Tendia®

Description

Tendia® contains Tramadol Hydrochloride as active ingredient which is a centrally acting synthetic analgesic of the aminocyclohexanol group with opioid like effects. Tendia® has a dual mechanism of action at therapeutic doses: it possesses opioid agonist properties and modifies transmission of pain impulses at the spinal level by inhibition of monoamines. It has less effect on respiratory and cardiovascular functions at therapeutic doses than other opioid analgesics.

Indications and Uses

Tendia® is indicated for moderate to severe acute and chronic pain and in painful diagonostic and therapeutic measures. It is also indicated in wound pain, fractures, severe nerve pain and pain related to heart diseases.

Dosage and Administration

Adults and children aged 12 years and over:

Capsule:

The usual doses are 50 mg to 100 mg every 4 to 6 hours. For acute pain an initial dose of 100 mg is required. For chronic pain an initial dose of 50 mg is recommended. Subsequent doses should be 50 to 100 mg administered 4-6 hourly. The frequency of dosing will depend on the severity of the pain and the duration of therapy should be related to clinical need. The total daily oral dosage should not exceed 400 mg.

Injection:

A dose of 50 mg to 100 mg may be given every 4 to 4 hours by intramuscular or intravenous (over 2 to 3 minutes) or by intravenous infusion. For the treatment of post-operative pain, the initial dose is 100 mg followed by 50 mg every 10 to 20 minutes if necessary to a maximum of 250 mg in the first hour. The subsequent recommended daily doses are 50 mg to 100 mg every 4 to 6 hours. The total daily dose should not exceed 600 mg.

Children under 12 years old: Not recommended.

Use in pregnancy & lactation

Pregnancy: Safety in pregnancy has not been established. Tendia® should be prescribed in pregnant women prior to or during labor only if the potential benefits outweigh the risk. During pregnancy long term treatment should be avoided.

Lactating mother: Tramadol and its metabolites are found in small amounts in human breast milk, it should not be administered during breast feeding.

Side-effects

Most common side effects are nausea, seating, dry mouth, dizziness may occur. In rare cases, there may be side effects on heart and blood circulation. Moreover, headache, itching, vomiting, constipation, stomach troubles etc may be observed in rare cases.

Contraindications

Tendia® should not be administered to patients who have previously demonstrated hypersensitivity to Tramadol, any other component of this product or opioids. Tendia® is contraindicated in any situation where opioids are contraindicated, including acute intoxication with any of the following: alcohol, hypnotics, narcotics, centrally acting analgesics, MAO inhibitors.

Precautions

Tendia® should be administered cautiously in patients at risk for respiratory depression, patients with increased intracranial pressure or head injury, patients who are dependent on opioids.

Overdosage

Symptoms of overdose are typical of other opioid analgesics and other miosis, vomiting, cardiovascular collapse, sedation and coma, seizures and respiratory depression.

Drug interactions

Tendia® should be used with caution and in reduced dosage when administered to patients receiving CNS depressants such as alcohol, opioids, anesthetic agents, phenothiazines, tranquilizers or sedative hypnotics. It should not be used in patients who are taking MAO inhibitors.

Pharmaceutical precautions

Store in a cool, dry place. Protect from light.

Presentation

Tendia® capsule: Opaque light green body and cap. Each capsule contains Tramadol 50 mg as Hydrochloride BP.
Tendia® injection: Each 2 ml ampoule contains Tramadol 100 mg as Hydrochloride BP.

Package Quantities

Tendia® capsule: Carton of 30 capsules in Alu-PVC blister.
Tendia® injection: Carton of 5 ampoules.

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