ajanta pharma limited

SAFETY DATA SHEET

Omeprazole and Sodium Bicarbonate for Oral Suspension

20 mg/1,680 mg and 40 mg/1,680 mg

EMERGENCY OVERVIEW

OMEPRAZOLE AND SODIUM BICARBONATE FOR ORAL SUSPENSION contain an active drug substance omeprazole, sodium bicarbonate 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	**:**	Omeprazole and Sodium Bicarbonate for Oral Suspension
Potencies	**:**	20 mg /1,680 mg and 40 mg 1,680 mg
Chemical Name	**:**	Omeprazole: 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl) methyl] sulfinyl]-1*H*-benzimidazole. Sodium Bicarbonate: $NaHCo_3$
Therapeutic Category	**:**	Proton Pump Inhibitor
Product Use	**:**	Short-term treatment of active duodenal ulcer; Short-term treatment of active benign gastric ulcer; Treatment of Gastroesophageal reflux disease (GERD) ; Maintenance of healing of erosive esophagitis; Reduction of risk of upper Gl bleeding in critically ill patients.
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. During manufacturing process dust may generate which may cause respiratory irritation.

Eye Contact: Not expected to be hazardous in final pharmaceutical form. During manufacturing process dust may generate which may cause eye irritation. Prolonged eye exposure may include redness, pain, and tearing.

Skin Contact: Not expected to be hazardous in final pharmaceutical form. During manufacturing process dust may generate which may cause skin irritation. Prolonged skin contact can result in dermatitis.

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	Exposure Limit	CAS No.
Active ingredient		
Omeprazole	Not Available	73590-58-6
Sodium Bicarbonate	Not Available	144-55-8
Inactive ingredients		
Xylitol	10 mg/m^3	87-99-00
Sucralose	10 $mg/111^3$	56038-1
Xanthan gum	15 mg/m^3	11138-66-2
Colloidal silicon dioxide	2 mg/m^3	7631-86-9
Flavorings	--	Not assigned

Section 4. First aid measures

This product in the final dosage form (Powder for Oral suspension) does not pose a problem of exposure to active moieties, and does not cause inhalation, skin and eye irritation problem. The lose powder exposure hazards are during the manufacturing process.

Inhalation : If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms persist.

Skin Contact : Rinse skin with water. Remove exposed or contaminated clothing, taking care not to contaminate eyes. Get medical attention if initiation develops and persists.

Eye Contact	:	If the powder enters the eyes, wash victim's eyes under gently running water. Use sufficient force to keep eyelids open, have victim "roll" eyes and flush for at least 15 minutes. Get medical attention if irritation develop and persists.
Ingestion	:	If large quantities of this product are swallowed, call physician or poison control centre for most current information. Do not induce vomiting, unless directed by medical personnel. Have victim rinse mouth with water, if conscious. Never induce vomiting or give a diluent (e.g., water) to someone who is unconscious, having convulsions, or unable to swallow. If contaminated individual is convulsing, maintain an open airway and obtain immediate medical attention.
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	:	Manifestations were variable, but included confusion, drowsiness, blurred vision, tachycardia, nausea, vomiting, diaphoresis, flushing, headache, dry mouth, and other adverse reactions similar to those seen in normal clinical experience. Symptoms were transient, and no serious clinical outcome has been reported when omeprazole was taken alone. No specific antidote for omeprazole overdosage is known. Omeprazole is extensively protein bound and is, therefore, not readily dialyzable. In the event of overdosage, treatment should be symptomatic and supportive.

Section 5. Fire-fighting measures

Flash Point	:	Not Available
Extinguishing Media	:	Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.
Special Fire Fighting Procedures	:	For single units (packages): No special requirements needed. For larger amounts (multiple packages) of product: Incipient fire responders should wear eye protection. Structural firefighters must wear self-contained breathing apparatus and full protective equipment. Move containers from fire area if it can be done without risk to personnel. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive area.
General Fire Hazards/Hazardous Combustible Products	:	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

Section 6. Accidental release measures

Personal Precautions : For consumer use, no unusual precautions are necessary. In laboratory, medical or industrial setting wear protective clothing and equipment such as shoe covering, hood and head coverings may be necessary.

Environmental Precautions : For large spills, take precautions to prevent entry into waterways sewers, or surface drainage systems.

Clean-up Methods : Collect and place it in a suitable, properly labeled container for recovery or disposal.

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.

Storage : Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Keep this medication out of the hands of children. Keep container tightly closed. Protect from light and moisture.

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 goggles, lab coat and gloves as recommended.

Recommended Facilities : Eye wash, washing facilities

General hygiene considerations : Handle in accordance with good hygiene and safety practice.

Section 9. Physical and chemical properties

Appearance : **Omeprazole and Sodium Bicarbonate for Oral Suspension 20 mg/1,680 mg:** Each packet contains white to off-white flavoured powder of 20 mg omeprazole USP, 1680 mg sodium bicarbonate USP and other excipient and supplied as 30 packets carton (NDC 27241-029-31).

Omeprazole and Sodium Bicarbonate for Oral Suspension 40 mg/1,680 mg: Each packet contains white to off-white, flavoured powder of 40 mg omeprazole USP, 1680 mg sodium bicarbonate USP and other excipient and are supplied as 30 packets cai1on (NDC 27241-030-31).

Other Information : **Omeprazole** is a white to off-white crystalline powder which melts with decomposition at about 155°C. It is a weak base, freely soluble in ethanol and methanol, and slightly soluble in acetone and isopropanol and very slightly soluble in water. The stability of omeprazole is a function of pH; it is rapidly degraded in acid media, but has acceptable stability under alkaline conditions.

Section 10. Stability and reactivity

Stability : Stable

Incompatibility : Omeprazole and sodium bicarbonate for oral suspension is not compatible with strong bases, strong acids, and powerful oxidizers.

Hazardous Decomposition : Thermal decomposition of this product can generate particulates, irritating fumes, and toxic gases (e.g., Carbon monoxide and Carbon dioxide).

Conditions to Avoid : Avoid contact with incompatible chemicals.

Section 11. Toxicological information

Acute toxicity : Single oral doses of Omeprazole at 1350, 1339, and 1200 mg/kg were lethal to mice, rats, and dogs respectively

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 : When used as directed, this product is not expected to cause reproductive toxicity in humans.

Section 12. Ecological information

Eco toxicity of drug substance: The drug substance in powder for oral suspension dosage form is not expected to present significant adverse environmental effects.
In the finished product form: There is no potential for air borne contamination since the drug substance is consolidated and contended inside a sealed packet.

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: 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 transpo1t of dangerous goods

Section 15. Regulatory information

DEA: None of the ingredient are regulated by DEA.
FDA: Omeprazole and Sodium Bicarbonate for oral suspension 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 infomiation and the suitability of the material or product for any paiticular purpose.

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

Date: Nov 15, 2021

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION