PRODUCT NAME	: Trazodone Hydrochloride Tablets	COUNTRY : US	LOCATION :		Supersedes A/W No.:		V. No.: 01	
ITEM / PACK	: Outsert	NO. OF COLORS: 1	REMARK :					
DESIGN STYLE	: Front	PANTONE SHADE NOS.:	SUBSTRATE : 40 g/m ² Bible Paper					
CODE	: 8097087	Black	Activities	Department		Name	Signature	Date
DIMENSIONS (MM)	: 490 x 340		Prepared By	Pkg.Dev				
ART WORK SIZE	: S/S		Reviewed By	Pkg.Dev				
DATE	: 27-09-2024	Font Size 6 pt_Medi_10 pt	Approved By	Quality				

eases the risk of serotonin syndrome

drugs [see Warnings and Precautions (5.2)].

warfarin, rivaroxaban, dabigatran, clopidogrel

and Administration (2.5)].

envtoin dose as necessary

alcohol, barbiturates

Antibiotics: gatifloxacin

The concomitant use of MAOIs and serotonergic drugs including trazodone

Trazodone is contraindicated in patients taking MAOIs, including MAOIs

such as linezolid or intravenous methylene blue [see Contraindications (4), Dosage and Administration (2.3, 2.4), and Warnings and Precautions

isocarboxazid, moclobemide, phenelzine, selegiline, tranylcypromine

The concomitant use of serotonergic drugs including trazodone and othe

serotonergic drugs increases the risk of serotonin syndrome. Monitor patients for signs and symptoms of serotonin syndrome,

particularly during trazodone initiation. If serotonin syndrome occurs, consider discontinuation of trazodone and/or concomitant serotonergic

fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John's Wort

Serotonin release by platelets plays an important role in hemostasis. The

ncurrent use of an antiplatelet agent or anticoagulant with trazodone may

otentiate the risk of bleeding. form patients of the increased risk of bleeding with the concomitant use

of trazodone and antiplatelet agents and anticoagulants. For patients taking warfarin, carefully monitor the international normalized ratio (INR) when initiating or discontinuing trazodone [see Warnings and Precautions (5.5)].

e concomitant use of trazodone and strong CYP3A4 inhibitors increased

If trazodone is used with a potent CYP3A4 inhibitor, the risk of adverse

eactions, including cardiac arrhythmias, may be increased and a lowe

ne concomitant use of trazodone and strong CYP3A4 inducers decreased

Patients should be closely monitored to see if there is a need for an

increased dose of trazodone when taking CYP3A4 inducers [see Dosage

Digoxin and phenytoin are narrow therapeutic index drugs. Concomita

Measure serum digoxin or phenytoin concentrations before initiating concomitant use of trazodone. Continue monitoring and reduce digoxin or

Patients should be counseled that trazodone may enhance the response to

Concomitant use of drugs that prolong the QT interval may add to the QT

effects of trazodone and increase the risk of cardiac arrhythmia. Avoid the use of trazodone in combination with other drugs known to

use of trazodone can increase digoxin or phenytoin concentrations.

the exposure of trazodone compared to the use of trazodone alone.

dose of trazodone should be considered [see Dosage and Adm (2.5), Warnings and Precautions (5.3)].

the exposure of trazodone compared to the use of trazodone alone.

nazole, ketoconazole, clarithromycin, indinavi

rifampin, carbamazepine, phenytoin, St. John's wort

Trazodone may enhance the response CNS depressants

alcohol, barbiturates, and other CNS depressants.

prolong QTc [see Warnings and Precautions (5.3)].

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to

Published prospective cohort studies, case series, and case reports over several decades with

trazodone use in pregnant women have not identified any drug-associated risks of major birth defects, miscarriage, or adverse maternal or fetal outcomes *(see Data)*. Trazodone hydrochloride has been shown to cause increased fetal resorption and other adverse effects on the fetus in the rat when

given at dose levels approximately 7.3 to 11 times the maximum recommended human dose (MBHD)

of 400 mg/day in adults on a mg/m² basis. There we maximum recommender fundational conservation of 400 mg/day in adults on a mg/m² basis. There was also an increase in congenital anomalies in the rabbit at approximately 7.3 to 22 times the MRHD on a mg/m² basis (see Data).

The estimated background risk of major birth defects and miscarriage for the indicated population is

In the unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

A prospective, longitudinal study followed 201 pregnant women with a history of major depressive disorder who were euthymic and taking antidepressants at the beginning of pregnancy. The women who discontinued antidepressants during pregnancy were more likely to experience a relapse of

major depression that women who continued antidepressants. Consider the risk of untreated

depression when discontinuing or changing treatment with antidepressant medication during

While available studies cannot definitively establish the absence of risk published data from prospective cohort studies cannot definitely establish the absence of risk, published data nom prospective cohort studies, case series, and case reports over several decades have not identified an association with trazodone use during pregnancy and major birth defects, miscarriage, or other

adverse maternal or fetal outcomes. All available studies have methodological limitations, including

No teratogenic effects were observed when trazodone was given to pregnant rats and rabbits during

the period of organogenesis at oral doses up to 450 mg/kg/day. This dose is 11 and 22 times, in rats and rabbits, respectively, the maximum recommended human dose (MRHD) of 400 mg/day in adults on a mg/m² basis. Increased fetal resorption and other adverse effects on the fetus in rats at 7.3 to

11 times the MBHD and increase in congenital anomalies in rabbits at 7.3 to 22 times the MBHD or

Data from published literature report the transfer of trazodone into human milk. There are no data on

the effect of trazodone on milk production. Limited data from postmarketing reports have not

The developmental and health benefits of breasteeding should be considered along with the mother's clinical need for trazodone and any potential adverse effects on the breastfed child from

afety and effectiveness in the pediatric population have not been established. Antidepre

Class 3 antiarrhythmics: amiodarone, sotalol:

Class 1A antiarrhythmics: quinidine, procainamide, disopyrami

psychotics: ziprasidone, chlorpromazine, thioridazine

ints during pregnancy. Healthcare providers are encouraged to register patients by calling

triptans, antidepressants (tricyclic and serotonin uptake inhibitor

Note: Pharma code/ Bar code and adjacent text must be visible on folded leaflet. These details can be moved by printed to arrange pharma code/ Bar code and adjacent text visible on folded leaflet.

