SAFETY DATA SHEET

Fenofibrate Tablets, USP 54 mg and 160 mg

EMERGENCY OVERVIEW

Fenofibrate Tablets contain an active drug substance Fenofibrate 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	**:**	Fenofibrate Tablets, USP
Potencies	**:**	54 mg and 160 mg
Chemical Name	**:**	2-[4-(4-chlorobenzoyl) phenoxy]-2-methyl-propanoic acid, 1-methylethyl ester.
Therapeutic Category	**:**	Anticholesteremic
Product Use	**:**	To reduce elevated LDL-C, Total-C, TG and Apo B, and to increase HDL-C in adult patients with primary hypercholesterolemia or mixed dyslipidemia. For treatment of adult patients with severe hypertriglyceridemia
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.

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 dosage form.

Section 3. Composition / information on ingredients

Components Active ingredient	Exposure Limit	CAS No.
Fenofibrate USP	Not available.	49562-28-9

Inactive ingredients: Each tablet contains multiple functional inactive ingredients such as colloidal silicon dioxide, croscarmellose sodium, crospovidone, iron oxide yellow, lactose monohydrate, lecithin, microcrystalline cellulose, polyvinyl alcohol, povidone, sodium lauryl sulfate, sodium starch glycolate, sodium stearyl fumarate, talc, titanium dioxide, xanthan gum, and D&C yellow #10 lake.

Section 4. First aid measures

The product is a film coated tablet and in the final dosage form (Tablets) does not pose a problem of exposure to active drug substance and should not cause inhalation, skin and eye irritation problem. However, in case of exposure:

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 : There is no specific treatment for overdose with fenofibrate. General supportive care of the patient is indicated, including monitoring of vital signs and observation of clinical status, should an overdose occur. If indicated, elimination of unabsorbed drug should be achieved by emesis or gastric lavage; usual precautions

should be observed to maintain the airway. Because fenofibrate is highly bound to plasma proteins, hemodialysis should not be considered.

Section 5. Fire-fighting measures

Flash Point	:	Not available.
Extinguishing Media	:	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
General Fire Hazards/ Hazardous Combustible Products	:	Hazardous combustion or decomposition products are expected when the product is exposed to fire.
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	:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

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]. Protect from moisture.

Section 8. Exposure controls/personal protection

Exposure Limits	**:**	0.5mg/m^3 TWA
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	**:**	Fenofibrate tablets, USP are available in two strengths: 54 mg - Light yellow to yellow colored, round-shaped, film-coated tablets debossed "FN1" on one side and plain on other side. Available in bottles of 90 (NDC 27241-116-03) and bottles of 500 (NDC 27241-116-05). 160 mg - White to off-white colored, oval-shaped, film-coated tablets debossed "FN2" on one side and plain on other side. Available in bottles of 90 (NDC 27241-117-03) and bottles of 500 (NDC 27241-117-05).
Other Information	**:**	Fenofibrate, USP is insoluble in water. The melting point is 79°C to 82°C. Fenofibrate, USP is a white powder which is stable under ordinary conditions.

Section 10. Stability and reactivity

Stability	**:**	Stable
Incompatibility	**:**	Strong oxidizing agents.
Hazardous Decomposition	**:**	carbon dioxide
Conditions to Avoid	**:**	Data not available.

Section 11. Toxicological information

Acute toxicity	**:**	Oral LD50 = 1600 mg/kg (Rats) >5000 mg/kg (Mice Dogs Hamsters)
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	**:**	Based on available data, the classification criteria are not met.

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 tablets.

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: Fenofibrate 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: Nov 17, 2021

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