

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

1. What Meptid Tablets are and what they are used for
2. What you need to know before you take Meptid Tablets
3. How to take Meptid Tablets
4. Possible side effects
5. How to store Meptid Tablets
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 taking it suddenly.

1. What Meptid Tablets are and what they are used for

This medicine has been prescribed for you for the short term treatment of moderate pain. 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 taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

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.

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 prescriber before taking 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 take 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.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking 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 taking 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 taking 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. Taking 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 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

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 taking this medicine.

You should not take Meptid Tablets during **pregnancy** or while **breast-feeding** unless your doctor thinks that it is essential.

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

Do not take 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.

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

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 taking the medicine.

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.

If you stop taking Meptid

Do not suddenly stop taking this medicine. If you want to stop taking 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 taking 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 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

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

Drug Withdrawal

When you stop taking 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 taking Meptid, it could be a sign that you have become addicted.

- You need to take 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 taking the medicine you feel unwell, and you feel better once taking 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 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 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 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 polacrillin 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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