TRAMADOL HYDROCHLORIDE - tramadol hydrochloride tablet
Alivio Medical Products, LLC

Drug Facts

Each capsule contains:

Tramadol Hydrochloride, USP .....50 mg

Usual Dosage: For dosage and other prescribing

information, see accompanying insert.

Store at 20 to 25 C (68 to 77 F); excursions

permitted to 15 to 30 C (59 to 86 F)[See

USP Controlled Room Temperature]

Dispense in a tight container as defined in

the USP.

Keep out of reach of children.

DESCRIPTION

Tramadol hydrochloride tablets, USP are a centrally acting analgesic.

CLINICAL PHARMACOLOGY

PHARMACODYNAMICS Tramadol Hydrochloride contains tramadol, a centrally acting synthetic opoid

analgesic.

CLINICAL STUDIES

Tramadol hydrochloride has been given in single oral doses pf 50, 75 and 100 mg to patients with pain following surgical procedures and pain following oral surgery (extraction if impacted molars).

INDICATIONS AND USAGE

Tramadol hydrochloride tablets, USP are indicated for the management of moderate to

moderately severe pain in adults.

CONTRAINDICATIONS

Tramadol hydrochloride tablets, USP should not be administered to patients who have previously demonstrated hypersensitivity to tramadol, any other component of this product or opoids.

WARNINGS

Seizure Risk Seizures have been reported in patients receiving Tramadol hydrochloride within the recommended dosage range.

PRECAUTIONS

Acute Abdominal Conditions The administration of tramadol hydrochloride may complicate the clinical assessment

of patients with acute abdominal conditions

ADVERSE REACTIONS

Tramadol hydrochloride was administered to 550 patients during the double-blind or open-label extension periods in U.S. clinical studies of chronic nonmalignant pain.

DRUG ABUSE AND DEPENDENCE.

Abuse Tramadol has mu-opoid agonist activity.

OVERDOSAGE

Acute overdosage with tramadol can be manifested by respiratory depression, somnolence progressing to

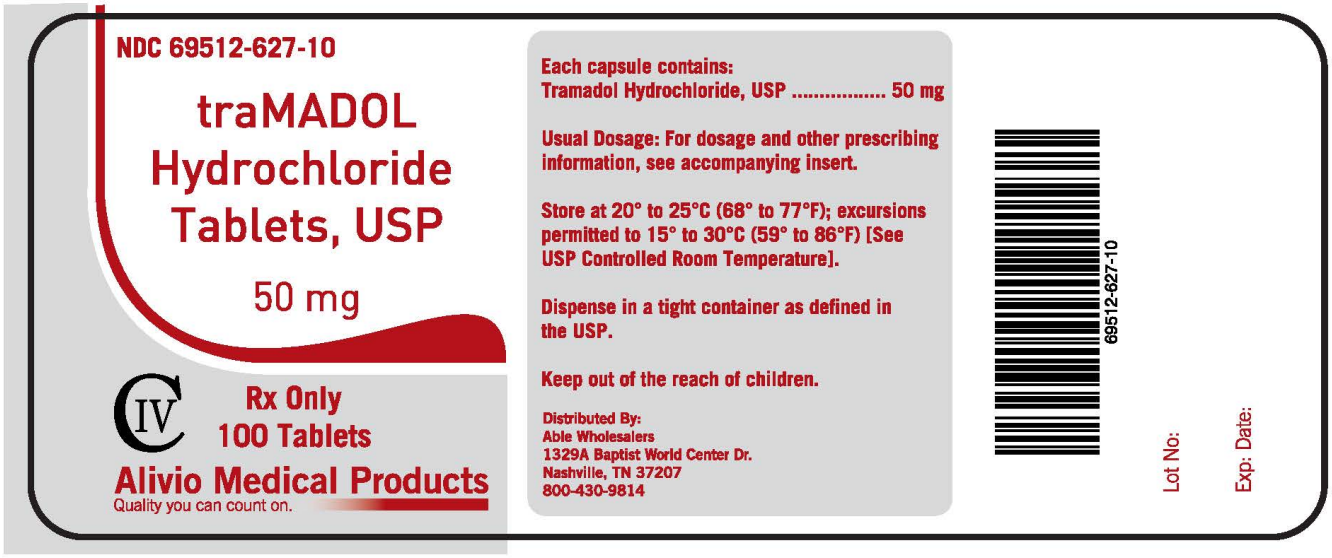
stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, seizures,

bradycardia, hypotension, cardiac arrest, and death.

DOSAGE AND ADMINISTRATION

Adults (17 years of age and older) For patients with moderate to moderately severe chronic pain not requiringrapid onset of analgesic effect, the tolerability of tramadol hydrochloride, USP can be improved by

initiating therapy with a titration regimen:



TRAMADOL HYDROCHLORIDE

tramadol hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69512-627
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TRAMADOL HYDROCHLORIDE (UNII: 9N7R477WCK) (TRAMADOL - UNII:39J1LGJ30J)	TRAMADOL HYDROCHLORIDE	50 mg in 50 mg

Inactive Ingredients	
Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	white (White)	**Score**	no score
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	AN;627
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69512-627-10	100 in 1 BOTTLE		
1		50 mg in 1 CAPSULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076003	10/01/2015	

Labeler - Alivio Medical Products, LLC (079670828)

Revised: 10/2015 Alivio Medical Products, LLC