



HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
e-mail : contact@heterodrugs.com URL : http://www.heterodrugs.com

SAFETY DATA SHEET

Section 1: Identification	
Material	Quetiapine Fumarate Tablets USP, 25 mg, 50 mg, 100 mg, 200 mg, 300 mg and 400 mg
Recommended use	Pharmaceutical product
Manufacturer	Hetero Labs Limited Unit III 22-110, Part-II, IDA, Jeedimetla, Hyderabad-500 055, Telangana, India.
Distributor	Camber Pharmaceuticals, Inc. , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Fire and Explosion	Expected to be non-combustible.
Health	No Contraindication reported.
Environment	No information is available about the potential of this product to produce adverse environmental effects.
Section 3: Composition/Information on Ingredients	
Ingredients	Quetiapine Fumarate
CAS	111974-72-2
Section 4: First-Aid Measures	
Inhalation	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
Ingestion	If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention.
Skin Contact	Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.
Eye Contact	Flush eyes with plenty of water. Get medical attention.
Section 5: Fire-Fighting Measures	
Extinguishing Media	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for fire fighters.



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Section 6: Accidental Release Measures																									
Clean-up Methods	Collect and place it in a suitable, properly labeled container for recovery or disposal.																								
Personal Precautions:	Wear protective clothing and equipment consistent with the degree of hazard.																								
Environmental Precautions:	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.																								
Section 7: Handling and Storage																									
Handling:	No special control measures required for the normal handling of this product.																								
Storage:	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F)																								
Section 8: Exposure Controls/Personal Protection																									
Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.																									
Section 9: Physical and Chemical Properties																									
Physical Form	Tablet																								
Description	<p>Quetiapine fumarate tablets USP, 25 mg are peach colored, round shaped, biconvex, filmcoated tablets debossed with '44' on one side and 'I' on the other side. They are supplied as follows:</p> <table><tbody><tr><td>100s</td><td>31722-764-01</td></tr><tr><td>500s</td><td>31722-764-05</td></tr><tr><td>10x10's Alu</td><td>31722-764-32</td></tr><tr><td>15x10's PVC-PVdC</td><td>31722-764-34</td></tr></tbody></table> <p>Quetiapine fumarate tablets USP, 50 mg are white colored, round shaped, biconvex, filmcoated tablets debossed with '47' on one side and 'I' on the other side. They are supplied as follows:</p> <table><tbody><tr><td>100s</td><td>31722-765-01</td></tr><tr><td>500s</td><td>31722-765-05</td></tr><tr><td>10x10's Alu</td><td>31722-765-32</td></tr><tr><td>10x10's PVC-PVdC</td><td>31722-765-34</td></tr></tbody></table> <p>Quetiapine fumarate tablets USP, 100 mg are yellow colored, round shaped, biconvex, film-coated tablets debossed with '55' on one side and 'I' on the other side. They are supplied as follows:</p> <table><tbody><tr><td>100s</td><td>31722-766-01</td></tr><tr><td>500s</td><td>31722-766-05</td></tr><tr><td>10x10's Alu</td><td>31722-766-32</td></tr><tr><td>10x10's PVC-PVdC</td><td>31722-766-34</td></tr></tbody></table> <p>Quetiapine fumarate tablets USP, 200 mg are white colored, round shaped, biconvex, film-coated tablets debossed with '56'</p>	100s	31722-764-01	500s	31722-764-05	10x10's Alu	31722-764-32	15x10's PVC-PVdC	31722-764-34	100s	31722-765-01	500s	31722-765-05	10x10's Alu	31722-765-32	10x10's PVC-PVdC	31722-765-34	100s	31722-766-01	500s	31722-766-05	10x10's Alu	31722-766-32	10x10's PVC-PVdC	31722-766-34
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	on one side and 'I' on the other side. They are supplied as follows:
100s	31722-767-01
500s	31722-767-05
10x10's Alu	31722-767-32
10x10's PVC-PVdC	31722-767-34
	Quetiapine fumarate tablets USP, 300 mg are white colored, capsule shaped, biconvex, film-coated tablets debossed with '45' on one side and 'I' on the other side. They are supplied as follows:
60s	31722-768-60
100s	31722-768-01
500s	31722-768-05
10x10's Alu	31722-768-32
10x10's PVC-PVdC	31722-768-34
	Quetiapine fumarate tablets USP, 400 mg are yellow colored, capsule shaped, biconvex, film-coated tablets debossed with '57' on one side and 'I' on the other side. They are supplied as follows:
100s	31722-769-01
500s	31722-769-05
10x10's Alu	31722-769-32
10x10's PVC-PVdC	31722-769-34

