

Anadol[®]

Tramadol Hydrochloride BP

COMPOSITION

Anadol[®] R 50 Tablet: Each Retard tablet contains Tramadol Hydrochloride BP 50 mg.

Anadol[®] capsule: Each capsule contains Tramadol Hydrochloride BP 50 mg.

Anadol[®] 100 SR capsule: Each sustained release capsule contains Tramadol Hydrochloride BP 100 mg.

Anadol[®] 100 Injection: Each 2 mL injection contains Tramadol Hydrochloride BP 100 mg.

Anadol[®] 100 suppository: Each suppository contains Tramadol Hydrochloride BP 100 mg.

PHARMACOLOGY

Anadol[®] (Tramadol) is a centrally acting synthetic analgesic compound. It inhibits the re-uptake of neurotransmitters- serotonin and noradrenaline. Thus it modifies the transmission of pain impulses by activating both descending serotonergic pathways and noradrenergic pathways involved in analgesia. The analgesic effects of Tramadol are mediated via stimulation of mu-opioid receptors and indirect modulation of central monoaminergic inhibitory pathways.

INDICATION

Anadol[®] (Tramadol) is used for the treatment of moderate to severe painful conditions. These include: Postoperative pain, Colic and spastic pain, Cancer pain, Joint pain, Neck and back pain & Pain associated with osteoporosis.

DOSAGE AND ADMINISTRATION

Anadol[®] R 50: Adults (17 years or older): 50 to 100 mg retard tablet orally in the morning & evening. Maximum dose: 400 mg per day.

Anadol[®] Capsule: Usual doses are 50 to 100 mg every four to six hours. For acute pain, an initial dose of 100 mg is required. For chronic painful conditions, an initial dose of 50 mg is recommended. Subsequent doses should be 50 to 100 mg administered 4-6 hourly. The dose level and frequency of dosing will depend on the severity of the pain. The total daily dosage by mouth should not exceed 400 mg.

Anadol[®] SR capsule: One SR capsule every 12 hours, for example first one in the morning and then at the same time in the evening. The number of capsules taken at a time will depend upon severity of pain, but it should not be taken more frequently than every 12 hours. The total daily dosage by mouth should not exceed 400 mg.

Anadol[®] Injection: A dose of 50-100 mg may be given every 4 to 6 hours by intramuscular or by intravenous injection over 2 to 3 minutes or by intravenous infusion. For the treatment of postoperative 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. Thereafter, doses are 50 to 100 mg every 4 to 6 hours up to a total daily dose of 600 mg.

Anadol[®] Suppository: **Anadol[®]** suppository should be administered rectally. For adults, usual dose is 100 mg Tramadol Hydrochloride 6 hourly. In general, 400 mg Tramadol Hydrochloride (= 4 Anadol suppository) per day sufficient. However, for the treatment of Cancer pain and severe pain after operations much higher daily doses can be used.

SIDE EFFECTS

Commonly occurring side-effects are dizziness/vertigo, nausea, constipation, headache, somnolence, vomiting, pruritus, CNS stimulation, asthenia, sweating, dyspepsia, dry mouth, diarrhoea. Less commonly occurring side-effects include malaise, allergic reaction, weight loss, vasodilatation, palpitations, abdominal pain, anorexia, flatulence, GI bleeding, hepatitis, stomatitis etc.

CONTRAINDICATION

Tramadol is contraindicated in patients having hypersensitivity to this drug. It is also contraindicated in acute intoxication with alcohol, hypnotics, centrally acting analgesics, opioids or psychotropic drugs.

WARNING & PRECAUTION

Respiratory depression: When large doses of Tramadol are administered with anaesthetic medications or alcohol, respiratory depression may result. Therefore, Tramadol should be administered cautiously in patients at risk for respiratory depression.

Opioid dependence: Tramadol is not recommended for patients who are dependent on opioids.

Concomitant CNS depressants: Tramadol should be used with caution and in reduced dosages when administering to patients receiving CNS depressants such as alcohol, opioids, anesthetic agents, phenothiazine, tranquilizers or sedative hypnotics.

Concomitant MAO inhibitors: Tramadol should be used with great caution in patients taking MAO inhibitors,

since Tramadol inhibits the uptake of norepinephrine and serotonin.

Tramadol should be used with caution in patients with increased intracranial pressure or head injury and patients with acute abdominal conditions.

USE IN PREGNANCY AND LACTATION

Safe use of Tramadol in pregnancy has not been established. Tramadol has been shown to cross the placenta. There are no adequate and well controlled studies in pregnant women. Therefore, Tramadol should be used during pregnancy only if the potential benefit justifies the risk to the fetus. Tramadol Hydrochloride should not be administered during breast feeding as Tramadol and its metabolites have been detected in breast milk.

USE IN CHILDREN

In children from the age of one-year, Tramadol Hydrochloride can be given in a dose of 1-2 mg/kg body weight. However, suppository (100 mg Tramadol Hydrochloride) should not be administered in children and adolescents below the age of 14 years. Tramadol Hydrochloride 100 mg SR Capsules have not been studied in children. Therefore, safety and efficacy have not been established and the product should not be used in children.

DRUG INTERACTION

In general, physician need not be concerned about drugs interacting with Tramadol. The monoamine oxidase (MAO) inhibitors represent the only drug class not recommended for combination with Tramadol. Concomitant administration of carbamazepine with Tramadol causes a significant increase in Tramadol metabolism and it requires to increase the dose of Tramadol.

OVERDOSE

Acute overdosage with Anadol can be manifested by respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, and, in some cases, pulmonary edema, bradycardia, QT prolongation, hypotension, partial or complete airway obstruction, atypical snoring, and death. Marked mydriasis rather than miosis may be seen with hypoxia in overdose situations.

STORAGE CONDITION

For R Tablet: Store below 30°C in a dry place. Keep away from light. Keep out of reach of children.

For Capsule & Injection: Store below 30° C in dry place. Keep away from light. Keep out of reach of children.

For Suppository: Store below 25° C in dry place. Keep away from light. Keep out of reach of children.

HOW SUPPLIED

Anadol[®] R 50 Tablet: Each box contains 30 tablets in blister pack.

Anadol[®] Capsule: Each box contains 40 capsules in blister pack.

Anadol[®] 100 SR Capsule: Each box contains 30 capsules in blister pack.

Anadol[®] 100 Injection: Each box contains 10 ampoules in blister pack.

Anadol[®] 100 Suppository: Each box contains 20 suppository in blister pack.

Manufactured by-



SQUARE
PHARMACEUTICALS PLC.
Bangladesh