

# Tranal®

Tramadol Hydrochloride

## Description

Tramadol hydrochloride (Tranal®) is an opioid analgesic. It also has noradrenergic and serotonergic properties that may contribute to its analgesic activity.

## Mode of action

Tramadol hydrochloride (Tranal®) does appear to have two actions. It binds with certain opioid receptors; this blocks pain impulses from reaching the brain, in the same way as with NSAIDs and opioids. In addition, it inhibits reuptake of norepinephrine and serotonin, altering the way the brain monitors pain signals.

## Pharmacokinetics

Tramadol hydrochloride (Tranal®) is rapidly and almost completely absorbed after oral administration. The mean absolute bioavailability of a 100 mg oral dose is approximately 75%. The peak plasma concentration occurs after 2-3 hours of administration. Food does not affect the rate or extent of absorption. The binding to plasma protein is approximately 20%. Tramadol is extensively metabolized after oral administration. Approximately 30% of the dose is excreted in the urine unchanged and 60% as metabolites. The plasma elimination half-life is 6-7 hours.

## Composition

**Tranal® 50 mg Capsule:** Each capsule contains Tramadol Hydrochloride BP 50 mg.

**Tranal® 100 mg Injection:** Each 2 ml ampoule contains Tramadol Hydrochloride BP 100 mg.

**Tranal® 100 mg Suppository:** Each suppository contains Tramadol Hydrochloride BP 100 mg.

## Indications

Moderate to moderately severe pain.

## Dosage & administration

Oral: For the treatment of painful conditions, 50 mg to 100 mg can be taken as needed for relief in every four to six hours, not to exceed 400 mg per day. For moderate pain, 50 mg may be adequate as the initial dose, and for more severe pain, 100 mg is usually more effective as the initial dose. Injection: Adults and children over 14 years: In moderate pain, 50 mg (1 ml) as a single dose. If there is no pain relieving effect after 30 to 60 minutes, another 50 mg (1 ml) can be administered. If in severe pain a higher dose is necessary, 100 mg (2 ml) is 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 of tramadol are not necessary. Depending on the

pain, the effect lasts for 4 to 8 hours. In general, 400 mg (8 ml) tramadol hydrochloride per day need not to be exceeded. However, for the treatment of cancer pain much higher doses may be necessary. Children aged 1-13 years: 1-2 mg per kg body weight as a single dose.

## Side effects

The most frequently reported side effects include constipation or diarrhoea, difficulty in sleeping, dizziness, drowsiness, dry mouth, false sense of well being, feeling of unreality, mood changes, headache and indigestion. More serious side effects that may include changes in vision, difficulty in breathing, shortness of breath, fast or irregular heartbeat, hallucinations, passing urine more frequently than usual, or not passing urine as often as usual, skin reactions and seizures.

## Contraindications

Known allergy to tramadol hydrochloride.

## Use in pregnancy & lactation

There are no adequate and well controlled studies in pregnant women. Tramadol should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. Tramadol should not be used by lactating mothers.

## Precautions

Do not drive, use machinery, or do anything that needs mental alertness until you know how tramadol affects you. Avoid alcohol while taking tramadol.

## Drug interactions

Carbamazepine, anticoagulants, antidepressants.

## Overdosage

Serious potential consequences of overdosage with tramadol are central nervous system depression, respiratory depression and death. In treating an overdose, primary attention should be given to maintaining adequate ventilation along with general supportive treatment.

## Storage

Store in a cool and dry place, protected from light.

## Packaging

**Tranal® 50 mg Capsule:** Each carton contains 10X2 capsules in blister pack.

**Tranal® 100 mg Injection:** Each carton contains 5X1 ampoules in blister pack.

**Tranal® 100 mg Suppository:** Each carton contains 5X2 suppositories in strip pack.



Manufactured by  
Opsonin Pharma Limited  
Rupatali, Barishal, Bangladesh.  
® Registered Trade Mark.