

SAFETY DATA SHEET



1. Identification

Product identifier

Montelukast Sodium Chewable Tablets

Other means of identification

Montelukast Sodium 5-mg Chewable Tablets are pink, capsule-shaped tablets, debossed with "5" on one side and plain on the other.

Montelukast Sodium 4-mg Chewable Tablets are pink, square-shaped tablets, debossed with "4" on one side and plain on the other.

Indication and Usage

- Prophylaxis and chronic treatment of asthma in patients 2 years of age and older.
- Acute prevention of exercise-induced bronchoconstriction (EIB) in patients 6 years of age and older.
- Relief of symptoms of allergic rhinitis (AR): seasonal allergic rhinitis (SAR) in patients 2 years of age and older, and perennial allergic rhinitis (PAR) in patients 2 years of age and older.

Recommended restrictions

None known.

Manufacturer /Distributor information

Manufactured by

Hangzhou Minsheng Binjiang Pharma.

Address

658 Bin'an Rd., Hangzhou, Zhejiang, P.R. China 310951

Distributed by

Slate Run Pharmaceuticals, LLC.
Columbus, Ohio 43215

2. Hazard(s) identification

Physical hazards

Not classified.

Health hazards

Not classified.

OSHA defined hazards

Not classified.

Label elements

Hazard symbol

None.

Hazard statement

Keep this and all drugs out of the reach of children.

Precautionary statement

Prevention

Observe good industrial hygiene practices.

Response

Wash hands after handling.

Storage

Store at 25°C (77°F), excursions permitted to 15 to 30 °C (59 - 86 °F). [See USP Controlled Room Temperature].
Protect from moisture and light. Store in original package.

Disposal

Incineration of waste at an approved USEPA incinerator is recommended.

Hazard(s) not otherwise classified (HNOC)

None known.

3. Composition/information on ingredients

Substances

Chemical name	Common name and synonyms	CAS number
MONTELUKAST SODIUM		151767-02-1

4. First-aid measures

Inhalation

If dust from the material is inhaled, remove the affected person immediately to fresh air. Call a physician if symptoms develop or persist.

Skin contact

Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact

Rinse with water. Get medical attention if irritation develops and persists.

Ingestion

Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed
Indication of immediate medical attention and special treatment needed
General information

Most common side effects are behavior and mood-related changes including agitation including aggressive behavior or hostility, attention problems, bad or vivid dreams, depression, disorientation, feeling anxious, hallucinations, irritability, memory problems, restlessness, sleep walking, suicidal thoughts and actions, tremor, trouble sleeping, and uncontrolled muscle movement, increase in certain white blood cells and possible inflamed blood vessels throughout the body. Most common side effects include: upper respiratory infection, fever, headache, sore throat, cough, stomach pain, diarrhea, earache or ear infection, flu, runny nose, and sinus infection. For more side effects possibly related to Montelukast Sodium Chewable Tablets, please refer to the package insert of the drug.

Tell your healthcare provider right away if you get one or more of these symptoms including a feeling of pins and needles or numbness of arms or legs, a flu-like illness, rash, and severe inflammation (pain and swelling) of the sinuses (sinusitis).

No specific antidotes are recommended. Provide general supportive measures and treat symptomatically.

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

Unsuitable extinguishing media

Do not use water jet as an extinguisher, as this will spread the fire.

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

Use water spray to cool unopened containers.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards

No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment (See Section 8).

Methods and materials for containment and cleaning up

Sweep up and place into a proper container for disposal. Minimize dust generation and accumulation. Collect dust using a vacuum cleaner equipped with HEPA filter. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Avoid contact with eyes, skin, and clothing. Avoid breathing dust. Wash hands thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Store at 25°C (77°F), excursions permitted to 15 to 30 °C (59 - 86 °F). [See USP Controlled Room Temperature].
Protect from moisture and light. Store in original package.

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Dust	PEL	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value	Form
Dust	TWA	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Dust	TWA	3 mg/m ³	Respirable particles.
		10 mg/m ³	Inhalable particles.

Biological limit values No biological exposure limits noted for the ingredient(s).

Individual protection measures, such as personal protective equipment

Eye/face protection None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

Skin protection

Hand protection

For consumer use, no unusual precautions are necessary.

Other

None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

Respiratory protection

None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state

Solid.

Form

Chewable Tablet.

Color

Pink.

Odor

Not available.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

Not available.

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Freely Soluble

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

decomposition temperature Not available.

Viscosity Not available.

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Inhalation of dusts may cause respiratory irritation.

Skin contact Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust may irritate skin.

Eye contact Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust may irritate the eyes.

Ingestion Ingestion may cause irritation and malaise.

Symptoms related to the physical, chemical and toxicological characteristics Most common side effects are upper respiratory infection, fever, headache, pharyngitis, cough, abdominal pain, diarrhea, otitis media, influenza, rhinorrhea, sinusitis, otitis.

Information on toxicological effects

Acute toxicity	May be harmful if swallowed in large quantities.
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.
Respiratory or skin sensitization	
Respiratory sensitization	Not a respiratory sensitizer.
Skin sensitization	This product is not expected to cause skin sensitization.
Germ cell mutagenicity	Not expected to be mutagenic.
Carcinogenicity	This product is not considered to be a carcinogen by NTP, IARC, or OSHA.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	
Not listed.	
Reproductive toxicity	Because there are no adequate and well-controlled studies in pregnant women, this drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
	Pregnancy Category B
	It is not known whether this product is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when administering to a nursing woman
Specific target organ toxicity - single exposure	Not classified.
Specific target organ toxicity - repeated exposure	Not classified.
Aspiration hazard	Due to the physical form of the product it is not an aspiration hazard.
Further information	See package insert.

12. Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available.
Mobility in soil	Product components are soluble in water and will slowly dissolve and disperse.
Other adverse effects	Refer to package insert.

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable for now.

15. Regulatory information

US federal regulations

This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

Over-the-counter drugs in their solid final form (i.e. tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**Hazard categories**

Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

Not listed.

US state regulations**US. Massachusetts RTK - Substance List**

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No

New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	28-May-2018
Revision date	-
Version #	01
References	1) Montelukast Sodium Chewable Tablets package insert, Anbison Lab. Co., Ltd. 2) Montelukast Sodium Chewable Tablets label, Anbison Lab. Co., Ltd. 3) Montelukast Sodium Chewable Tablets patient information, Anbison Lab. Co., Ltd.
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