Safety Data Sheet
Omeprazole Delayed-release Capsules, USP

Strength: 10/20/40 mg per Capsule **Pack Size:** 30/90/100/500/1000 capsules per bottle **Revision No.:** 02

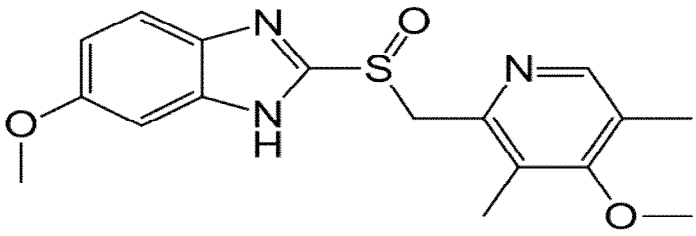
EMERGENCY OVERVIEW

Omeprazole Delayed-release capsule for oral administration that contains omeprazole 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:	Omeprazole Delayed-release Capsules, USP
Formula:	$C_{17}H_{19}N_3O_3S$
Chemical Name:	substituted benzimidazole, 5-methoxy-2-[[(4-methoxy-3, 5-dimethyl-2-pyridinyl) methyl] sulfinyl]1H-benzimidazole



Omeprazole

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
Emergency Telephone No.	Tel.: +91 79 6868100
Recommended use / Therapeutic Category	Omeprazole delayed-release capsules are proton pump inhibitor indicated for: • Treatment in adults of duodenal ulcer and gastric ulcer. • Treatment in adults and children of gastroesophageal reflux disease (GERD) and maintenance of healing of erosive esophagitis.

Restriction on Use / Contraindications:

Omeprazole delayed-release capsules are contraindicated in patients with known hypersensitivity to substituted benzimidazoles or to any component of the formulation. Hypersensitivity reactions may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, interstitial nephritis and urticarial.

Section 2. Hazard(s) Information

Dose and Administration

Omeprazole delayed-release capsules should be taken before eating. Patients should be informed that the omeprazole delayed-release capsules should be swallowed whole.

- **Short-Term Treatment of Active Duodenal Ulcer-** The recommended adult oral dose of omeprazole is 20 mg once daily.

- **H. pylori Eradication for the Reduction of the Risk of Duodenal Ulcer Recurrence**

  Triple Therapy (omeprazole/clarithromycin/amoxicillin)

  The recommended adult oral regimen is omeprazole 20 mg plus clarithromycin 500 mg plus amoxicillin 1000 mg each given twice daily for 10 days. In patients with an ulcer present at the time of initiation of therapy, an additional 18 days of omeprazole 20 mg once daily is recommended for ulcer healing and symptom relief.

  Dual Therapy (omeprazole/clarithromycin)

  The recommended adult oral regimen is omeprazole 40 mg once daily plus clarithromycin 500 mg three times daily for 14 days. In patients with an ulcer present at the time of initiation of therapy, an additional 14 days of omeprazole 20 mg once daily is recommended for ulcer healing and symptom relief.

- **Gastric Ulcer**

  The recommended adult oral dose is 40 mg once daily for 4 to 8 weeks.

- **Gastroesophageal Reflux Disease (GERD)**

  The recommended adult oral dose for the treatment of patients with symptomatic GERD and no esophageal lesions is 20 mg daily for up to 4 weeks. The recommended adult oral dose for the treatment of patients with erosive esophagitis and accompanying symptoms due to GERD is 20 mg daily for 4 to 8 weeks.

- **Maintenance of Healing of Erosive Esophagitis**

  The recommended adult oral dose is 20 mg daily.

- **Pathological Hypersecretory Conditions**

  The dosage of omeprazole in patients with pathological hypersecretory conditions varies with the individual patient. The recommended adult oral starting dose is 60 mg once daily. Doses should be adjusted to individual patient needs and should continue for as long as clinically indicated. Doses up to 120 mg three times daily have been administered. Daily dosages of greater than 80 mg should be administered in divided doses. Some patients

with Zollinger-Ellison syndrome have been treated continuously with omeprazole for more than 5 years.

- **Pediatric Patients**

For the treatment of GERD and maintenance of healing of erosive esophagitis, the recommended daily dose for pediatric patients 1 to 16 years of age is as follows:

Patient Weight	Omeprazole Daily Dose
5 < 10 kg	5 mg
10 < 20 kg	10 mg
≥20 kg	20 mg

Alternative administrative options can be used for pediatric patients unable to swallow an intact capsule

- **Alternative Administration Options**

For patients who have difficulty swallowing capsules, the contents of an omeprazole delayed-release capsule can be added to applesauce. One tablespoon of applesauce should be added to an empty bowl and the capsule should be opened. All of the pellets inside the capsule should be carefully emptied on the applesauce. The pellets should be mixed with the applesauce and then swallowed immediately with a glass of cool water to ensure complete swallowing of the pellets. The applesauce used should not be hot and should be soft enough to be swallowed without chewing. The pellets should not be chewed or crushed. The pellets/applesauce mixture should not be stored for future use.

Use with clopidogrel

Avoid concomitant use of clopidogrel and omeprazole. Coadministration of clopidogrel with 80 mg omeprazole, a proton pump inhibitor that is an inhibitor of CYP2C19, reduces the pharmacological activity of clopidogrel if given concomitantly or if given 12 hours apart.