Section 10: Stability and Reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Carcinogenesis:

Carcinogenicity studies were conducted in C57BL mice and Wistar rats. Quetiapine was administered in the diet to mice at doses of 20, 75, 250, and 750 mg/kg and to rats by gavage at doses of 25, 75, and 250 mg/kg for two years. These doses are equivalent to 0.1, 0.5, 1.5, and 4.5 times the maximum human dose (800 mg/day) on a mg/m² basis (mice) or 0.3, 0.9, and 3.0 times the maximum human dose on a mg/m² basis (rats). There were statistically significant increases in thyroid gland follicular adenomas in male mice at doses of 250 and 750 mg/kg or 1.5 and 4.5 times the maximum human dose on a mg/m² basis and in male rats at a dose of 250 mg/kg or 3.0 times the maximum human dose on a mg/m² basis. Mammary gland adenocarcinomas were statistically significantly increased in female rats at all doses tested (25, 75, and 250 mg/kg or 0.3, 0.9, and 3.0 times the maximum recommended human dose on a mg/m² basis).

Thyroid follicular cell adenomas may have resulted from chronic stimulation of the thyroid gland by thyroid stimulating hormone (TSH) resulting from enhanced metabolism and clearance of thyroxine by rodent liver. Changes in TSH, thyroxine, and thyroxine clearance consistent with this mechanism were observed in subchronic toxicity studies in rat and mouse and in a 1-year toxicity study in rat; however, the results of these studies were not definitive. The relevance of the increases in thyroid follicular cell adenomas to human risk, through whatever mechanism, is unknown.



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Antipsychotic drugs have been shown to chronically elevate prolactin levels in rodents. Serum measurements in a 1-year toxicity study showed that quetiapine increased median serum prolactin levels a maximum of 32- and 13-fold in male and female rats, respectively. Increases in mammary neoplasms have been found in rodents after chronic administration of other antipsychotic drugs and are considered to be prolactin-mediated. The relevance of this increased incidence of prolactin-mediated mammary gland tumors in rats to human risk is unknown.

Mutagenesis:

The mutagenic potential of quetiapine was tested in six in vitro bacterial gene mutation assays and in an in vitro mammalian gene mutation assay in Chinese Hamster Ovary cells. However, sufficiently high concentrations of quetiapine may not have been used for all tester strains. Quetiapine did produce a reproducible increase in mutations in one Salmonella typhimurium tester strain in the presence of metabolic activation. No evidence of clastogenic potential was obtained in an in vitro chromosomal aberration assay in cultured human lymphocytes or in the in vivo micronucleus assay in rats.

Impairment of Fertility

Quetiapine decreased mating and fertility in male Sprague-Dawley rats at oral doses of 50 and 150 mg/kg or 0.6 and 1.8 times the maximum human dose on a mg/m² basis. Drug-related effects included increases in interval to mate and in the number of matings required for successful impregnation. These effects continued to be observed at 150 mg/kg even after a two-week period without treatment. The no-effect dose for impaired mating and fertility in male rats was 25 mg/kg, or 0.3 times the maximum human dose on a mg/m² basis. Quetiapine adversely affected mating and fertility in female Sprague-Dawley rats at an oral dose of 50 mg/kg, or 0.6 times the maximum human dose on a mg/m² basis. Drug-related effects included decreases in matings and in matings resulting in pregnancy, and an increase in the interval to mate. An increase in irregular estrus cycles was observed at doses of 10 and 50 mg/kg, or 0.1 and 0.6 times the maximum human dose on a mg/m² basis. The no effect dose in female rats was 1 mg/kg, or 0.01 times the maximum human dose on a mg/m² basis.

Section 12: Ecological Information

No relevant studies identified

Section 13: Disposal Considerations

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

Section 14: Transport Information

IATA/ICAO - Not Regulated

IATA Proper shipping Name : N/A
IATA UN/ID No : N/A
IATA Hazard Class : N/A
IATA Packaging Group : N/A
IATA Label : N/A

IMDG - Not Regulated

IMDG Proper shipping Name : N/A
IMDG UN/ID No : N/A
IMDG Hazard Class : N/A
IMDG Flash Point : N/A
IMDG Label : N/A



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DOT - Not Regulated

DOT Proper shipping Name : N/A
DOT UN/ID No : N/A
DOT Hazard Class : N/A
DOT Flash Point : N/A
DOT Packing Group : N/A
DOT Label : N/A

Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

Issue Date : 02-07-2022

Version : 00

Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Hetero Labs Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Hetero Labs Limited reserves the right to revise this SDS.