Safety Data Sheet
Mesalamine Delayed-release Tablets

Strength: 1.2 g **Pack Size:** NDC 68382-711-64 in bottles of 34 tablets **Revision No.:** 00
NDC 68382-711-19 in bottles of 120 tablets

EMERGENCY OVERVIEW

Each Mesalamine Delayed-release Tablets intended for oral administration contains Mesalamine and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

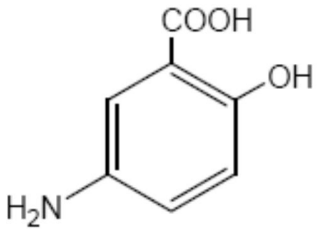
Section 1. Identification

Identification of the product

Product Name: Mesalamine Delayed-release Tablets

Formula: $C_7H_7NO_3$

Chemical Name: 5-amino-2-hydroxybenzoic acid



Manufacturer / supplier identification

Company: Cadila Healthcare Ltd. Ahmedabad, India

Address: Sarkhej – Bavla. N.H. 8A, Moraiya. Tal. Sanand.
Dist. Ahmedabad – 382210. State: Gujarat. India

Contact for information: Tel.: +91 79 6868100 Fax: +91 79 3750319

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Recommended use / Therapeutic Category Topical anti-inflammatory effect

Restriction on Use / Contraindications: Mesalamine delayed-release tablets are contraindicated in patients with known hypersensitivity to salicylates or aminosalicylates or to any of the ingredients of mesalamine delayed-release tablets.

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Section 2. Hazard(s) Identification

Dose and Administration

Mesalamine Delayed-release Tablets 1.2 g are pale red-brown, oval-shaped, biconvex, bevel film-coated tablets debossed with the '711' on one side and plain on other side – each containing 1.2 g Mesalamine.

The recommended dosage for the induction of remission in adult patients with active, mild to moderate ulcerative colitis is two to four 1.2 g tablets taken once daily with a meal for a total daily dose of 2.4 g or 4.8 g. The recommended dosage for the maintenance of remission is two 1.2 g tablets taken once daily with a meal for a total daily dose of 2.4 g.

Adverse Effects

The following reactions have been reported during treatment with mesalamine.

Renal Impairment

Renal impairment, including minimal change nephropathy, acute and chronic interstitial nephritis and rarely renal failure has been reported in patients given products such as mesalamine delayed-release tablets that contain mesalamine or are converted to mesalamine.

It is recommended that patients have an evaluation of renal function prior to initiation of mesalamine delayed-release tablets therapy and periodically while on therapy. Exercise caution when using mesalamine delayed-release tablets in patients with known renal dysfunction or a history of renal disease.

In animal studies, the kidney was the principal organ for toxicity

Mesalamine-Induced Acute Intolerance Syndrome

Mesalamine has been associated with an acute intolerance syndrome that may be difficult to distinguish from an exacerbation of ulcerative colitis. Although the exact frequency of occurrence has not been determined, it has occurred in 3% of patients in controlled clinical trials of mesalamine or sulfasalazine. Symptoms include cramping, acute abdominal pain and bloody diarrhea, and sometimes fever, headache and rash. Observe patients closely for worsening of these symptoms while on treatment. If acute intolerance syndrome is suspected, promptly discontinue treatment with mesalamine delayed-release tablets.

Hypersensitivity Reactions

Some patients who have experienced a hypersensitivity reaction to sulfasalazine may have a similar reaction to mesalamine delayed-release tablets or to other compounds that contain or are converted to mesalamine.

Mesalamine-induced cardiac hypersensitivity reactions (myocarditis and pericarditis) have been reported with mesalamine delayed-release tablets and other mesalamine medications. Caution should be taken in prescribing this medicine to patients with conditions predisposing them to the development of myocarditis or pericarditis.

Hepatic Impairment

There have been reports of hepatic failure in patients with preexisting liver disease who have been administered mesalamine. Caution should be exercised when administering mesalamine delayed-release tablets to patients with liver disease.

Upper GI Tract Obstruction

Pyloric stenosis or other organic or functional obstruction in the upper gastrointestinal tract may cause prolonged gastric retention of mesalamine delayed-release tablets which would delay mesalamine release in the colon.

Interference with Laboratory Tests

Use of mesalamine may lead to spuriously elevated test results when measuring urinary normetanephrine by liquid chromatography with electrochemical detection because of the similarity in the chromatograms of normetanephrine and mesalamine's main metabolite, N-acetylaminosalicylic acid (N-Ac-5-ASA). An alternative, selective assay for normetanephrine should be considered.

Over Dose Effect

Mesalamine is an aminosalicylate, and symptoms of salicylate toxicity may include tinnitus, vertigo, headache, confusion, drowsiness, sweating, seizures, hyperventilation, dyspnea, vomiting, and diarrhea. Severe intoxication may lead to disruption of electrolyte balance and blood-pH, hyperthermia, dehydration, and end organ damage.

There is no specific known antidote for mesalamine overdose; however, conventional therapy for salicylate toxicity may be beneficial in the event of acute over dosage. Fluid and electrolyte imbalance should be corrected by the administration of appropriate intravenous therapy. Adequate renal function should be maintained.

Contraindications

Mesalamine delayed-release tablets are contraindicated in patients with known hypersensitivity to salicylates or aminosalicylates or to any of the ingredients of mesalamine delayed-release tablets.

