

PACKAGE LEAFLET: INFORMATION FOR THE USER

Meptid 100 mg/ml Solution for Injection

Meptazinol Hydrochloride

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Meptid Injection is and what it is used for
2. Before Meptid Injection is used
3. How Meptid Injection is used
4. Possible side effects
5. How to store Meptid Injection
6. Further 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. BEFORE MEPTID INJECTION IS USED

Do not use Meptid Injection if you

- are allergic (hypersensitive) to Meptazinol or any of the other ingredients of Meptid Injection (*see Section 6 'Further information'*)
- 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)

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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken 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

Using 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 MEPTID INJECTION IS USED

The dose will be decided by your doctor.

The usual 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.

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, Meptid Injection 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, please 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.

5. HOW TO STORE Meptid Injection

Do not store above 25°C.

Keep out of the reach and sight of children.

Do not use Meptid Injection after the expiry date which is stated on the carton after EXP. Your doctor or nurse giving you this injection will have checked that this medicine is still before its expiry date.

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

Medicines should not be disposed of via wastewater or household waste. The doctor or pharmacist will dispose of any unused solution. These measures will help to protect the environment. Your doctor or nurse giving you this injection will take care of proper disposal of this medicine.

6. FURTHER INFORMATION

What Meptid Injection contains

- The active substance is meptazinol
- The other ingredients are glucose and water

What Meptid Injection looks like and contents of the pack

Meptid Injection is a clear and colourless or slightly yellow 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:

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

Manufacturer:

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

This leaflet was last approved in September 2008.

[Almirall logo]

* Trade Mark

TECHNICAL LEAFLET

Meptid 100 mg/ml Solution for Injection

Meptazinol Hydrochloride

Composition

Each ampoule contains 100 mg of meptazinol (as hydrochloride). In addition, each ampoule 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, warnings, etc.

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
- avoid injection in pheochromocytoma (risk of pressor response to histamine release)

Precautions

1. Clinical studies have indicated absence of clinically significant respiratory depression but caution should be exercised in patients already severely compromised.
2. Patients with moderate to severe renal impairment should be given a reduced dose as the effect in these patients may be prolonged and increased. Cerebral sensitivity may also be increased. Patients with hepatic impairment should be given a reduced dose as opioid analgesics may precipitate coma in these patients.
3. Repeated administration of opioid analgesics may cause dependence and tolerance (severe withdrawal symptoms if withdrawn abruptly). Regular use should therefore be advised after consideration of the risks and benefits. The patient should then be placed under specialist supervision and assessed at regular intervals.

4. Safety for use in myocardial infarction has not been established.
5. Meptazinol should also be used with caution in patients with the following conditions: hypotension, hypothyroidism, asthma (avoid during an attack), and convulsive disorders.
6. The interaction between MAOIs and meptazinol stated below is reported as a particular hazard.

Interactions

The following undesirable effects could occur as a result of possible interaction with meptazinol hydrochloride:

- Antidepressants: CNS excitation or depression manifesting as hypertension or hypotension may occur if meptazinol is administered to patients receiving monoamine-oxidase inhibitors (MAOIs) (including moclobemide). Avoid concomitant use and for two weeks after an MAOI is discontinued. Possible increased sedation if meptazinol used with tricyclic antidepressants.
- Antipsychotics: enhanced sedative and hypotensive effect.
- Antivirals: avoid concomitant use with ritonavir as plasma concentration of meptazinol may be increased.
- Alcohol: enhanced sedative and hypotensive effect.
- Quinolones (ciprofloxacin): avoid premedication with meptazinol as a reduced plasma-ciprofloxacin concentration may be experienced.
- Anxiolytics and hypnotics: enhanced sedative effect.
- Drugs used in nausea and vomiting: concomitant use of metoclopramide and domperidone may result in antagonism of gastro-intestinal side effects.
- Ulcer healing drugs: cimetidine may inhibit metabolism of meptazinol resulting in increased plasma concentration.

Use in pregnancy and lactation

Meptid injection is a useful analgesic in labour, but in accordance with general medical principles, it should not be given in other stages of pregnancy unless considered essential by the physician. There is no evidence from animal reproduction studies to anticipate a teratogenic risk.

Meptid should not be given to lactating women unless considered essential by the physician.

Warnings

Since dizziness and occasionally drowsiness have been reported, patients should be cautioned against driving or operating machinery until it is established that they do not become dizzy or drowsy while taking meptazinol.

Treatment of overdose

Overdosage 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 be reversed in part 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.

Side effects

The most commonly reported adverse reactions after treatment with meptazinol are nausea, vomiting, dizziness, diarrhoea and increased sweating, constipation, abdominal pain, rash, vertigo, headache, drowsiness, somnolence and dyspepsia. Occasional reports of psychiatric disorders (hallucination, confusion, depression) have been received, but any causal relationship with the use of meptazinol has not been established. Other uncommon effects are hypotension and respiratory depression.

Reactions not already stated which are attributable to opioid analgesics include ureteric or biliary spasm, dry mouth, facial flushing, bradycardia, tachycardia, palpitations, hypothermia, dysphoria, mood changes, miosis, decreased libido or potency, urticaria and pruritus.

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

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