DRUG INTERACTIONS

tervention

Clinical Impact:

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xamples

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Clinical Impact:

Clinical Impact:

terventior

xamples

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vamnle

Strong CYP3A4 Inhibitors

Strong CYP3A4 Inducers

Digoxin and Phenytoin

Central Nervous System (CNS) Depressants

ical Impact

Clinical Impact:

OT Interval Prolo

8 USE IN SPECIFIC POPULATIONS

Pregnancy Exposure Registry

Clinical Impact:

tervention

8.1 Pregnancy

Risk Summary

Clinical Considerations

pregnancy and postpartum.

Data

Human Data

Animal Data

8.2 Lactation

Risk Summary

8.4 Pediatric Use

8.5 Geriatric Use

Disease-associated maternal and/or embryofetal risk

small sample size and inconsistent comparator groups.

a mg/m² basis were observed. No further details on these studies are ava

identified and association of adverse effects on the breastfed child

trazodone or from the underlying maternal condition.

Examples

tervention:

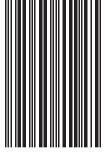
Other Serotonergic Drugs

Antiplatelet Agents and Anticoagulants









HIGHLIGHTS OF PRESCRIBING INFORMATION These highlights do not include all the information needed to use TRAZODONE HYDROCHLORIDE TABLETS safely and effectively. See full prescribing information for TRAZODONE HYDROCHLORIDE TABLETS. TRAZODONE HYDROCHLORIDE tablets, for oral use

Initial U.S. Approval: 1981

- WARNING: SUICIDAL THOUGHTS and BEHAVIORS
- See full prescribing information for complete boxed warning. Antidepresants increased the risk
- suicidal thoughts and behaviors in pediatric and young adult patients (5.1) Closely monitor for clinical worsening
- and emergence of suicidal thoughts and behaviors (5.1)
- Trazodone hydrochloride tablets are not approved for use in pediatric patients (8.4)

-----INDICATIONS AND USAGE------Trazodone hydrochloride tablets are a selective serotonin reuptake inhibitor indicated for the treatment of major depressive disorder (MDD)

--- DOSAGE AND ADMINISTRATION-----· Starting dose: 150 mg in divided doses daily. May be increased by 50 mg per day every

- three to four days. Maximum dose: 400 mg per day in divided doses (2). Trazodone hydrochloride tablets should be blurred vision, syncope, drowsiness, fatigue,
- taken shortly after a meal or light snack (2). Tablets should be swallowed whole or broken To report SUSPECTED ADVERSE REACTIONS, in half along the score line, and should not be
- chewed or crushed (2). When discontinued, gradual dose reduction is recommended (2).
- -----DOSAGE FORMS AND STRENGTHS------· Scored tablets: 50 mg, 100 mg, 150 mg and
- 300 mg (3). ---CONTRAINDICATIONS-----Concomitant use of monoamine oxidase inhibitors (MAOIs), or use within 14 days of
- stopping MAOIs (4). ---WARNINGS AND PRECAUTIONS---
- · Serotonin Syndrome: Increased risk when co-administered with other serotonergic agents (e.g., SSRI, SNRI, triptans), but also when taken alone. If it occurs, discontinue trazodone hydrochloride tablets and initiate supportive treatment (5.2).
- Cardiac Arrhythmias: Increases the QT
- FULL PRESCRIBING INFORMATION: CONTENTS* 6 ADVERSE REACTIONS WARNING: SUICIDAL THOUGHTS AND

BEHAVIORS INDICATIONS AND USAGE

- 2 DOSAGE AND ADMINISTRATION Dose Selection Important Administration Instructions
- 2.3 Screen for Bipolar Disorder Prior to Starting Trazodone Hydrochloride
- 2.4 Switching to or from Monoamine Oxidase Inhibitor Antidepressant 2.5 Dosage Recommendations for
- Concomitant Use with Strong CYP3A4
- Inhibitors or Inducers 2.6 Discontinuation of Treatment with
- Trazodone Hydrochloride Tablets
- **3 DOSAGE FORMS AND STRENGTHS**
- CONTRAINDICATIONS WARNINGS AND PRECAUTIONS
- Suicidal Thoughts and Behaviors in Pediatric and Young Adult Patients
- 5.2 Serotonin Syndrome Cardiac Arrhythmias
- Orthostatic Hypotension and Syncope
- Increased Risk of Bleeding
- Activation of Mania or Hypomania Discontinuation Syndrom
- Potential for Cognitive and Motor 5.9
- Impairment 5.10 Angle-Closure Glaucoma

FULL PRESCRIBING INFORMATION

WARNING: SUICIDAL THOUGHTS and BEHAVIORS Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors [see Warnings and Precautions (5.1)]. Trazodone hydrochloride tablets are not approved for use in pediatric patients [see Use in Specific Populations (8.4)].

1 INDICATIONS AND USAGE

Trazodone hydrochloride tablets are indicated for the treatment of major depressive disorder (MDD)

- 2 DOSAGE AND ADMINISTRATION 2.1 Dose Selection
- An initial dose of 150 mg/day in divided doses is suggested. The dosage should be initiated at a

low-dose and increased gradually, noting the clinical response and any evidence of intolerance. Occurrence of drowsiness may require the administration of a major portion of the daily dose at bedtime or a reduction of dosage. The dose may be increased by 50 mg/day every 3 to 4 days. The maximum dose for outpatients

usually should not exceed 400 mg/day in divided doses. Inpatients (i.e., more severely depressed patients) may be given up to but not in excess of 600 mg/day in divided doses. Once an adequate response has been achieved, dosage may be gradually reduced, with subsequent

nent depending on therapeutic response

2.2 Important Administration Instructions razodone hydrochloride tablets can be swallowed whole or administered as a half tablet by breaking the tablet along the score line

Trazodone hydrochloride tablets should be taken shortly after a meal or light snack.

2.3 Screen for Bipolar Disorder Prior to Starting Trazodone Hydrochloride Tablets

Prior to initiating treatment with trazodone hydrochloride tablets or another antidepressant, screen patients for a personal or family history of bipolar disorder, mania, or hypomania [see Warnings and Precautions (5.7)1.

