

Safety Data Sheet

| SECTION 1. IDENTIFICATION | |
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| Common/Trade Name: Amitriptyline Hydrochloride Tablets USP | |
| Chemical Name: 10,11-Dihydro-N,N-dimethyl-5H-dibenzo[a, d] cycloheptene- Δ 5 , γ -propylamine hydrochloride | |
| Synonyms: Not Available | |
| Molecular Formula: C ₂₀ H ₂₃ N.HCl | |
| Molecular Weight: 313.90 | |
| CAS No: 549-18-8 | |
| Product Group: Antidepressant | |
| Manufacturer's Name | Unichem Laboratories Limited |
| Address | Unichem Laboratories Limited, Pilerne, Bardez, Goa, India. |
| Marketed by | Unichem Pharmaceuticals (USA), Inc. 1 Tower Center Blvd., Suite 2200 East Brunswick, NJ 08816 |
| Phone Number | (732) 253 5954 (Fax : (732) 325 0572) |
| Emergency Phone No. | 1-866-562-4616 |
| Recommended Use: Amitriptyline Hydrochloride is indicated for the relief of symptoms of depression. Endogenous depression is more likely to be alleviated than are other depressive states. | |
| Restriction on Use: Prescription Only. | |
| SECTION 2. HAZARD(s) IDENTIFICATION | |
| Emergency Overview | <p>Physical State:</p> <p>10 mg: Pink colored, round shaped, film-coated tablets, debossed with "60" on one side and "U" on the other side.</p> <p>25 mg: Yellow colored, round shaped, film-coated tablets, debossed with "420" on one side and "U" on the other side</p> <p>50 mg: Brown colored, round shaped, film-coated tablets, debossed with "421" on one side and "U" on the other side</p> <p>75 mg: Yellow colored, round shaped, film-coated tablets, debossed with "422" on one side and "U" on the other side</p> <p>100 mg: Orange colored, round shaped, film-coated tablets, debossed with "423" on one side and "U" on the other side</p> <p>150 mg: Green colored, Capsule shaped, film-coated tablets, debossed with "424" on one side and "U" on the other side</p> <p>Odor: No Data Available</p> <p>WARNING:</p> <ul style="list-style-type: none"> Clinical Worsening and Suicide Risk: Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressant medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been a long-standing concern, however, that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients during the early phases of treatment. |

