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

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

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.

Meptid Injection belongs to a group of medicines known as opioid analgesics, which are used to relieve pain. It contains meptazinol as the active ingredient.

Meptid Injection is used to treat moderate to severe pain, including post-operative pain, pain during childbirth and the pain of renal colic.

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 doctor or pharmacist before using Meptid Injection.
Take special care with Meptid Injection if you
- have any liver or kidney problems
- have any severe breathing problems such as asthma (do not take 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 taking, have recently taken or might take 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
Ask your doctor or pharmacist for advice before taking any 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.

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

The dose will be decided by your doctor.

The recommended dose is:

Adults and elderly patients
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.

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.

The most commonly reported side effects are:
- feeling or being sick
- constipation or diarrhoea
- stomach pains, indigestion
- dizziness and vertigo
- drowsiness and sleepiness
- sweating
- headache
- rash.

Occasionally the following side effects have been reported, which may have been due to Meptid Injection:
- confusion
- depression
- hallucinations
- low blood pressure
- breathing problems.

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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store

**Ireland**
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [www.hpra.ie](http://www.hpra.ie), e-mail: medsafety@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.
INFORMATION FOR THE HEALTHCARE PROFESSIONAL

Meptid 100 mg/ml Solution for Injection

Meptazinol

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

**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 overdosage**
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 overdosage 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

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


Manufacturer’s Part No.