2.4 Switching to or from Monoamine Oxidase Inhibitor Antidepressant At least 14 days must elapse between discontinuation of a monoamine oxidase inhibitor (MAOI) antidepressant and initiation of trazodone hydrochloride tablets. In addition, at least 14 days must

elapse after stopping trazodone hydrochloride tablets before starting an MAOI antidepressant [see ontraindications (4), Warnings and Precautions (5.2)]. 2.5 Dosage Recommendations for Concomitant Use with Strong CYP3A4 Inhibitors or Inducers

Coadministration with Strong CYP3A4 Inhibitors

Consider reducing trazodone dose based on tolerability when trazodone is coadministered with a strong CYP3A4 inhibitor [see Drug Interactions (7.1)]

Coadministration with Strong CYP3A4 Inducers interval. Avoid use with drugs that also Consider increasing trazodone dose based on therapeutic response when trazodone is increase the QT interval and in patients with

risk factors for prolonged QT interval (5.3).

Orthostatic Hypotension and Syncope: Warn

patients of risk and symptoms of hypotension

Increased Risk of Bleeding: Concomitant use

of aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), other antiplatelet drugs,

warfarin, and other anticoagulants may

Priapism: Cases of painful and prolonged

penile erections and priapism have been

reported. Immediate medical attention should

be sought if signs and symptoms of

prolonged penile erections or priapism are

Activation of Mania or Hypomania: Screen for

Potential for Cognitive and Motor

Impairment: Has potential to impair

udgment, thinking, and motor skills. Advise

patients to use caution when operating

Angle-Closure Glaucoma: Avoid use of

antidepressants, including trazodone hydrochloride tablets, in patients with

untreated anatomically narrow angles (5.10)

----ADVERSE REACTIONS-----

Most common adverse reactions (incidence \geq 5% and twice that of placebo) are: edema,

contact Torrent Pharma Inc. at 1-800-912-9561

-----DBUG INTERACTIONS-----

· CNS Depressants: Trazodone may enhance

effects of alcohol, barbiturates, or other CNS

depressants (7).CYP3A4 Inhibitors: Consider Trazodone dose

CYP3A4 Inducers: Increase in Trazodone

Digoxin or Phenytoin: Monitor for increased

in or phenytoin serum levels (7)

Warfarin: Monitor for increased or decreased

See 17 for PATIENT COUNSELING

RMATION and Medication Guide

Drugs Having Clinically Important Interactions with Trazodone

Revised: 9/2024

reduction based on tolerability (2.5, 7)

dosage may be necessary (2.5, 7).

prothrombin time (7).

6.1 Clinical Trials Experience
6.2 Postmarketing Experience
7 DRUG INTERACTIONS

Hydrochloride Tablets

USE IN SPECIFIC POPULATIONS

Pregnancy

Pediatric Use

Geriatric Use

12.1 Mechanism of Action

12.2 Pharmacodynamics

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

17 PATIENT COUNSELING INFORMATION

14 CLINICAL STUDIES 16 HOW SUPPLIED/STORAGE AND HANDLING

* Sections or subsections omitted from the full prescribing information are not listed.

Henatic Imnairmen

DRUG ABUSE AND DEPENDENCE

Controlled Substance

8.6 Renal Impairmen

9.2 Ahuse

10 OVERDOSAGI

11 DESCRIPTION

12.3 Phar

Lactation

FDA at 1-800-FDA-1088 or

diarrhea, nasal congestion, weight loss (6).

bipolar disorder and monitor for mania or

increase this risk (5.5).

observed (5.6).

hypomania (5.7).

machinery (5.9).

www.fda.gov/medw

(5.4)

istered with a strong CYP3A4 inducer [see Drug Interactions (7.1)]

2.6 Discontinuation of Treatment with Trazodone Hydrochloride Tablets Adverse reactions may occur upon discontinuation of trazodone hydrochloride tablets [See Warnings and Precautions (5.8)]. Gradually reduce the dosage rather than stopping trazodone hydrochloride

tablets abruptly whenever possible 3 DOSAGE FORMS AND STRENGTHS

50 mg Tablets, white to off white, round, biconvex, uncoated tablets debossed with "13" bisect "30" on one side and plain on other side

100 mg Tablets, white to off white, round, biconvex, uncoated tablets debossed with "13" bisect "31 on one side and plain on other side.

150 mg Tablets, white to off white, oval, flat faced beveled edge uncoated tablets with a full bisect and two partial trisects. Debossed "13" bisect "32" on one side and "50 50 50" on other side 300 mg white to off white, oval, flat faced beveled edge uncoated tablets with a full bisect and two partial trisects. Debossed "13" bisect "33" on one side and "100 100 100" on other side with middle "100" perpendicular to others.

CONTRAINDICATIONS

rodone hydrochloride tablets are contraindicated in: Patients taking, or within 14 days of stopping, monoamine oxidase inhibitors (MAOIs), including MAOIs such as linezolid or intravenous methylene blue, because of an increased risk of serotonin syndrome [see Warnings and Precautions (5.2), Drug Interactions (7.1)]. WARNINGS AND PRECAUTIONS

5.1 Suicidal Thoughts and Behaviors in Pediatric and Young Adult Patients

In pooled analyses of placebo-controlled trials of antidepressant drugs (SSRIs and other antidepressant classes) that included approximately 77,000 adult patients and over 4,400 pediatric patients, the incidence of suicidal thoughts and behaviors in pediatric and young adult patients was greater in antidepressant-treated patients than in placeb-treated patients. The drug-placebo differences in the number of cases of suicidal thoughts and behaviors per 1,000 patients treated are provided in Table 1.