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| | <p>All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. The following symptoms, anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania, have been reported in adult and pediatric patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and nonpsychiatric. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, there is concern that such symptoms may represent precursors to emerging suicidality.</p> <p>Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.</p> <p>Families and caregivers of patients being treated with antidepressants for major depressive disorder or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to health care providers. Such monitoring should include daily observation by families and caregivers.</p> <p>Prescriptions for amitriptyline hydrochloride tablets should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose</p> <ul style="list-style-type: none"> • Screening Patients for Bipolar Disorder: A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with an antidepressant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. Whether any of the symptoms described above represent such a conversion is unknown. However, prior to initiating treatment with an antidepressant, patients with depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. It should be noted that amitriptyline hydrochloride is not approved for use in treating bipolar depression. <p>Amitriptyline hydrochloride may block the antihypertensive action of guanethidine or similarly acting compounds.</p> <p>It should be used with caution in patients with a history of seizures and, because of its atropine-like action, in patients with a history of urinary retention or angle-closure glaucoma. In patients with angle closure glaucoma, even average doses may precipitate an attack.</p> <p>Patients with cardiovascular disorders should be watched closely. Tricyclic antidepressant drugs, including amitriptyline hydrochloride, particularly when given in high doses, have been reported to produce arrhythmias, sinus tachycardia, and prolongation of the conduction time. Myocardial infarction and stroke have been reported with drugs of this class.</p> <p>Close supervision is required when amitriptyline hydrochloride is given to hyperthyroid patients or those receiving thyroid medication.</p> <p>Amitriptyline hydrochloride may enhance the response to alcohol and the effects of barbiturates and other CNS depressants. In patients who may use alcohol excessively, it should be borne in mind that the potentiation may increase the danger inherent in any suicide attempt or overdosage. Delirium has been reported with concurrent administration of amitriptyline and disulfiram.</p> <ul style="list-style-type: none"> • Angle-Closure Glaucoma: The pupillary dilation that occurs following use of many |
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| | <p>antidepressant drugs including amitriptyline hydrochloride may trigger an angle closure attack in a patient with anatomically narrow angles who does not have a patent iridectomy.</p> <ul style="list-style-type: none"> <p>Usage in Pregnancy: Teratogenic effects were not observed in mice, rats, or rabbits when amitriptyline was given orally at doses of 2 to 40 mg/kg/day (up to 13 times the maximum recommended human dose¹). Studies in literature have shown amitriptyline to be teratogenic in mice and hamsters when given by various routes of administration at doses of 28 to 100 mg/kg/day (9 to 33 times the maximum recommended human dose), producing multiple malformations. Another study in the rat reported that an oral dose of 25 mg/kg/day (8 times the maximum recommended human dose) produced delays in ossification of fetal vertebral bodies without other signs of embryotoxicity. In rabbits, an oral dose of 60 mg/kg/day (20 times the maximum recommended human dose) was reported to cause incomplete ossification of cranial bones.</p> <p>Amitriptyline has been shown to cross the placenta. Although a causal relationship has not been established, there have been a few reports of adverse events, including CNS effects, limb deformities, or developmental delay, in infants whose mothers had taken amitriptyline during pregnancy.</p> <p>There are no adequate and well-controlled studies in pregnant women. Amitriptyline hydrochloride should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.</p> <p>¹Based on a maximum recommended amitriptyline dose of 150 mg/day or 3 mg/kg/day for a 50 kg patient.</p> <p>Nursing Mothers: Amitriptyline is excreted into breast milk. In one report in which a patient received amitriptyline 100 mg/day while nursing her infant, levels of 83 to 141 ng/mL were detected in the mother's serum. Levels of 135 to 151 ng/mL were found in the breast milk, but no trace of the drug could be detected in the infant's serum.</p> <p>Because of the potential for serious adverse reactions in nursing infants from amitriptyline, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.</p> <p>Usage in Pediatric Patients: In view of the lack of experience with the use of this drug in pediatric patients, it is not recommended at the present time for patients under 12 years of age.</p> | | | | |
| Primary Route(s) of Entry | Ingestion | | | | |
| Potential Health | <table border="1"> <tr> <td data-bbox="474 1199 636 1234">Eyes</td> <td data-bbox="636 1199 1471 1234">Not expected to be hazard to eyes in final pharmaceutical form.</td> </tr> <tr> <td data-bbox="474 1234 636 1270">Skin</td> <td data-bbox="636 1234 1471 1270">May cause an allergic skin reaction.</td> </tr> </table> | Eyes | Not expected to be hazard to eyes in final pharmaceutical form. | Skin | May cause an allergic skin reaction. |
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| Effects: | <table border="1"> <tr> <td data-bbox="474 1234 636 1289">Inhalation</td> <td data-bbox="636 1234 1471 1289">Not expected to be an inhalation hazard in the final pharmaceutical form</td> </tr> </table> | Inhalation | Not expected to be an inhalation hazard in the final pharmaceutical form | | |
| Inhalation | Not expected to be an inhalation hazard in the final pharmaceutical form | | | | |
| Toxicity Data: | Please see Patient Package Insert for further information | | | | |
| Effects of Over Exposure: | <p>See Section 11</p> <p>Deaths may occur from overdosage with this class of drugs. Multiple drug ingestion (including alcohol) is common in deliberate tricyclic antidepressant overdose. As the management is complex and changing, it is recommended that the physician contact a poison control center for current information on treatment. Signs and symptoms of toxicity develop rapidly after tricyclic antidepressant overdose, therefore, hospital monitoring is required as soon as possible.</p> <p>Critical manifestations of overdose include: cardiac dysrhythmias, severe hypotension, convulsions, and CNS depression, including coma. Changes in the electrocardiogram particularly in QRS axis or width, are clinically significant indicators of tricyclic antidepressant toxicity. In addition, a rightward axis shift in the terminal QRS complex together with a prolonged QT interval and sinus tachycardia are specific and sensitive indicators of first generation tricyclic overdose. The absence of these findings is not exclusionary. Prolonged PR interval, ST-T wave changes, ventricular tachycardia and fibrillation may also occur.</p> <p>Other signs of overdose may include: impaired myocardial contractility, confusion, disturbed concentration, transient visual hallucinations, dilated pupils, disorders of ocular motility, agitation, hyperactive reflexes polyradiculoneuropathy, stupor, drowsiness, muscle rigidity, vomiting, hypothermia, hyperpyrexia, or any of the symptoms listed under</p> | | | | |

