TRAZOLAM 50 mg Tablets (Trazodone HCI USP) (USP Specifications)
TRAZOLAM 100 mg Tablets (Trazodone HCI USP) (USP Specifications)



## Prescribing Information:

## **DESCRIPTION:**

TRAZOLAM (Trazodone HCI USP) is a triazolopyridine derivative, broad spectrum SARI antidepressant .

## **INDICATIONS & USES:**

TRAZOLAM is indicated for the treatment of depression, depression with sleep disturbance and/or anxiety. The efficacy of TRAZOLAM has been demonstrated in both in-patients & out-patients setting and for depressed patients with or without anxiety and/ or sleep disturbance. TRAZOLAM successfully treats depression of all types including depression associated with anxiety symptoms of depression likely to respond in the first week of treatment includes depressed mood, insomnia, suicidal thoughts, anxiety, somatic symptoms & hypochondriasis.

#### **CONTRA-INDICATIONS:**

TRAZOLAM (Trazodone) is contra-indicated in patients hypersensitive to trazodone.

## PRECAUTIONS:

As with all drugs acting on CNS patient should be warned against the risk of handling machinery and driving vehicles. Interaction between TRAZOLAM and MAO inhibitors have not been reported. However, on grounds of clinical caution TRAZOLAM is not recommended for concurrent administration with MAO inhibitors or within two weeks of terminating treatment with these compounds. TRAZOLAM should be administered with care in patients with severe hepatic or renal disease.

#### PREGNANCY & LACTATION:

Although studies on animals have not shown any direct teratogenic effect, the safety of trazodone in human pregnancy has not been established. On basic principle, therefore, it's use during the first trimester should be avoided. The possibility of trazodone being excreted in the milk should also be considered in nursing mothers.

## SIDE EFFECTS:

Drowsiness is sometimes experienced during the first days of treatment but usually disappears on continued therapy. TRAZOLAM is virtually free from anticholinergic side effects as they are comparable to placebo. No major side effects have been reported even in patients treated continuously for periods over one year. The following symptoms which are commonly reported in cases of untreated depression, have also been recorded in small number of patients receiving trazolam therapy: dizziness, headache, nausea & vomiting, weakness, decreased alertness, weight loss, tremors, dry mouth, bradycardia, tachycardia, postural hypo-tension, constipation, diarrhoea, blurred vision, restlessness, confusional states, insomnia and skin rash.

## **OVER DOSAGE:**

There is no specific antidote to trazolam. The stomach should be emptied as quickly as possible. Treatment should be symptomatic and supportive in the case of hypotension and excessive sedation.

# DOSAGE & ADMINISTRATION:

Initial 100 mg at bed time, add 50mg every three to four days until optimum response is achieved. The dosage at which optimum response achieved is usually 150mg to 200mg. Above 200mg should be administered in divided dosage and major portion at bed time. The maximum dosage for out-patients should not exceed 400mg/day and for in-patients 600mg/day. Maintenance dosage should be kept at lowest effective level. Once an adequate response is achieved dosage may be adjusted according to therapeutic response.

## PRESENTATION:

Trazolam (Trazodone HCI) 50mg Tablets available in 3x10's blister packs. Trazolam(Trazodone HCI) 100mg Tablets available in 3x10's blister packs.



