Meptid 200 mg Film-Coated Tablets

Meptazinol

Read all of this leaflet carefully before you start taking 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
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1. What Meptid Tablets are and what they are used for

The name of this medicine is Meptid 200 mg Film-Coated Tablets but will be referred to as Meptid Tablets throughout the remainder of the leaflet.

Meptid Tablets belong to a group of medicines known as opioid analgesics, which are used to relieve pain. They contain meptazinol as the active ingredient.

Meptid Tablets are used for the short-term treatment of moderate pain from a variety of causes.

2. What you need to know before you take Meptid Tablets

Do not take Meptid Tablets 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 paralysis of the gut (intestine) known as paralytic ileus
- have a head injury, or build-up of pressure in the head (raised intracranial pressure)
- are having problems breathing
- 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 taking Meptid Tablets.

**Take special care with Meptid Tablets 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 take Meptid Tablets.

**Other medicines and Meptid Tablets**
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 Tablets:
- 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 Tablets 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.
You should not take Meptid Tablets 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.

**Meptid Tablets contain sunset yellow FCF (E 110)**
Meptid Tablets contain the colouring agent sunset yellow FCF (E 110), which may cause allergic reactions.

3. **How to take Meptid Tablets**
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

**Adults and elderly patients**
Swallow one tablet, with a glass of water, every four hours; your doctor may vary the dose if necessary.

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

Do not take more than your doctor has recommended.

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

**Use in children**
Meptid Tablets are not recommended for use in children.

**If you take more Meptid Tablets than you should**
If you think you have taken too many tablets contact your doctor or the local hospital casualty department at once. Take any remaining tablets and the packaging with you.

**If you forget to take Meptid Tablets**
If you forget to take a dose at the right time, take it as soon as you remember, unless it is almost time for your next dose.
If you miss a dose completely, do not take a double dose to make up for the forgotten one. Instead, skip the missed one and take the next dose as usual.
4. Possible side effects

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

If you experience any of the following, stop taking Meptid Tablets and contact your doctor or go to the casualty department of your nearest hospital immediately:

- Severe Allergic reactions. Signs of an allergic reaction include itching, rash, difficulty breathing, swelling of the face, lips, tongue or throat.

At the correct dose Meptid Tablets 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

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

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of the month.

Store below 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. **Contents of pack and other information**

**What Meptid Tablets contain**
- The active substance is meptazinol. Each tablet contains 200 mg of meptazinol (as hydrochloride).
- The other ingredients are magnesium stearate, microcrystalline cellulose and polacrilin potassium in the tablet core. The film coating contains hypromellose, macrogol 400 and the colours erythrosine (E 127), titanium dioxide (E 171) and sunset yellow (E 110) (see end of Section 2).

**What Meptid Tablets look like and contents of the pack**
Meptid Tablets are film-coated tablets and orange and oval shaped. The film-coated tablets are engraved with ‘MPL 023’ on one side and are available in blister packs of 6, 28, 56, 100 or 112 tablets. Not all pack sizes may be marketed.

**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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