| ADVERSE REACTIONS section of Patient Package Insert. | | | | |
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| SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS | | | | |
| Composition | | CAS # | Quantity | |
| Amitriptyline Hydrochloride (active ingredient) | | 549-18-8 | 10 mg, 25 mg, 50 mg, 75 mg, 100 mg and 150 mg | |
| Hazardous | | | | |
| Ingredient | CAS Number | EU EINECS/ELINCS List | EU Classification | % |
| Lactose Monohydrate | 10039-26-6 | Not listed | Not listed | * |
| Microcrystalline Cellulose | 9004-34-6 | 232-674-9 | Not listed | * |
| Croscarmellose Sodium | 74811-65-7 | Not listed | Not listed | * |
| Hydroxypropyl Cellulose | 9004-64-2 | 618-388-0 | Not listed | * |
| Isopropyl alcohol | 67-63-0 | 200-661-7 | Not listed | * |
| Magnesium Stearate | 557-04-0 | 209-150-03 | Not listed | * |
| HPMC 2910/Hypromellose | 9004-65-3 | Not listed | Not listed | * |
| Titanium Dioxide | 13463-67-7 | 236-675-5 | Not listed | * |
| Macrogol/PEG 400 | 25322-68-3 | 500-038-2 | Not listed | * |
| D&C Red #27/Phloxine Aluminum Lake | 15876-58-1 | 240-012-5 | Not listed | * |
| D&C Yellow #10 Aluminum Lake | 68814-04-0 | Not listed | Not listed | * |
| FD&C Blue #1/Brilliant Blue FCF Aluminum Lake | 68921-42-6 | 272-939-6 | Not listed | * |
| Iron Oxide Yellow | 51274-00-1 | 257-098-5 | Not listed | * |
| FD&C Red # 40/ Allura Red AC Aluminum Lake | 68583-95-9 | 271-524-7 | Not listed | * |
| FD& C Blue # 2/Indigo Carmine Aluminum Lake | 16521-38-3 | 240-589-3 | Not listed | * |
| D&C Red# 30/Helendon Pink Aluminum Lake | 2379-74-0 | 219-163-6 | Not listed | * |
| Ferrosoferric Oxide/ Black Iron Oxide | 1317-61-9 | 215-277-5 | Not listed | * |
| *Proprietary information | | | | |
| Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. | | | | |
| REFER to PHYSICIAN'S DESK REFERENCE for common components | | | | |
| Target Organs: | Brain | | | |
| SECTION 4. FIRST-AID MEASURES | | | | |
| Eye Contact | Rinse cautiously with water. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention. | | | |
| Skin Contact | Remove contaminated clothing. Wash off with soap and plenty of water. Obtain medical attention if irritation develops or persists. | | | |
| Ingestion | Do not induce vomiting. Rinse mouth. Immediately call a POISON CENTER or doctor/physician. | | | |
| Inhalation | Move to fresh air. Call a physician if symptoms develop or persist. | | | |
| Most important symptoms/effects, acute and delayed | For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information. | | | |
| Indication of immediate medical attention and special treatment needed | If you feel unwell, seek medical advice (show the label where possible) | | | |
| General information | The recommendations in this section are intended for manufacturing or other situations where exposure to contents may occur. | | | |
| SECTION 5. FIRE-FIGHTING MEASURES | | | | |
| Flammability | No data available | | | |
| Flash Point | No data available | | | |
| Extinguishing Media | Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry | | | |

