial infections)
- domperidone and metoclopramide (for nausea and vomiting)
- cimetidine (for ulcers)
- anti-anxiety and sleeping medicines such as diazepam and nitrazepam

Meptid Injection with food and drink

Avoid taking alcohol with this medicine as it may make you feel especially dizzy and sleepy.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Meptid Injection is sometimes given to relieve pain during labour. However, you should not use Meptid Injection during **pregnancy** or while **breast-feeding** unless your doctor thinks that it is essential.

If you use Meptid during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not use Meptid while you are breastfeeding as meptazinol passes into breast milk and will affect your baby.

Driving and using machines

If this product makes you dizzy or drowsy, you should not drive or operate machinery.

3. How to use Meptid Injection

Your prescriber should have discussed with you, how long the course of Meptid will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop using the medicine.

The dose will be decided by your doctor.

The recommended dose is:

Adults and elderly patients

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|--------------------------|--|
| Moderate to severe pain: | 75 to 100 mg by injection into a muscle. The injection may be repeated every two to four hours as required. |
| Pain during childbirth: | 100 to 150 mg by injection into a muscle according to the weight. |

If an injection is given into a vein, the usual dose is 50 to 100 mg. These injections may be repeated every two to four hours as required. If vomiting occurs, a suitable medication can be co-administered.

If you have the impression that the effect of Meptid Injection is too strong or too weak, talk to your doctor or pharmacist.

Long term use of Meptid Injection may cause dependence and tolerance. If you are worried about this, talk to your doctor or pharmacist. Meptid Injection is usually only used for short-term treatment of pain.

Use in children

Meptid Injection is **not** recommended for use in children.

If you receive more Meptid Injection than you should

Since this medicine will be given to you by a doctor or nurse, it is unlikely that you will be given too much. However, if you are worried talk to the doctor or nurse.

If you stop using Meptid

Do not suddenly stop using this medicine. If you want to stop using this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop using this medicine.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

At the correct dose Meptid Injection should not generally cause any problems. Talk to your doctor if you get any of the following side-effects:

- Very common side effects (may affect more than 1 in 10 people) feeling or being sick
- constipation or diarrhoea
- stomach pains, indigestion
- dizziness and vertigo
- drowsiness and sleepiness
- sweating
- headache
- rash.

: Uncommon side-effects (may affect up to 1 in 100 people)

- low blood pressure
- breathing problems.

Very rare side-effects (may affect up to 1 in 10,000 people)

confusion
hallucination
depression

Unknown frequency: dependence and addiction (see section “How do I know if I am addicted?”).

Drug Withdrawal

When you stop using Meptid, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst using Meptid, it could be a sign that you have become addicted.

- You need to use the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed

- When you stop using the medicine you feel unwell, and you feel better once using the medicine again

If you notice any of these signs, it is important you talk to your prescriber

Other side effects that have not been mentioned above, but are associated with medicines that act in the same way as Meptid Injection include:

- difficulty in passing urine
- dry mouth
- red face
- unusually fast or slow heart beat, palpitations
- feeling unusually cold
- mood changes
- reduction in pupil size
- depression or anxiety (dysphoria)
- abdominal pain as a result of spasms of the bile duct or ureter
- decreased sexual desire, erectile dysfunction
- hives, rash, itching.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland

HPRA Pharmacovigilance,
Website: www.hpra.ie

5. How to store Meptid Injection

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the ampoule or carton after EXP. The expiry date refers to the last day of the month. Your doctor or nurse giving you this injection will have checked that this medicine is still before its expiry date.

Store below 25°C.

This medicine is for single use only. Discard any unused contents.

Do not throw away any medicines via wastewater or household waste. The doctor or pharmacist will dispose of any unused solution. These measures will help protect the environment. Your doctor or nurse giving you this injection will take care of proper disposal of this medicine.

6. Contents of the pack and other information

What Meptid Injection contains

- The active substance is meptazinol. Each 1 ml of solution contains 100 mg of meptazinol (as hydrochloride).
- The other ingredients are anhydrous glucose and water for injections.

What Meptid Injection looks like and contents of the pack

Meptid Injection is a clear and colourless solution and comes in glass ampoules filled with 1 ml of solution for injection. The ampoules are packed in cartons of 10.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Almirall S.A., Ronda General Mitre 151, 08022 Barcelona, Spain

Manufacturer:

Kern Pharma SL, Poligono Ind. Colón II, Venus 72, E-08228, Terrassa, Spain.

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INFORMATION FOR THE HEALTHCARE PROFESSIONAL **Meptid 100 mg/ml Solution for Injection**

Meptazinol

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| Refer to the Summary of Product Characteristics for the full prescribing information |
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Composition

Each 1 ml of solution contains 100 mg of meptazinol (as hydrochloride). In addition, each 1ml of solution contains 50 mg anhydrous glucose and 1 ml water for injection.

Uses

Meptid injection is indicated for the treatment of moderate to severe pain, including post-operative pain, obstetric pain and the pain of renal colic.

Dosage and administration

Adults

Intramuscular dosage: 75 to 100 mg meptazinol. The injection may be repeated 2 to 4 hourly as required. For obstetric pain a dose of 100 to 150 mg should be used according to weight. This dose should approximate 2 mg/kg.

Intravenous dosage: 50 to 100 mg meptazinol by slow intravenous injection. The injection may be repeated 2 to 4 hourly as required. If vomiting occurs, a suitable anti-emetic should be given.

Epidural/intrathecal use: This formulation is not suitable for these routes.

Elderly

The adult dosage schedule can be used in the elderly.

Children

Meptid injection has not been evaluated for use in children.

Contra-indications

Patients with the following conditions:

- known hypersensitivity to the active ingredient or to any of the excipients
- acute alcoholism and where there is a risk of paralytic ileus
- raised intracranial pressure or head injury (in addition to interfering with respiration, affects papillary responses vital for neurological assessment)
- acute respiratory depression
- phaeochromocytoma (risk of pressor response to histamine release)
- during an asthma attack
- patients on monoamine-oxidase inhibitors (MAOIs) and for 14 days after discontinuing an MAOI.

Treatment of overdose

Overdose with Meptid Injection has not been reported. Large doses, including seven times the recommended therapeutic dose, have been given in balanced and total intravenous anaesthesia without significant respiratory depressant effects.

In the event of cardiovascular and respiratory collapse, normal resuscitative procedures should be employed. Respiratory depression caused by overdose with meptazinol may only be partially reversed with therapeutic doses of naloxone. Naloxone has a short duration of action in comparison with meptazinol. Repeated administration or administration by continuous intravenous infusion may be considered necessary.

Incompatibilities

Meptid Injection should not be mixed with other drugs in the same infusion solution or in the same syringe. Meptid Injection is an acidic solution of the hydrochloride salt of meptazinol and is therefore pharmaceutically incompatible with injection solutions known to be strongly basic (for example thiopentone) as precipitation of the meptazinol base may occur.

Pharmaceutical precautions

Do not store above 25°C.

Legal Category POM

Package quantities 10 x 1 ml ampoules per pack or 1 x 1 ml ampoule per pack

Product Licence Number PL 16973/0018 PA 968/5/1

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Manufactured by Kern Pharma SL, Poligono Ind. Colón II, Venus * Trade Mark
72- E-08228, Terrassa, Spain.

Manufacturer's Part No.