

SAFETY DATA SHEET

Entacapone Tablets, USP 200 mg

EMERGENCY OVERVIEW

Entacapone Tablets, USP contain an active drug substance Entacapone USP and pharmaceutical excipients generally considered safe, non-toxic and non-hazardous. The quantities of the excipients used in the product are well within the IID (Inactive Ingredient Database) limits prescribed by USFDA for oral route.

WARNING: Accidental ingestion of large amounts may be harmful.

Section 1. Identification of the substance

Identification of the product

Product name	: Entacapone Tablets, USP
Potencies	: 200 mg
Chemical Name	: (E)-2-cyano-3-(3,4-dihydroxy-5-nitrophenyl)-N,N-diethyl-2-propenamide.
Therapeutic Category	: catechol- <i>O</i> -methyltransferase (COMT) inhibitor.
Product Use	: Treatment of Parkinson's disease as an adjunct to levodopa and carbidopa therapy
Marketed by	: Ajanta Pharma USA Inc. Bridgewater, NJ 08807. Made in India
Contact Information	: 855-664-7744

Section 2. Health hazards information

Potential Health Effects	: Inhalation: Not expected to be hazardous in final pharmaceutical form. Eye Contact: Not expected to be hazardous in final pharmaceutical form. Skin Contact: Not expected to be hazardous in final pharmaceutical form.
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Ingestion: Health injuries are not known or expected under normal use. Exposures above clinical dosage could result in adverse effects. Minor occupational exposures are not expected to be harmful.

Effects of Overexposure : The potential for exposure is reduced in finished pharmaceutical form.

Section 3. Composition / information on ingredients
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Components Active ingredient	Exposure Limit	CAS No.
Entacapone USP	Not available.	1185241-19-3

Inactive ingredients: Each tablet contains inactive ingredients includes microcrystalline cellulose, sodium starch glycolate, hypromellose, polyoxyl 40 hydrogenated castor oil, purified water, magnesium stearate, polyethylene glycols, ferric oxide red, ferric oxide yellow and titanium dioxide.

Section 4. First aid measures

This product in the final dosage form (tablets) does not pose a problem of exposure to active moieties, and does not cause inhalation, skin and eye irritation problem.

- Eye Contact** : Immediately flush eyes with water for at least 15 minutes. Get medical attention.
- Skin Contact** : Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.
- Ingestion** : Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. DO NOT induce vomiting unless directed to do so by medical personnel.
- Inhalation** : Remove to fresh air. If not breathing, give artificial respiration or oxygen by trained personnel. Get immediate medical attention immediately.
- Medical Treatment** : Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient’s airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient’s vital signs, blood gases, serum electrolytes, etc.
- Over dosage** : The post-marketing data includes isolated cases of overdose in which the reported highest daily dose of

entacapone has been 16,000 mg. The acute symptoms and signs in these cases of overdose included confusion, decreased activity, somnolence, hypotonia, skin discoloration and urticaria.

Section 5. Fire-fighting measures

- Flash Point** : Not available.
- Extinguishing Media** : Use alcohol resistant foam, carbon dioxide, water, or dry chemical spray.
- General Fire Hazards/
Hazardous Combustible
Products** : Hydrogen cyanide. Carbon oxides. Nitrogen oxides (NOx).
- Special Fire Fighting
Procedures** : Wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

Section 6. Accidental release measures

- Personal Precautions** : Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
- Environmental Protections** : Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
- Clean-up Methods** : Wipe up with a damp cloth and place in container for disposal. Avoid generating airborne dust. Clean spill area thoroughly. Prevent discharge to drains.
- Additional Consideration for
Large Spills** : Vacuum or sweep material into appropriate container for disposal. Avoid generating airborne dust. Close container and move it to a secure holding area. Prevent discharge to drains.

Section 7. Handling and storage

- Handling** : No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product. If tablets are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin and

clothing. Use adequate ventilation. Minimize dust generation and accumulation.

Storage : Store at 25°C (77° F); excursions permitted to 15°C to 30° C (59° F to 86°F). [See USP Controlled Room Temperature.]

Section 8. Exposure controls/personal protection

Exposure Limits : Not available.

Engineering Controls : For consumer use, no unusual precaution are necessary for handling packets. In laboratory, medical or industrial setting use appropriate ventilation.

Respiratory Protection : For consumer use, no unusual precaution are necessary. However, for handling packets, in laboratory, medical or industrial setting use NIOSH/MSHA approved respirators for protection if necessary.

Personal Protection : For consumer use, no unusual precaution are necessary. However, for handling packets in laboratory, medical or industrial setting use gloves as recommended.

Recommended Facilities : None

Section 9. Physical and chemical properties

Appearance : **Entacapone Tablets, USP 200 mg:**
The oval-shaped tablets are light brown colored, biconvex film-coated tablets with 'EN1' engraved on one side and plain on other side. Supplied as pack of 100 tablets in HDPE bottle (NDC 27241-049-10).

Other Information : The molecular formula is $C_{14}H_{15}N_3O_5$, representing a molecular weight of 305.29. Entacapone, USP is a greenish-yellow to yellow powder. Practically insoluble in water.

Section 10. Stability and reactivity

- Stability** : Stable
- Incompatibility** : Incompatible with oxidizing agents.
- Hazardous Decomposition** : Hydrogen cyanide. Carbon oxides. Nitrogen oxides (NO_x).
- Conditions to Avoid** : Heat, flames and sparks. Extremes of temperature and direct sunlight.

Section 11. Toxicological information

- Acute toxicity** : The toxicological effect of this product have not been thoroughly studied. Entacapone – Toxicity Data: Oral TDLO (rat): 10 mg/kg; Oral TDLO (rat): 140 mg/kg/7D (intermittent);
- Carcinogenesis** : None of the components of this product are suspected to be a carcinogen.
- Mutagenesis** : When processed and used as directed, this product is not expected to produce mutagenic effects in humans.
- Impairment of Fertility** : In studies of reproduction toxicity, decreased foetal weight and a slightly delayed bone development were noticed in rabbits at systemic exposure levels in the therapeutic range.

Section 12. Ecological information

- Eco toxicity of drug substance** : Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.
- In the finished product form** : There is no potential for air borne contamination since the drug substance is in consolidated form as compressed tablet.

Section 13. Disposal Consideration

Waste Disposal Considerations: Dispose the material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended. At home: If pharmacy service available, return unused Tablets to pharmacy for disposal. Discard away from children's reach.

Section 14. Transport information

This product is not subject to the regulations for the safe transport of hazardous chemicals

DOT: Not regulated for transport of dangerous goods.

IATA: Not regulated for transport of dangerous goods

IMDG: Not regulated for transport of dangerous goods

Section 15. Regulatory information

DEA: Not Available.

FDA: Entacapone tablets, USP is an approved prescription medication.

Section 16. Disclaimer

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. 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.

Ajanta shall not be held liable for any damage resulting from handling or from contact with the above product.

Date: April 01, 2022

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION