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| | chemical or CO ₂ . | | | | |
| Special Fire Fighting Procedures | During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus. | | | | |
| Unusual Fire/Explosion Hazards | Not applicable | | | | |
| Hazardous Combustion Products | No data available | | | | |
| SECTION 6. ACCIDENTAL RELEASE MEASURES | | | | | |
| STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES ARE SPILLED: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment. Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. Clean surface thoroughly to remove residual contamination. | | | | | |
| SECTION 7. HANDLING AND STORAGE | | | | | |
| Precautions General Handling: | If tablets are broken/crushed, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). | | | | |
| Storage | 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], in a tight, light resistant container. | | | | |
| SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION | | | | | |
| Engineering Controls | Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. | | | | |
| Respiratory Protection | Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place. | | | | |
| Personal Protection | Eye/face Protection | Safety glasses with side shields recommended. If splash potential or dusty operations, wear goggles/face shield. | | | |
| | Skin Protection | Chemical resistant gloves. | | | |
| | General Hygiene Considerations | Engineering controls should be used as the primary means to control workplace exposures. Follow good workplace hygiene practices such as washing hands after handling this material. | | | |
| | Other | Chemical-resistant gloves and impermeable body covering to minimize skin contact. | | | |
| Recommended Facilities | Eye wash, washing facilities | | | | |
| SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES | | | | | |
| Appearance | Solid – film coated tablets | Melting point | 198 -200°C | Solubility in water | freely soluble in water and alcohol |
| Odor | N/A | Boiling point | N/A | Specific Gravity | N/A |
| Taste | N/A | Vapor Pressure | N/A | Flashpoint | N/A |
| pH | N/A | Density | N/A | Flammability Limits | N/A |
| SECTION 10. STABILITY AND REACTIVITY | | | | | |
| Stability | Stable under recommended handling and storage conditions (see section 7). | | | | |
| Incompatibility | Strong oxidizing agents | | | | |
| Hazardous Decomposition | Formation of toxic gases is possible during heating or in case of fire. | | | | |
| Conditions to Avoid | Heat | | | | |
| Hazardous Polymerization | Data not available | | | | |
| SECTION 11. TOXICOLOGICAL INFORMATION | | | | | |
| Oral toxicity (LD50): 240 mg/kg [Rat] | | | | | |
| Maximum Daily Dose (MDD), Oral | | | | | |
| Amitriptyline Hydrochloride: 300 mg | | | | | |
| Carcinogenicity, Mutagenesis, Impairment of Fertility: Data not available. | | | | | |
| Teratogenicity: Teratogenic effects were not observed in mice, rats, or rabbits when amitriptyline was given orally at doses of 2 to 40 mg/kg/day (up to 13 times the maximum recommended human dose ¹). Studies in literature have shown amitriptyline to be teratogenic in mice and hamsters when given by various routes of administration at doses of 28 to 100 mg/kg/day (9 to 33 times the maximum recommended human dose), producing multiple malformations. Another study in the rat reported that an oral dose of 25 mg/kg/day (8 times the maximum recommended human dose) produced delays in ossification of fetal vertebral bodies without other signs of embryotoxicity. In rabbits, an oral dose of 60 mg/kg/day (20 | | | | | |

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| <p>times the maximum recommended human dose) was reported to cause incomplete ossification of cranial bones. Amitriptyline has been shown to cross the placenta. Although a causal relationship has not been established, there have been a few reports of adverse events, including CNS effects, limb deformities, or developmental delay, in infants whose mothers had taken amitriptyline during pregnancy.</p> <p>There are no adequate and well-controlled studies in pregnant women. Amitriptyline hydrochloride should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.</p> <p>¹Based on a maximum recommended amitriptyline dose of 150 mg/day or 3 mg/kg/day for a 50 kg patient.</p> |
| SECTION 12. ECOLOGICAL INFORMATION |
| Slightly hazardous for water. Do not allow undiluted product to reach ground water, water course or sewage system Avoid release to the environment. |
| SECTION 13. DISPOSAL CONSIDERATIONS |
| Waste Disposal Method Dispose of contents and container according to local, regional, national, and international regulations |
| SECTION 14. TRANSPORT INFORMATION |
| The Material Safety Data Sheet (MSDS) should accompany all shipments for reference in the event of spillage or accidental release. Transportation and shipping of this product is not restricted. It has no known significant hazards requiring special packaging or labeling for air, maritime or ground transport purpose. |
| SECTION 15. REGULATORY INFORMATION |
| US FDA: Amitriptyline Hydrochloride Tablets USP are an approved prescription medication in USA. |
| SECTION 16. OTHER INFORMATION |
| <p>ABBREVIATIONS:</p> <p>CNS: Central Nervous System</p> <p>USP: United States Pharmacopoeia</p> <p>US FDA: United States Food & Drug Administration</p> <p>Prepared by: Unichem Laboratories Limited</p> |
| <p>References:</p> <ol style="list-style-type: none"> 1. Amitriptyline Hydrochloride Safety data sheet (SDS# VPCL/SDS/006/00) by Vasudha Pharma Chem Limited., India. 2. British Pharmacopoeia – Safety Data Sheet (Version no. 2), Revision: 07.06.2013 3. Amitriptyline Hydrochloride Tablets USP, Package Insert, Unichem Laboratories Limited, India. 4. EU EINECS/ELINCS List |
| Date: March 15, 2022 - Version: 001 |
| SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION |

Notice to Reader: To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.