

## PACKAGE LEAFLET: INFORMATION FOR THE USER

**<invented name> 100 mg capsules, hard**  
Active substance: flupirtine maleate

**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.

### What is in this leaflet

1. What <invented name> is and what it is used for
2. What you need to know before you take <invented name>
3. How to take <invented name>
4. Possible side effects
5. How to store <invented name>
6. Contents of the pack and other information

#### 1. What <invented name> is and what it is used for

<invented name> is a medicine used to treat acute and chronic pain of various origins known as a mono-analgesic.

<invented name> is used to treat acute and chronic pain such as

- muscle pain involving the musculoskeletal system
- tension headaches
- tumour pain
- dysmenorrhoea (a gynaecological medical condition characterized by severe uterine pain during menstruation)
- pain after trauma-related/orthopaedic surgery and injuries.

#### 2. What you need to know before you take <invented name>

##### Do not take <invented name>

- if you are allergic to flupirtine maleate or any of the other ingredients of this medicine (listed in section 6).
- if you are at risk of hepatic encephalopathy and patients with cholestasis, <invented name> should not be administered, as onset or deterioration of encephalopathy or ataxia may occur in these patients.
- if you suffer from **myasthenia gravis** because <invented name> is a muscle-relaxant
- if you have, or have had, any **liver problems** since <invented name> may affect your liver.
- if you suffer, or have suffered, from **tinnitus**. Studies with this group of patients have shown a possible risk of an elevation of liver enzymes.
- *Warnings and precautions* if you take medicines that prevent blood clotting (anticoagulants) (e.g. coumarin derivatives) at the same time as <invented name>
- if you are **over 65 years of age** or your **kidney function** is markedly impaired or your level of **albumin in blood serum are abnormally low** (hypoalbuminaemia) (see also *How to take <invented name>*) a dose adjustment might be necessary
- if you have **kidney problems**.

If any of these apply to you, tell your doctor before taking <invented name>

**Warnings and precautions**

Talk to your doctor or pharmacist before taking <invented name>

Your doctor may take a blood test to make sure that your liver and kidneys are working normally, and this may be repeated during treatment.

Only drink small quantities of **alcohol** whilst taking <invented name>. Excessive alcohol intake could worsen any liver problems.

Patients being treated with flupirtine maleate can have false positive results for bilirubin, urobilinogen, and urine protein on urine test strips. Reactions to test methods for the quantitative analysis of serum bilirubin can also be falsified.

In rare cases, urine may turn green at high doses, but this is not clinically relevant.

**Children and adolescents**

The safety and efficacy of flupirtine maleate in children and adolescents aged under 18 years have not been established.

**Other medicines and <invented name>**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Do not take <invented name> with medicines containing **paracetamol** or **carbamazepine**.
- <invented name> can increase the effect of alcohol and medications that have sedative or muscle-relaxant properties.
- Because treatment with <invented name> might increase the effect of anticoagulant drugs (e.g. warfarin), patients who take such medicines should have their prothrombin time checked regularly.
- An increase in the effect of diazepam cannot be ruled out if it is combined with <invented name>.
- Liver enzyme levels should be monitored in good time and at regular intervals when <invented name> is co-administered with other medicines which are likewise mainly degraded via the liver.

**<invented name> with food, drink and alcohol**

In general, when taking medicines, patients should avoid consuming alcoholic beverages.

**Pregnancy and breast-feeding**

There is no clinical data available about the use of <invented name> during pregnancy. Therefore do not take <invented name> if you are pregnant unless your doctor considers that it is absolutely necessary.

Flupirtine, the active ingredient in <invented name>, is excreted in small amounts in breast-milk. Therefore do not take <invented name> if you are breast-feeding unless your doctor considers that it is absolutely necessary. If your doctor considers that taking <invented name> during breast-feeding is absolutely necessary, you will need to wean your baby.

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.

**Driving and using machines**

This medicinal product can affect your ability to react, even if taken as instructed. If you feel sleepy or dizzy while taking <invented name> you should not drive or operate machines. This is especially true if it is combined with alcohol.

### **3. How to take <invented name>**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed, the recommended dose is 100 mg of flupirtine maleate with liquid 3 to 4 times a day at intervals spaced as evenly as possible.

The dose should be adjusted to the severity of the pain and your responsiveness to it.

For severe pain it is possible to increase the dose to 200 mg of flupirtine maleate 3 times a day. Do not exceed a daily dose of 600 mg of flupirtine maleate.