No suicides occurred in any of the pediatric studies. There were suicides in the adult studies, but the per was not sufficient to reach any conclusion about antidepressant drug effect on suicide. Table 1: Risk Differences of the Number of Cases of Suicidal Thoughts or Behaviors in the Pooled

Placebo-Controlled Trials of Antidepressants in Pediatric and Adult Patients Drug-Placebo Difference in Number of Patients of Suicidal Age Range Thoughts or Behaviors per 1,000 Patients Treated

	Increases Compared to Placebo
< 18	14 additional patients
18 - 24	5 additional patients
	Decreases Compared to Placebo
25 - 64	1 fewer patient
≥ 65	6 fewer patients
lt is unknown whethe	r the rick of quicidal thoughts and behaviors in pediatric and young

idal thoughts and behaviors in pediatric and young adult patients extends to longer-term use, i.e., beyond four months. However, there is substantial, evidence from placebo-controlled maintenance trials in adults with MDD that antidepressants delay the recurrence of depression

Monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors, especially during the initial few months of drug therapy and at times of dosage changes. Counsel family members or caregivers of patients to monitor for changes in behavior and to alert the healthcare provider. Consider changing the therapeutic regimen, including possibly discontinuing trazodone hydrochloride tablets, in patients whose depression is persistently worse, or who are experiencing emergent suicidal thoughts or behaviors.

5.2 Serotonin Syndrome

Serotonin-norepinephrine reuptake inhibitors (SNRIs) and SSRIs, including trazodone, can precipitate serotonin syndrome, a potentially life-threatening condition. The risk is **increased with** concomitant use of other serotonergic drugs (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John's Wort) and with drugs that impair metabolism of serotonin, i.e., MAOIs [see Contraindications (4), Drug Interactions (7.1)]. Serotonin syndrome can also occur when these drugs are used alone.

Serotonin syndrome signs and symptoms may include mental status changes (e.g., agitation berotomi synoromi synoromi synoromi synoromi synoromi may include i nema status changes (e.g., agradom), hallucinations, delirium, and coma), autonomic instability (e.g., tachycardia, labile blodo pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (e.g., tremor, rigidity, myoclonus, hyperreflexia, incoordination), seizures, and gastrointestinal symptoms (e.g., nausea niting, diarrhea).

The concomitant use of trazodone with MAOIs is contraindicated. In addition, do not initiate trazodone in a patient being treated with MAOIs such as linezolid or intravenous methylene blue. No reports involved the administration of methylene blue by other routes (such as oral tablets or local itissue injection). If it is necessary to initiate treatment with an MAOI such as linezolid or intravenous methylene blue in a patient taking trazodone hydrochloride tablets, discontinue trazodone before initiating treatment with the MAOI *[see Contraindications (4), Drug Interactions (7,1)]*.

Monitor all patients taking trazodone for the emergence of serotonin syndrome. Discontinue treatment with trazodone and any concomitant serotonergic agents immediately if the above symptoms occur, and initiate supportive symptomatic treatment. If concomitant use of trazodone with other serotonergic drugs is clinically warranted, inform patients of the increased risk for nin syndrome and monitor for symptom

5.3 Cardiac Arrhythmias

Clinical studies indicate that trazodone hydrochloride may be arrhythmogenic in patients with preexisting cardiac disease. Arrhythmias identified include isolated PVCs, ventricular couplets prevising cardia disease. An inviting index in the index is a cardial couples, including torsade depointes have been reported at doses of 100 mg or less with the immediate-release form of trazodone. Trazodone should also be avoided in patients with a history of cardiac arrhythmias, as well as other ances that may increase the risk of the occurrence of torsade de pointes and/or sudde death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and the presence of concentral prolongation of the QT interval. Trazodone is not recommended for use during the initial ecovery phase of myocardial infarction. Caution should be used when administering trazodone to patients with cardiac disease and such patients should be closely monitored, since antidepressan drugs (including trazodone) may cause cardiac arrhythmias [see Adverse Reactions (6.2)].

Trazodone prolongs the OT/OTc interval. The use of trazodone should be avoided in patients with anown QT prolongation or in combination with other drugs that are inhibitors of CYP3A4 (e.g. itraconazole, clarithromycin, voriconazole), or known to prolong QT interval including Class 1A antiarrhythmics (e.g., quinidine, procainamide) or Class 3 antiarrhythmics (e.g., amiodarone, sotalol), certain antipsychotic medications (e.g., ziprasidone, chlorpromazine, thioridazine), and certain antibiotics (e.g., gatifloxacin). Con tion of drugs may increase the risk o cardiac arrhythmia [see Drug Interactions (7.1)]

5.4 Orthostatic Hypotension and Syncope Hypotension, including orthostatic hypotension and syncope has been reported in patients receiving trazodone hydrochloride. Concomitant use with an antihypertensive may require a reduction in the dose of the antihypertensive drug.

5.5 Increased Risk of Bleeding

Drugs that interfere with serotonin reuptake inhibition, including trazodone, increase the risk of bleeding events. Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs (NSAIDS), othe antiplatelet drugs, warfarin, and other anticoagulants may add to this risk. Case reports and iological studies (case-control and cohort design) have demonstrated an association between use of drugs that interfere with serotonin reuptake and the occurrence of gastrointestinal bleeding ding events related to drugs that interfere with serotonin reuptake have ranged from ecchymosis

hematoma, epistaxis, and petechiae to life-threatening hemorrhages. Inform patients about the risk of bleeding associated with the concomitant use of trazodone and antiplatelet agents or anticoagulants. For patients taking warfarin, carefully monitor coagulation indices when initiating, titrating, or discontinuing trazodone.

5.6 Priapism Cases of priapism (painful erections greater than 6 hours in duration) have been reported in men receiving trazedone. Priapism, if not treated promptly, can result in irreversible damage to the erectile tissue. Men who have an erection lasting greater than 4 hours, whether painful or not, should immediately discontinue the drug and seek emergency medical attention [see Adverse Reactions

(6.2), Overdosage (10)]. Trazodone should be used with caution in men who have conditions that might predispose them to priapism (e.g., sickle cell anemia, multiple myeloma, or leukemia), or in men with anatomical

deformation of the penis (e.g., angulation, cavernosal fibrosis, or Peyronie's disease). 5.7 Activation of Mania or Hypomania In patients with bipolar disorder, treating a depressive episode with trazodone or another

reported in a small proportion of patients with major affective disorder who were treated with antidepressants. Prior to initiating treatment with trazodone, screen patients for any personal or family history of bipolar disorder, mania, or hypomania [see Dosage and Administration (2.3)].

