

# Pentadol™

## Tapentadol

### COMPOSITION

**Pentadol™ 50 Tablet:** Each film coated tablet contains Tapentadol 50 mg as Tapentadol hydrochloride INN .

**Pentadol™ 75 Tablet:** Each film coated tablet contains Tapentadol 75 mg as Tapentadol hydrochloride INN .

**Pentadol™ 100 Tablet:** Each film coated tablet contains Tapentadol 100 mg as Tapentadol hydrochloride INN .

### PHARMACOLOGY

Tapentadol is a centrally-acting synthetic analgesic. Although its exact mechanism is unknown, analgesic efficacy is thought to be due to  $\mu$  opioid agonist activity and the inhibition of norepinephrine reuptake.

### INDICATION

**Pentadol™** tablet is indicated for the relief of moderate to severe acute pain in patients 18 years of age or older.

### DOSAGE AND ADMINISTRATION

As with many centrally-acting analgesic medications, the dosing regimen should be individualized according to the severity of pain being treated, the previous experience with similar drugs and the ability to monitor the patient.

The dose is 50 mg, 75 mg, or 100 mg every 4 to 6 hours depending upon pain intensity. On the first day of dosing, the second dose may be administered as soon as one hour after the first dose, if adequate pain relief is not attained with the first dose. Subsequent dosing is 50 mg, 75 mg, or 100 mg every 4 to 6 hours and should be adjusted to maintain adequate analgesia with acceptable tolerability.

Daily doses greater than 700 mg on the first day of therapy and 600 mg on subsequent days have not been studied and are not recommended.

### CONTRAINDICATION

This drug is contraindicated in patients with impaired Pulmonary Function, It is also contraindicated in patients with acute or severe bronchial asthma or hypercapnia in unmonitored settings or the absence of resuscitative equipment. This drug is contraindicated in any patient who has or is suspected of having paralytic ileus.

### PRECAUTION

Tapentadol should be administered with caution to patients with conditions accompanied by hypoxia, hypercapnia respiratory problems such as: asthma, chronic obstructive pulmonary disease etc. Besides this in case of patient with sleep apnea syndrome, myxedema, kyphoscoliosis, central nervous system (CNS) depression should have to be cautious prior administration of Tapentadol. Patients receiving other mu-opioid agonist analgesics, general anesthetics, phenothiazines, other tranquilizers, sedatives, hypnotics, or other CNS depressants (including alcohol) concomitantly with Tapentadol may exhibit additive CNS depression.

### PEDIATRIC & GERIATRIC USE

The safety and effectiveness of Tapentadol in pediatric patients less than 18 years of age have not been established.

In general, recommended dosing for elderly patients with normal renal and hepatic function is the same as for younger adult patients with normal renal and hepatic function. consideration should be given to starting elderly patients with the lower range of recommended doses.

#### Use in Renal Disease

In patients with severe renal impairment, the safety and effectiveness of Tapentadol has not been established.

#### Use in Hepatic Disease

Tapentadol should be used with caution in patients with moderate hepatic impairment. Tapentadol has not been studied in patients with severe hepatic impairment.

### ADVERSE REACTIONS

The following treatment-emergent adverse events may happen:

heart rate increased, heart rate decreased, visual disturbance, abdominal discomfort, impaired gastric emptying, irritability, edema, drug withdrawal syndrome, hypersensitivity, involuntary muscle contractions, sensation of heaviness, hypoesthesia, paresthesia, disturbance in attention, sedation, dysarthria, memory impairment, ataxia, presyncope, syncope, coordination abnormal, seizure, urticaria, blood pressure decreased etc.

### USE IN PREGNANCY & LACTATION

Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. This preparation should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Neonates whose mothers have been taking Tapentadol should be monitored for respiratory depression.

### STORAGE

Store in a cool and dry place, protected from light and moisture. Keep the medicine out of the reach of children.

### HOW SUPPLIED

**Pentadol™ 50 Tablet:** Each box contains 20 tablets in blister pack.

**Pentadol™ 75 Tablet:** Each box contains 10 tablets in blister pack.

**Pentadol™ 100 Tablet:** Each box contains 10 tablets in blister pack.

Manufactured by :



**SQUARE**

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