TORVIN

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

Abbreviated Prescribing information for TORVIN (Flupirtine Maleate 100 mg Capsules) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Flupirtine maleate is a nonopioid centrally-acting analgesic agent. Flupirtine is the head of the class of substances defined as SNEPCO (Selective Neuronal Potassium Channel Opener-substances that open on a selective neuronal potassium channels).

INDICATION: For the treatment of acute and chronic pain, i.e., for painful increased muscle tone of the posture and motor muscles, primary headache, tumor pain, dysmenorrheal and pain after traumatologic/orthopedic and injuries.

DOSAGE AND ADMINISTRATION: Adults: The average recommended dose is 300-400 mg /day (1 capsule 100 mg repeated every 6-8 hours). In the opinion of the doctor, up to a maximum of 600 mg / day (200 mg every 8 hours). The maximum dose (600 mg / day) should be used only under medical supervision. In patients with severe renal impairment or hypoalbuminemia, daily dose must not exceed the dose of 300 mg Flupirtine maleate.

CONTRAINDICATION: Hypersensitivity to the active substance or any excipients. In patients with myasthenia gravis**.**

WARNINGS & PRECAUTIONS: Flupirtine should be used with caution in patients with liver disorders and/ or alcoholism. Patients with impaired liver or kidney function should be monitored by regular and repeated liver enzymes as well as serum creatinine values: in such cases it is necessary to make an adjustment in dosage and interval between doses. Patients with hepatic encephalopathy: Flupirtine should not be used as the onset or worsening encephalopathy may occure, as well as ataxia and motor disorders. Treatment with Flupirtine maleate can manifest false positive test for bilirubin, urobilinogen and urine proteins in urinary casts. Keep out of reach of children.

DRUG INTERACTION: Flupirtine may increase the effect of alcohol and substances with sedative or muscle relaxant activity. In the case of warfarin and diazepam, the displacement from albumin binding reached a level where one cannot exclude an increase in the pharmacological action of these products, concomitant administration of Flupirtine maleate. In patients treated concurrently with Flupirtine and coumarin derivatives, it is therefore recommended to make the test more often so quick to highlight the possible effects or to reduce the dose of coumarin administered if required. Flupirtine when used in combination with other medicines which are mainly metabolized in the liver, should be monitored for the liver enzymes at the beginning of treatment and at regular intervals thereafter. Association of Flupirtine maleate with drugs containing paracetamol and /or carbamazepine should be avoided.

ADVERSE REACTIONS: Fatigue, dizziness, heartburn, nausea / vomiting, stomach upset, constipation, sleep disturbances, sweating, lack of appetite, depression, tremor, headache, abdominal pain, dry mouth, restlessness / nervousness, flatulence, diarrhea, disorientation, visual disturbances and allergic reactions can manifest as rash, hives and itching in isolated cases accompanied by an increase in body temperature. Transaminases increased and drug-induced hepatitis.

MARKETED BY:

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(Additional information is available on request)