Renal impairment may occur. Assess renal function at the beginning of treatment and periodically during treatment.

	Mesalamine-induced acute intolerance syndrome has been reported. Observe patients closely for worsening of these symptoms while on treatment. Use caution when treating patients who are hypersensitive to sulfasalazine. Mesalamine-induced cardiac hypersensitivity reactions (myocarditis and pericarditis) have been reported. Hepatic failure has been reported in patients with pre-existing liver disease. Use caution when treating patients with liver disease. Upper GI tract obstruction may delay onset of action. Use of mesalamine may lead to spuriously elevated test results when measuring urinary normetanephrine by liquid chromatography with electrochemical detection.
Pregnancy Comments	**Pregnancy Category B** Reproduction studies with mesalamine have been performed in rats at doses up to 1000 mg/kg/day (1.8 times the maximum recommended human dose based on a body surface area comparison) and rabbits at doses up to 800 mg/kg/day (2.9 times the maximum recommended human dose based on a body surface area comparison) and have revealed no evidence of impaired fertility or harm to the fetus due to mesalamine. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Mesalamine is known to cross the placental barrier.

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component:		
Mesalamine	Not Found	89-57-6
Inactive Ingredients:		
Carboxymethylcellulose sodium	Not Found	9004-32-4

Colloidal silicon dioxide	Not Found	7631-86-9
Hypromellose	Not Found	9004-65-3
Iron oxide yellow	Not Found	51274-00-1
Iron oxide red	Not Found	1309-37-1
Magnesium stearate	Not Found	557-04-0
Methacrylic acid copolymer	Not Found	79-41-4
Microcrystalline cellulose	Not Found	9004-34-6
Polyethylene glycol	Not Found	25322-68-3
Sodium starch glycolate	Not Found	9063-38-1
Triethyl citrate	Not Found	77-93-0
Talc	Not Found	14807-96-6
Titanium dioxide	Not Found	13463-67-7

Section 4. First -aid measures

General

Inhalation:
Allow the victim to rest in a well-ventilated area. Seek immediate medical attention.

Skin contact:
No known effect on skin contact, rinse with water for a few minutes.

Eye contact:
No known effect on eye contact, rinse with water for a few minutes.

	Ingestion: Do not induce vomiting. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention.
Overdose Treatment	Mesalamine is an aminosalicylate, and symptoms of salicylate toxicity may include tinnitus, vertigo, headache, confusion, drowsiness, sweating, seizures, hyperventilation, dyspnea, vomiting, and diarrhea. Severe intoxication may lead to disruption of electrolyte balance and blood-pH, hyperthermia, dehydration, and end organ damage. There is no specific antidote known for the treatment of mesalamine overdose. Conventional therapy for salicylate toxicity might prove to be beneficial in the event of acute overdosage. Fluid and electrolyte imbalance should be corrected by the administration of appropriate intravenous therapy. Adequate renal function should be maintained.

Section 5. Fire -fighting measures

Flash point	Not Found	**Upper Flammable Limit:** Not Found	
Auto-Ignition Temperature	Not Found	**Lower Flammable Limit:** Not Found	

Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted

Section 6. Accidental Release Measures

Spill Response	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.

Section 7. Handling and Storage

Storage:	Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Dispense in a tight, light-resistant container.
	Precautions for safe handling Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. If ingested, seek medical advice immediately and show the container or the label.

Section 8. Exposure controls / personal protection

Engineering Controls	Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.
Personal Protection	Safety glasses. Lab coat.
Eye/face protection	If contact is likely, safety glasses with side shields are recommended.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.
Personal Protection in Case of a Large Spill	Splash goggles. Full suit. Boots. Gloves. Suggested protective clothing might not be sufficient; consult a specialist before handling this product.
Exposure Limit	Data not available

Section 9. Physical and chemical properties

Appearance	Mesalamine Delayed-release Tablets, 1.2 g are pale red-brown, oval-shaped, biconvex, bevel film-coated tablets debossed with the '711' on one side and plain on other side.		
Solubility	Not available	**Odor**	Odorless or may have a slight characteristic odor.
Boiling point	Not available.	**Melting Point**	Not available.
Evaporation rate	Not available.	**Vapour density**	Not available.
Reactivity in water	Not available.	**Vapour pressure**	Not available.
% Volatile by volume	Not available.	**Specific gravity**	Not available.
Other information	Mesalamine is a light tan to pink colored, needle-shaped crystals. Color may darken on exposure to air. It is odorless or may have a slight characteristic odor.		

Section 10. Stability and Reactivity

Conditions to avoid	Contact with incompatible materials.
Stable	Not available.
Hazardous reactions	Not available.
Decomposition products	Not available.
Incompatible materials	Not available.

Section 11. Toxicological information

General	Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.
Toxicity to Animals	Acute oral toxicity (LD50): 2800 mg/kg [Rat]

Chronic Effects on Humans	The substance is toxic to blood, liver, gastrointestinal tract, upper respiratory tract, skin, central nervous system (CNS).
Other Toxic Effects on Humans	No specific information is available in our database regarding the Other toxic effects of this material for humans.

Section 12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil.

Section 13. Disposal Consideration

Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

Section 15. Regulatory Information

Generic Medicine. ANDA Number is 091640

Section 16. Other information

None

Date of issue: 08/06/2017 **Supersedes edition:** New Edition