5.8 Discontinuation Syndrome

Adverse reactions after discontinuation of serotonergic antidepressants, particularly after abrupt tinuation, include: nausea, sweating, dysphoric mood, irritability, agitation, dizziness, ser disturbances (e.g., paresthesia, such as electric shock sensations), tremor, anxiety, confusion headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. A gradual reduction in dosage rather than abrupt cessation is recommended whenever possible [See Dosage and Administration (2.6)].

5.9 Potential for Cognitive and Motor Impairment

hyponatremia include headache, difficulty conce

and Warnings and Precautions (5.1)]

Serotonin Syndrome [see Warnings and Precautions (5.2)] Cardiac Arrythmias [see Warnings and Precautions (5.3)]

Angle-Closure Glaucoma [see Warnings and Precautions (5.10)] Hyponatremia [see Warnings and Precautions (5.11)]

Inpatients

another drug and may not reflect the rates observed in practice.

done hydrochloride tablets may cause somnolence or sedation and may impair the mental and/or physical ability required for the performance of potentially hazardous tasks. Patients should be cautioned about operating hazardous machinery, including automobiles, until they are reasonably certain that the drug treatment does not affect them adversely 5.10 Angle-Closure Glaucoma

pupillary dilation that occurs following use of many antidepressant drugs including trazodone hydrochloride may trigger an angle closure attack in a patient with anatomically narrow angles who does not have a patent iridectomy. Avoid use of antidepressants, including trazodone, in patients with untreated anatomically narrow angles.

5.11 Hyponatremia Hyponatremia may occur as a result of treatment with SNRIs and SSRIs, including trazodone. Cases

hormone secretion (SIADH).

ADVERSE REACTIONS

6.1 Clinical Trials Experience

Controled Clinical Studies

Allergic Skin Condition/Edema

ecreased Concentration

dominal/Gastric Dis

ziness/Liaht-H

wsiness

ervousness

eadache

arrhea

Musculoskeleta

ological

Eves Red/Tired/Itchina

Vasal/Sinus Congestion

lead Full-Heavy

Weight Gain

long-term studies.

Eve disorders: diplopia

6.2 Postmarketing Experience

Blood and lymphatic system disorders: hemolytic anemia, leukocytosis

intestinal disorders: increased salivation, nausea/vomiting

of 100 mg per day or less [see Warnings and Precautions (5.3)].

Endocrine disorders: inappropriate ADH syndrome

Metabolism and nutrition disorders: methemoalobinemia

grand mal seizures, paresthesia, tardive dyskinesia, vertigo

Renal and urinary disorders: urinary incontinence, urinary retention

estigations: increased amylase

reaction, psychosis, stupor

Vascular disorders: vasodilation

urticaria

ches/Pains

ncoordinatio

emors

utonomic

onstipatio ry Mouth

CNS

ardiovascula

urred Vision

7.1 Drugs Having Clinically Important Interactions with Trazodone Hydrochloride Tablets Table 3: Clinically Important Drug Interactions with Trazodone Hydrochloride Tablets Monoamine Oxidase Inhibitors (MAOIs) Clinical Impact:

with serum sodium lower than 110 mmol/L have been reported. Signs and symptoms of and unsteadiness, which can lead to falls. Signs and symptoms associated with more severe and/or acute cases have included hallucination, syncope, seizure, coma, respiratory arrest, and death. In hany cases, this hyponatremia appears to be the result of the syndrome of inappropriate anti In patients with symptomatic hyponatremia, discontinue trazodone and institute appropriate medical

intervention. Elderly patients, patients taking diuretics, and those who are volume-depleted may be greater risk of developing hyponatremia with SSRIs and SNRIs [see Use in Specific Popula

The following serious adverse reactions are described elsewhere in the labeling: Suicidal Thoughts and Behavior in Children, Adolescents and Young Adults [see Boxed Warning

Orthostatic Hypotension and Syncope [see Warnings and Precautions (5.5)] Increased Risk of Bleeding [see Warnings and Precautions (5.5)] Priapism [see Warnings and Precautions (5.6)]

Activation of Mania or Hypomania [see Warnings and Precautions (5.7)] Discontinuation Syndrome [see Warnings and Precautions (5.8)] Potential for Cognitive and Motor Impairment [see Warnings and Precautions (5.9)]

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of

Outpatients

inpatients		Outpatients			
Trazodone Hydrochloride Tablets	Placebo N=95	Trazodone Hydrochloride Tablets	Placebo N=158		
N=142		N=157			
00/	40/	70/	10/		
3%	1%	7%	1%		
00/	10/	150/	40/		
6%	4%	15%	4%		
7%	4%	8%	6%		
15%	8%	34%	20%		
000/	10/	40/	*		
20%	1%	1%			
7%	1%	4%	0		
3%	2%	5%	1%		
50/	0	201	00/		
5%	0	6%	8%		
3%	2%	1%	0		
2%	0		0		
20%	5%	28%	15%		
24%	6%	41%	20%		
11%	4%	6%	3%		
10%	5%	20%	16%		
15%	11%	6%	8%		
4%	4%	6%	4%		
0	1%	5%	1%		
10%	1%	13%	10%		
6%	3%	5%	3%		
5%	0	2%	*		
3%	1%	5%	4%		
3%	0	0	0		
3%	0	0	0		
3%	0	0	0		
3%	0	6%	3%		
1%	0	5%	2%		
*	3%	6%	3%		

Other adverse reactions occurring at an incidence of <2% with the use of trazodone hydrochloride in anemia, chest pain, delayed urine t early menses, flatulence, hallucinations/delusions, hematuria, hypersalivation, hypomania, impaired memory, impaired speech, impotence, increased appetite, increased libido, increased urinary frequency, missed periods, muscle twitches, numbress, paresthesia, retrograde ejaculation shortness of breath, and tachycardia/palpitations. Occasional sinus bradycardia has occurred in

The following adverse reactions have been identified during post-approval use of trazodone. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency or establish a causal relationship to drug exposure:

Cardiac disorders: cardiospasm, congestive heart failure, conduction block, orthostatic hypotension and syncope, palpitations, bradycardia, atrial fibrillation, myocardial infarction, cardiac arrest arrhythmia, ventricular ectopic activity, including ventricular tachycardia and QT prolongation Prolonged OT interval torsade de pointes and ventricular tachycardia have been reported at doses