Patients older than 65 years of age should initially take 100 mg of flupirtine maleate in the morning and evening. The dose can be increased depending on the severity of the pain and the tolerability of the medicine.

Patients with markedly impaired kidney function or patients with a medical condition where levels of albumin in blood serum are abnormally low (hypoalbuminaemia) should not exceed a daily dose of 300 mg of flupirtine maleate. If higher doses are necessary, patients should be carefully monitored by a doctor.

#### **Method of administration**

The capsules should be swallowed whole with plenty of fluids (preferably water). If possible, they should be taken with the upper body in an upright position.

In exceptional situations, the capsule can be opened and only the contents are swallowed/administered (e.g. via a tube). Because of its very bitter taste, we recommend that when the contents of the capsule are being administered by mouth the taste should be neutralised with a suitable food (e.g. bananas).

#### **Duration of administration**

The duration of administration is determined individually as prescribed by a physician.

Since flupirtine is metabolized primarily by the liver, liver enzyme values (transaminases) should be checked regularly if this medicine is administered over a long period, and any changes, particularly as compared to baseline values determined prior to therapy, should be monitored.

Please talk to your doctor or pharmacist if you have the impression that the effect of <invented name> is too strong or too weak.

#### **If you take more <invented name> than you should**

There have been cases of overdoses of flupirtine maleate, for which up to 5 g flupirtine maleate produced the following symptoms: nausea, abnormal fatigue, racing heart, compulsion to cry, light-headedness, loss of consciousness, dry mouth.

A recovery was made within 6 to 12 hours after vomiting or therapy with forced diuresis, activated charcoal and electrolyte infusions. Life-threatening conditions have not been seen.

In case of an overdose or intoxication, central nervous manifestations are likely based on the findings available from experimental animals, as well as potential hepatotoxicity in the form of increased metabolic stress on the liver. There is not known antidote. Treatment must be symptomatic.

If you take more of this medicine than you should, contact a doctor immediately.

#### **If you forget to take <invented name>**

Do not take a double dose to make up for a forgotten dose; just continue taking <invented name> as prescribed by your doctor.

#### **If you stop taking <invented name>**

You may stop treatment early if you do not tolerate it well.

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.

The following list of side effects was reported under treatment with flupirtine maleate.

- **Very common (may affect more than 1 in 10 people):**

Fatigue, especially at the start of treatment.

- **Common (may affect up to 1 in 10 people):**

Dizziness, heartburn, nausea/vomiting, stomach trouble, constipation, sleep problems, increased sweating, loss of appetite, depression, shaking (tremors), headache, abdominal pain, dry mouth, restlessness/nervousness, flatulence, diarrhoea.

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

Confusion, vision problems and allergic reactions.

Allergic reactions – accompanied in single cases by elevated temperatures – can manifest, for example, as rashes, hives (urticaria) or itching (pruritis).

- **Very rare (may affect up to 1 in 10,000 people):**

Reports from the practical experience comprise very rarely liver side effects: elevated liver enzyme values (mostly reversible upon dose reduction or discontinuation of flupirtine maleate), drug-induced hepatitis.

- **Not known (frequency cannot be estimated from the available data):**

Isolated cases of liver failure have been reported.

Because the side effects are predominantly dose-dependent, they can be managed to a certain degree by reducing the amount taken. In many cases side effects disappear over the course of further treatment or after discontinuing treatment.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

#### 5. How to store <invented name>

Keep this medicine out of the sight and reach of children.

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

This medicinal product does not require any special storage conditions

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 the pack and other information

##### What <invented name> contains

- The active substance is: flupirtine maleate  
Each capsule, hard, contains 100 mg flupirtine maleate.
- The other ingredients are:

Capsule Content: Calcium hydrogen phosphate dihydrate, copovidone, magnesium stearate and colloidal anhydrous silica.

Capsule Shell: Gelatine, titanium dioxide (E171) and red iron oxide (E172)

**What <invented name> looks like and contents of the pack**

Oblong, hard-shell gelatine capsules with a red body and a red cap of 18 mm.

<invented name> is available packed in blisters. The pack sizes are:

10, 30 and 50 capsules, hard

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

<to be completed nationally>

**Manufacturer**

<to be completed nationally>

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Germany:	Flupirtinmaleat TAM 100 mg Hartkapseln
Luxembourg:	Maléate de flupirtin TAM 100 mg gélule

**This leaflet was last revised in [MM/YYYY].**