Over Dose Effect confusion, drowsiness, blurred vision, tachycardia, nausea, vomiting, diaphoresis, flushing, headache, dry mouth, and

Medical Conditions Tell your doctor about all your medical conditions, including if you:

- Have been told that you have low magnesium levels in your blood
- Have liver problems
- are pregnant or plan to become pregnant. It is not known if omeprazole will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding or planning to breastfeed. You and your doctor should decide if you will take omeprazole or breastfeed. You should not do both.

Tell your doctor about all of the medicines you take including prescription and non-prescription drugs, anti-cancer drugs, vitamins and herbal supplements. Omeprazole may affect how other medicines work, and other medicines may affect how omeprazole works. In some cases, a

	drug you may be taking may need to be temporarily withdrawn. Especially tell your doctor if you take: atazanavir (Reyataz®*),nelfinavir (Viracept®*) ,saquinavir (Fortovase®*) ,cilostazol (Pletal®*) ,ketoconazole (Nizoral®*) ,voriconazole (Vfend®*) ,ampicillin (Unasyn®*) ,products that contain iron,warfarin (Coumadin®*),digoxin (Lanoxin®*,Lanoxincaps®*) ,tacrolimus (Prograf®*) ,diazepam (Valium®*) ,phenytoin (Dilantin®*) ,disulfiram (Antabuse®*) ,clopidogrel (Plavix®*) ,St. John's Wort (Hypericum perforatum) ,Rifampin, erlotinib ,methotrexate
Contraindications	Omeprazole delayed-release capsules are contraindicated in patients with known hypersensitivity to substituted benzimidazoles or to any component of the formulation. Hypersensitivity reactions may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, interstitial nephritis, and urticaria
Pregnancy Comments	There are no adequate and well-controlled studies on the use of omeprazole in pregnant women. This drug should be used during pregnancy only if clearly needed.
Pregnancy Category	C

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component:		
Omeprazole	Not Found	73590-58-6
Inactive Ingredients :		
Acetone	Not Found	67-64-1
di-sodium hydrogen phosphate dihydrate	Not Found	10028-24-7
FD&C blue 1	Not Found	NA
Gelatin	Not Found	9000-70-8
Hydroxypropyl cellulose	Not Found	9004-64-2
Hypromellose	Not Found	9004-65-3
Hypromellose phthalate	Not Found	9050-31-1
Polyethylene glycol	Not Found	25322-68-3
Sodium lauryl sulphate	Not Found	151-21-3
Sugar spheres	Not Found	NA
Talc	Not Found	14807-96-6
Titanium dioxide	Not Found	13463-67-7
Triethyl citrate	Not Found	77-93-0

Section 4. First -aid measures

General

Inhalation: Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

Contact with skin: Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

Contact with eyes: Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice

Ingestion: If swallowed, wash out mouth with water, provided person is conscious. Seek medical advice. Remove and wash/dispose of contaminated clothing promptly.

Overdose Treatment

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.
As with the management of any overdose, the possibility of multiple drug ingestion should be considered.

Section 5. Fire -fighting measures

Flash point	Not Found	**Upper Flammable limit:**	Not Found
Auto-Ignition Temperature:	Not Found	**Lower Flammable limit:**	Not Found
Extinguishing Media	Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.	**Fire and Explosion Hazard**	This material is assumed to be combustible.

Fire Fighting Procedure As with all fires, evacuate personnel to a safe area. Fire fighter should use self- contained breathing equipment and protective clothing.

Section 6. Accidental Release Measures

Spill Response

Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

Section 7. Handling and Storage

Storage

Store at 20° to 25°C (68° to 77°F) .Protect from light and moisture.
Keep in a tightly closed container. Dispense in a tight, light-resistant container.

Incompatibility

Reactive with oxidizing substance.

Section 8. Exposure controls / personal protection

Respiratory Protection	Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.
Skin Protection	Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.
Eye protection	Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.

Section 9. Physical and chemical properties

Appearance

Omeprazole Delayed-release Capsules, USP 10 mg are white to off-white free flowing pellets filled in size '3' hard gelatin capsules with amethyst purple-colored cap printed with "ZA-09"in black ink & white body printed with "10 mg" in black ink.

Omeprazole Delayed-release Capsules, USP 20 mg are white to off-white free flowing pellets filled in size '2' hard gelatin capsules with tan-colored cap printed with "ZA-10"in black ink & white body printed with "20 mg" in black ink.

Omeprazole Delayed-release Capsules USP, 40 mg are off-white to pale brown free flowing pellets filled in size'1' hard gelatin capsules with Amethyst purple colored cap printed with "ZA-11" in black ink & white body printed with "40 mg" in black ink.

Solubility	Freely soluble in ethanol and methanol, and slightly soluble in acetone and isopropanol and very slightly soluble in water.	**Odour**	No Data Available
Boiling point	No Data Available	**Melting Point**	About 155°C
Evaporation rate	No Data Available	**Vapour density**	No Data Available
Reactivity in water	No Data Available	**Evaporation rate**	No Data Available
Percentage Volatile by volume	No Data Available	**Specific gravity**	No Data Available
Vapour pressure	No Data Available	**Other information**	Not Applicable

Section 10. Stability and Reactivity

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	**Stable**	Stable under temperature if Store at 20° to 25°C
Decomposition Products	No Data Available	**Hazardous Reaction**	No data available.

Incompatibilities Reactive with oxidizing substance.

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.

Target organ Eye contact, Skin contact and inhalation is not great risk.

Other Not Applicable

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. Approved by USFDA & the ANDA Number is 91352

Section 16. Other information

None

Date of issue: 28/05/2015 **Supersedes edition of:** 01

The information contained herein is based on the state of our knowledge. It Characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.