General disorders and administration site conditions: chills, edema, unexplained death, weakness Hepatobiliary disorders: cholestasis, jaundice, hyperbilirubinemia, liver enzyme alterations

Nervous system disorders: aphasia, ataxia, cerebrovascular accident, extrapyramidal symptoms,

Psychiatric disorders: abnormal dreams, agitation, anxiety, hallucinations, insomnia, paranoid

increased the risk of suicidal thoughts and behaviors in pediatric patients [see Boxed Warning, Warnings and Precautions (5.1)]. Reproductive system and breast disorders: breast enlargement or engorgement, clitorism,

Respiratory, thoracic and mediastinal disorders: apnea Skin and subcutaneous tissue disorders: appeaa Skin and subcutaneous tissue disorders: alopecia, hirsutism, leukonychia, pruritus, psoriasis, rash,

literature and experience with trazodone has not identified differences in responses between elderly and younger patients. However, as experience in the elderly with trazodone hydrochloride is limited, it should be used with caution in geriatric patients Serotonergic antidepressants have been associated with cases of clinically significant hyponatremia

n elderly patients, who may be at greater risk for this adverse reaction [see Warnings and Precautions (5.11)1.

8.6 Renal Impairmen odone has not been studied in patients with renal impairment. Trazodone should be used with

caution in this population 8.7 Hepatic Impairment

Frazodone has not been studied in patients with hepatic impairment. Trazodone should be used with caution in this population

9 DRUG ARUSE AND DEPENDENCE 9.1 Controlled Substance

Frazodone hydrochloride tablets are not a controlled substance.

9.2 Abuse Although trazodone hydrochloride has not been systematically studied in preclinical or clinical studies for its potential for abuse, no indication of drug-seeking behavior was seen in the clinical studies with trazodone hydrochloride.

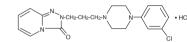
10 OVERDOSAGE

Death from overdose has occurred in patients ingesting trazodone and other CNS depressant drugs concurrently (alcohol: alcohol and chloral hydrate and diazepam; amobarbital: chlordiazepoxide: or

The most severe reactions reported to have occurred with overdose of trazodone alone have been priapism, respiratory arrest, seizures, and ECG changes, including QT prolongation. The reactions reported most frequently have been drowsiness and vomiting. Overdosage may cause an increase in ncidence or severity of any of the reported adverse reactions

There is no specific antidote for trazodone hydrochloride overdose. In managing overdosage position to possibility of multiple drug involvement. For current information on the management of poisoning or overdose, contact a poison control center (1-800-222-1222 or www.poison.org). 11 DESCRIPTION

Trazodone hydrochloride tablets for oral administration contain trazodone hydrochloride, a selective retorini reuptake inhibitor and 5HT2 receptor antagonist. Trazodone hydrochloride is a riazolopyridine derivative designated as 2-[3-[4-(3-chlorophenyl)-1-piperazinyl]propyl] -1,2,4-triazolo[4,3-a]pyridin-3(2H)-one hydrochloride. It is a white odorless crystalline powder which is freely soluble in water. The structural formula is represe nted as follows



Molecular Formula: C., H., CIN, O · HCI Molecular Weight: 408.33

Each tablet, for oral administration, contains 50 mg, 100 mg, 150 mg or 300 mg of trazodone hydrochloride. USP. In addition, each tablet contains the following inactive ingredients: colloidal silicon dioxide, agnesium stearate, nicrocrystalline cellulose, pregelatinized maize starch, sodium lauryl sulfate, and sodium stearate nicrocrystalline cellulose, pregelatinized maize starch, sodium lauryl sulfate, and sodium starch glycolate.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism of trazodone's antidepressant action is not fully understood, but is thought to be related to its enhancement of serotonergic activity in the CNS. Tradodne is both a selective serotonin reuptake inhibitor (SSRI) and a 5HT2 receptor antagonist and the net result of this action on serotonergic transmission and its role in trazodone's antidepressant effect is unknown 12.2 Pharmacodynamics

Preclinical studies have shown that trazodone selectively inhibits neuronal reuptake of serotonin (Ki = 367 nM) and acts as an antagonist at 5-HT-2A (Ki = 35.6 nM) serotonin receptors. Trazodone is also an antagonist at several other monoaminergic receptors including 5-HT2B (Ki = 78.4 nM). -HT2C (Ki = 224 nM), α1A (Ki = 153 nM), α2C (Ki = 155 nM) receptors and it is a partial agonist at -HT1A (Ki = 118 nM) receptor.

Trazodone antagonizes alpha 1-adrenergic receptors, a property which may be associated with postural hypotension

12.3 Pharmacokinetics

Absorption In humans, trazodone hydrochloride is absorbed after oral administration without selective localization in any tissue. When trazodone hydrochloride is taken shortly after ingestion of food. there may be an increase in the amount of drug absorbed, a decrease in maximum concentration and a lengthening in the time to maximum concentration. Peak plasma levels occur approximately one hour after dosing when trazodone hydrochloride is taken on an empty stomach or 2 hours after losing when taken with food.

Metabolism

In vitro studies in human liver microsomes show that trazodone is metabolized, via oxidative cleavage, to an active metabolite, m-chlorophenylpiperazine (mCPP) by CYP3A4. Other metabolic bathways that may be involved in the metabolism of trazodone have not been well characterized. Trazodone is extensively metabolized; less than 1% of an oral dose is excreted unchanged in the urine

Elimination

the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or visiting online at https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/ n some patients trazodone may accumulate in the plasma

Protein Binding Trazodone is 89 to 95% protein bound in vitro at concentrations attained with therapeutic doses in humans

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis o drug- or dose-related occurrence of carcinogenesis was evident in rats receiving trazodone in daily oral doses up to 7.3 times the maximum recommended human dose (MRHD) of 400 mg/day in adults on a mg/m2 basis.

Mutagenesis

oxicity studies were conducted with trazodone lo genoto

mpairment of Fertility

razodone has no effect on fertility in rats at doses up to 7.3 times the MRHD in adults on a mg/m² basis

14 CLINICAL STUDIES

The efficacy and safety of trazodone hydrochloride were established from inpatient and outpatient rials of the trazodone immediate release formulation in the treatment of major depressive disorder 16 HOW SUPPLIED/STORAGE AND HANDLING

Trazodone Hydrochloride Tablets, USP 50 mg are available for oral administration as white to off white, round, biconvex, uncoated tablets debossed with "13" bisect "30" on one side and plain on other side.

