

Winpain® 1ml & 2 ml Solution for Injection

Tramadol Hydrochloride injection



Presentation

Winpain® 1 ml IM/IV injection: Each 1 ml contains a concentrated solution of Tramadol Hydrochloride BP 50 mg.

Winpain® 2 ml IM/IV injection: Each 2 ml contains a concentrated solution of Tramadol Hydrochloride BP 100 mg.

Description

Tramadol hydrochloride is a centrally acting analgesic. The chemical name of Tramadol hydrochloride is (±) cis-2-[(dimethylamino) methyl]-1-(3-methoxyphenyl) cyclohexanol hydrochloride. Tramadol hydrochloride is a white, bitter, crystalline and odorless powder. It is readily soluble in water and ethanol and has a P^{ka} of 9.41.

Indications

Moderate to moderately severe pain.

Dosage & Administration

IM/IV: 50-100 mg every 4-6 hours (Over 2-3 minutes).

The dosage should be adjusted to the intensity of the pain and the sensitivity of the individual patients.

* In moderate pain, adults and adolescents above 14 years of age should receive 1 ml Tramadol hydrochloride (50 mg Tramadol hydrochloride) injection as a single dose.

* In case of severe pain a higher dose is necessary, 2 ml Tramadol hydrochloride (100 mg Tramadol hydrochloride) should be administered as a single dose.

* For the treatment of severe pain after operations, on-demand pain relief may require even higher doses in the first few hours. In general, over 24 hours more than the normal daily doses are not necessary.

In general, 16 ml Tramadol hydrochloride injection (800 mg Tramadol hydrochloride) per day should not be exceeded. However, for the treatment of cancer pain and severe pain after operations much higher doses may be necessary.

Dosage for Children

Children aged 1 to 13 years should receive 1-2 mg Tramadol hydrochloride per kg body weight as a single dose.

In this case Tramadol hydrochloride 1 ml injection is diluted in water for injection.

Geriatric patients

In acute pain Tramadol hydrochloride 1 ml injection is given once or a few times, and therefore a dose adjustment is not necessary. In chronic pain a dose adjustment is not usually necessary in elderly patients (up to 75 years) with no clinically manifested liver or kidney insufficiency. In old patients (above 75 years) elimination may be prolonged. Consequently the dose interval may have to be prolonged, depending on the individual patients.

Liver and kidney insufficiency

In acute pain Tramadol hydrochloride 1 ml injection is only given once or a few times, and therefore a dose adjustment is not necessary. In patients with severe liver and/or kidney insufficiency Tramadol hydrochloride injection should not be given. In less severe cases extending the dosage interval should be considered.

Side-effects

The following side effects have been reported.

Gastrointestinal system: Nausea, vomiting, dry mouth, heartburn, constipation.

Central nervous system and psychiatric: Fatigue, sedation, drowsiness, dizziness, confusion, hallucination and seizures.

Precautions

The administration of Tramadol Hydrochloride concurrently with central nervous system depressant medicines is likely to intensify and prolong CNS effects. Patients should be warned not to operate machinery or drive a car while taking Tramadol Hydrochloride.

Contraindications

Tramadol Hydrochloride is contraindicated in known hypersensitivity to Tramadol Hydrochloride or opioids, in acute intoxication with alcohol, hypnotic, analgesics or psychotropic medicines. Tramadol Hydrochloride must not be used for narcotic withdrawal treatment. Tramadol Hydrochloride should not be given to patients with respiratory depression especially in the presence of cyanosis and excessive bronchial secretions. Tramadol Hydrochloride should not be given to patients with increased intracranial pressure or central nervous system depression due to head injury or cerebral disease.

Use in Pregnancy & Lactation

Safety during pregnancy and lactation has not been established.

Drug Interactions

Tramadol Hydrochloride must not be combined with a MAO-inhibitor or within 14 days of discontinuation of it, as potentiation of serotonergic and noradrenergic effects may result.

Storage

Do not store above 30 °C. Keep away from light and out of the reach of children.

Commercial pack

Winpain® 1 ml IM/IV injection: Each box contains 5 Ampoules of 1 ml solution of Tramadol Hydrochloride.

Winpain® 2 ml IM/IV injection: Each box contains 5 Ampoules of 2 ml solution of Tramadol Hydrochloride.