Bottles of 30 Bottles of 100 Bottles of 500		NDC NDC	13668-33 13668-33 13668-33	30-0 30-0
Bottles of 1,000		NDC	13668-33	-0- ⁻

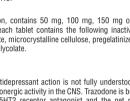
Trazodone Hydrochloride Tablets, USP 100 mg are available for oral administration as white to off white, round, biconvex, uncoated tablets debossed with "13" bisect "31" on one side and plain on other side.

Bottles of 30	NDC 13668-331-30
Bottles of 100	NDC 13668-331-01
Bottles of 500	NDC 13668-331-05
Bottles of 1,000	NDC 13668-331-10
	Tablets, USP 150 mg are available for oral administration as white to
off white, oval, flat faced b	beveled edge uncoated tablets with a full bisect and two partial trisects.
Debossed "13" bisect "32"	on one side and "50 50 50" on other side.

Bottles of 30	NDC 13668-332-30
Bottles of 100	NDC 13668-332-01
Bottles of 500	NDC 13668-332-05
Bottles of 1,000	NDC 13668-332-10
Directions for using the corr	oot oooro whon broaking

ons for using the correct score when breaking the tablet, please refer to the following: - For 50 mg, break the score on either the left or right side of the tablet (one-third of a tablet).



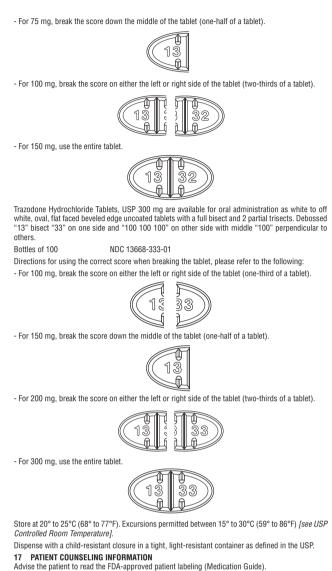




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PRODUCT NAME	:	Trazodone Hydrochloride Tablets	COUNTR
ITEM / PACK	:	Outsert	NO. OF C
DESIGN STYLE		Back	PANTON
CODE	:	8097087	
DIMENSIONS (MM)	:	490 x 340	
ART WORK SIZE	:	S/S	
DATE	:	27-09-2024	Font Size

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Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Suicidal Thoughts and Behaviors vise patients and caregivers to look for the emergence of suicidality, especially early during treatment and when the dosage is adjusted up or down and instruct them to report such symptoms to the healthcare provider [see Box Warning and Warnings and Precautions (5.1)]

Dosage and Administration ise patients that trazodone hydrochloride tablets should be taken shortly after a meal or light snack. Advise patients regarding the importance of following dosage titration instructions *[se* Dosage and Administration (2)]

Serotonin Syndrome Caution patients about the risk of serotonin syndrome, particularly with the concomitant use of trazodone with other serotonergic drugs including triptans, tricyclic antidepressants, fentanyl, thibition, tramadol, tryptophan, buspirone, St. John's Wort, and with drugs that impair metabolism of serotonin (in particular, MAOIs, both those intended to treat psychiatric disorders and also others, such as linezolid). Patients should contact their health care provider or report to the emergency room If they experience signs or symptoms of serotonin syndrome [see Warnings and Precautions (5.2) and Drug Interactions (7)].

Activation of Mania/Hypomania Advise patients and their caregivers to observe for signs of activation of mania/hypomania and instruct them to report such symptoms to the healthcare provider [see Warnings and Precautions

Increased Risk of Bleeding

Inform patients about the concomitant use of trazodone with aspirin, NSAIDs, other antiplatelet drugs, warfarin, or other anticoagulants because the combined use of drugs that interfere with serotonin reuptake and these medications has been associated with an increased risk of bleeding. Advise them to inform their health care providers if they are taking or planning to take any prescription or over-the-counter medications that increase the risk of bleeding [see Warnings and Precautions (5.5)]. Discontinuation Syndrome

Advise patients not to abruptly discontinue trazodone hydrochloride tablets and to discuss any hards participation with their healthcare provider. Adverse reactions can occur when trazodonic hydrochloride tablets is discontinued [see Warnings and Precautions (5.8)]. oncomitant Medications

Advise patients to inform their health care providers if they are taking, or plan to take any prescription or over-the-counter medications since there is a potential for interactions [see Drug Interactions

Advise patients to notify their healthcare provider if they become pregnant or intend to become pregnant during therapy with trazodone hydrochloride tablets. Advise patients that there is a pregnant during therapy with trazodone hydrochloride tablets. Advise patients that there is a hydrochloride tablets during pregnancy [see Use in Special Populations (8.1)].

MEDICATION GUIDE

Trazodone hydrochloride tablets, USP, for oral use (traz' oh done hye" droe klor' ide)

What is the most important information I should know about trazodone hydrochloride tablets?

Antidepressant medicines, depression or other serious mental illnesses, and suicidal thoughts or actions: Talk to vour healthcare provider about: • All risks and benefits of treatment with antidepressant

- medicines
- All treatment choices for depression or other serious mental illnesses
- 1. Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.
- 2. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions.

Some people may have a higher risk of having suicidal thoughts or actions. These include people who have or have a family history of bipolar illness (also called manic-depressive illness) or suicidal thoughts or actions.

- 3. How can I watch for and try to prevent suicidal thoughts and actions?
- Pay close attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
- Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you are worried about symptoms. Call a healthcare provider right away if you have any of the

following symptoms, especially if they are new, worse, or worry you:

- Thoughts about suicide or dving
- Attempts to commit suicide
- New or worse depression
- New or worse anxiety
- Feeling very agitated or restless
- Panic attacks
- Trouble sleeping (insomnia)
- New or worse irritability
- Acting aggressive, being angry or violent
- Acting on dangerous impulses
- An extreme increase in activity and talking (mania)
- Other unusual changes in behavior or mood What else do I need to know about antidepressant

medicines?

- Never stop an antidepressant medicine without first talking to a healthcare provider. Stopping an antidepressant medicine suddenly can cause other symptoms.
- Antidepressants are medicines used to treat depression and other illnesses. It is important to discuss all the risks of treating depression and also the risks of not treating it. You should discuss all treatment choices with your healthcare provider, not just the use of antidepressants.
- Antidepressant medicines have other side effects. Talk to your healthcare provider about the side effects of your medicines.
- Antidepressant medicines can interact with other **medicines.** Know all of the medicines that you take. Keep a list of all medicines to show your healthcare provider. Do not start new medicines without first checking with your healthcare provider.

It is not known if trazodone is safe and effective in children. What are trazodone hydrochloride tablets?

Trazodone hydrochloride tablets are a prescription medicine used in adults to treat major depressive disorder (MDD). Trazodone belongs to a class of medicines known as SSRIs (or selective serotonin reuptake inhibitors).

Do not take trazodone hydrochloride tablets:

- If you take a monoamine oxidase inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid, and intravenous methylene blue.
- Do not take an MAOI within 2 weeks of stopping trazodone hydrochloride tablets unless directed to do so by your healthcare provider.
- Do not start trazodone hydrochloride tablets if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your healthcare provider.

Before you take trazodone hydrochloride tablets tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems, including QT prolongation or a family history of it
- have ever had a heart attack
- have bipolar disorder
- have liver or kidney problems
- have other serious medical conditions

- are pregnant or plan to become pregnant. It is not known if trazodone hydrochloride tablets will harm your unborn baby. Talk to your healthcare provider about the risk to your unborn baby if you take trazodone hydrochloride tablets
- If you become pregnant during treatment with trazodone hydrochloride tablets, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants. You can register by calling 1-844-405-6185.
- are breastfeeding or plan to breastfeed. Trazodone hydrochloride tablets passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take trazodone hydrochloride tablets.
- have taken a Monoamine Oxidase Inhibitor (MAOI) or if you have stopped taking an MAOI in the last 2 weeks.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using trazodone hydrochloride tablets with certain other medicines can affect each other causing serious side effects. Especially tell your healthcare provider if you take:

- triptans used to treat migraine headache
- medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, SSRIs, SNRIs, buspirone, or antipsychotics
- tramadol
- over-the-counter supplements such as tryptophan or St. John's Wort
- nonsteroidal anti-inflammatory drugs (NSAIDS)
- warfarin (Coumadin, Jantoven)
- phenytoin (Mesantoin) diurctics

aspirin

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I take trazodone hydrochloride tablets?

- Take trazodone hydrochloride tablets exactly as your healthcare provider tells you.
- Trazodone hydrochloride tablets should be taken shortly after a meal or light snack.
- If you feel drowsy after taking trazodone hydrochloride tablets, talk to your healthcare provider. Your healthcare provider may change your dose or the time of day you take your trazodone hydrochloride tablets.
- Do not stop taking trazodone hydrochloride tablets without talking to your healthcare provider.
- Trazodone hydrochloride tablets should be swallowed whole or broken in half along the score line. Do not chew or crush trazodone hydrochloride tablets. Tell your healthcare provider if you cannot swallow trazodone either whole or as a half tablet.
- If you take too much trazodone hydrochloride, call your healthcare provider, your poison control center at 1-800-222-1222, or go to the nearest emergency room right away.

What should I avoid while taking trazodone hydrochloride tablets?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how trazodone hvdrochloride tablets affects you. Trazodone hydrochloride tablets can slow your thinking and motor skills
- Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking trazodone hydrochloride tablets until you talk with your healthcare provider. Trazodone hydrochloride tablets may make your sleepiness or dizziness worse if you take it with alcohol or other medicines that cause sleepiness or dizziness.

What are the possible side effects of trazodone hvdrochloride tablets? Trazodone hydrochloride tablets can cause serious side

1-800-FDA-1088 effects or death, including: • See "What is the most important information I should

know about trazodone hydrochloride tablets?"

Visual problems. eye pain changes in vision

symptoms listed above.

tablets include:

- swelling
- blurred vision
- dizziness sleepiness
- tiredness
- diarrhea
- stuffy nose

weight loss

1-800- FDA-1088.

tablets?

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Serotonin syndrome. Symptoms of serotonin syndrome include: agitation, hallucinations, problems with coordination, fast heartbeat, tight muscles, trouble walking, sweating, fever, nausea, vomiting, and diarrhea. Irregular or fast heartbeat or faint (OT prolongation) Low blood pressure. You feel dizzy or faint when you change positions (go from sitting to standing)

Unusual bruising or bleeding

Erection lasting for more than 6 hours (Priapism) Feeling high or in a very good mood, then becoming irritable, or having too much energy, feeling like you have to keep talking or do not sleep (mania).

Withdrawal symptoms. Symptoms of withdrawal can include anxiety, agitation, and sleep problems. Do not stop taking trazodone hydrochloride tablets without talking to your healthcare provider.

• swelling or redness in or around the eye

Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.

Low sodium in your blood (hyponatremia). Symptoms of hyponatremia include: headache, feeling weak, feeling confused, trouble concentrating, memory problems and feeling unsteady when you walk.

Get medical help right away, if you have any of the

The most common side effects of trazodone hydrochloride

These are not all the possible side effects of trazodone hydrochloride tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at

How should I store trazodone hydrochloride tablets?

• Store trazodone hydrochloride tablets at room temperature between 68°F to 77°F (20° C to 25°C).

 Keep in tight container Keep out of the light

• Safely throw away medicine that is out of date or no longer needed

Keep trazodone hydrochloride tablets and all medicines out of the reach of children.

General information about the safe and effective use of trazodone hydrochloride tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use trazodone hydrochloride tablets for a condition for which it was not prescribed. Do not give trazodone hydrochloride tablets to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about trazodone hydrochloride tablets that is written for health professionals.

What are the ingredients in trazodone hydrochloride

Active ingredient: trazodone hydrochloride, USP

Inactive ingredients: colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, pregelatinized maize starch, sodium lauryl sulfate, and sodium starch glycolate. For more information, go to www.torrentpharma.com or call

Dispense with Medication Guide available at: https://torrentpharma.com/pi/usa/products/



and Drug Administration.

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