Safety Data Sheet
Lansoprazole Delayed-release Capsules, USP

Strength: 15mg and 30 mg **Pack Size:** 30/1000 capsules per bottle for 15 mg
100 capsules per unit dose blisters for 15 mg
30/90/100/1000 capsules per bottle for 30 mg
100 capsules per unit dose blisters for 30 mg **Revision No.:** 01

EMERGENCY OVERVIEW

Lansoprazole delayed-release capsules for oral administration that contains lansoprazole and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

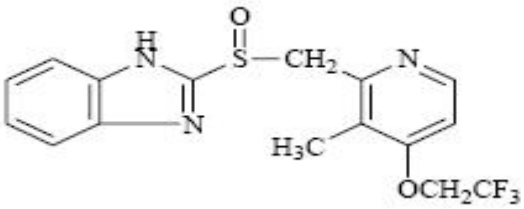
Section 1. Identification

Identification of the product

Product name: Lansoprazole delayed-release capsules

Formula: $C_{16}H_{14}F_3N_3O_2S$

Chemical Name: 2-[[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl]methyl] sulfinyl] benzimidazole



Lansoprazole

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Recommended use / Therapeutic Category Antacid

Restriction on Use / Contraindications Lansoprazole is contraindicated in patients with known severe hypersensitivity to any component of the formulation of lansoprazole delayed-release capsules.

Section 2. Hazard (s) Information

Dose and Administration

Lansoprazole is available as a capsule in 15 mg and 30 mg strengths.Lansoprazole should be taken before eating.You should swallow lansoprazole delayed-release capsules whole. Do not crush or chew lansoprazole delayed-release capsules.
If you have trouble swallowing a whole capsule, you can open the capsule and take the contents with certain foods or juices. See the "Instructions for Use" at the end of this Medication Guide for instructions on how to take lansoprazole delayed-release capsules with certain foods and juices.

Adverse Effects

Most commonly reported adverse reactions (≥ 1%): diarrhea, abdominal pain, nausea and constipation.

Over Dose Effect

Lansoprazole is not removed from the circulation by hemodialysis. In one reported overdose, a patient consumed 600 mg of lansoprazole with no adverse reaction.

Medical Conditions

Tell your doctor if you:have been told that you have low magnesium levels in your blood, have liver problems, have any other medical conditions, are pregnant or plan to become pregnant. It is not known if lansoprazole delayed-release capsules will harm your unborn baby, are breastfeeding or plan to breastfeed. It is not known if lansoprazole passes into your breast milk. You and your doctor should decide if you will take lansoprazole delayed-release capsules or breastfeed. You should not do both. Talk to your doctor about the best way to feed your baby if you take lansoprazole delayed-release capsules.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Lansoprazole delayed-release capsules may affect how other medicines work, and other medicines may affect how lansoprazole delayed-release capsules work.

Especially tell your doctor if you take: atazanavir (Reyataz®$) ,digoxin (Lanoxin®$) ,a product that contains iron ,ketoconazole (Nizoral®$) ,warfarin (Coumadin®$, Jantoven®$) ,tacrolimus (Prograf®$) ,theophylline (Theo-24®$, Elixophyllin®$, Theochron®$, Theolair®$) ,an antibiotic that contains ampicillin or clarithromycin ,methotrexate

Ask your doctor or pharmacist for a list of these medicines if you are not sure. Know the medicines that you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

Contraindications Lansoprazole is contraindicated in patients with known severe hypersensitivity to any component of the formulation of lansoprazole delayed-release capsules.

Pregnancy Comments There are no adequate or well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed

Pregnancy Category **B**

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Lansoprazole	Not Found	103577-45-3
Inactive Ingredients :		
Corn starch	Not Found	9005-25-8
D&C red # 28	Not Found	NA
FD&C blue # 1	Not Found	NA
FD&C red # 40	Not Found	NA
Gelatin	Not Found	9000-70-8
Hydroxypropyl cellulose	Not Found	9004-64-2
Hypromellose	Not Found	9004-65-3
Low substituted hydroxypropyl cellulose	Not Found	9004-64-2
Magnesium carbonate heavy powder	Not Found	546-93-0
Methacrylic acid copolymer dispersion	Not Found	NA
Polyethylene glycol	Not Found	25322-68-3
Polysorbate 80	Not Found	9005-65-6
Sucrose	Not Found	57-50-1

Sugar spheres	Not Found	NA
Talc	Not Found	14807-96-6
Titanium dioxide	Not Found	13463-67-7

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 concious. Seek medical advice

Remove and wash/dispose of contaminated clothing promptly.

Overdose Treatment Lansoprazole is not removed from the circulation by hemodialysis. In one reported overdose, a patient consumed 600 mg of lansoprazole with no adverse reaction.

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 at high temperature.

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 moisture.
Incompatibilities:	Reacting 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.
Engineering Control	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Section 9. Physical and chemical properties

Appearance	Lansoprazole Delayed-release Capsules USP, 15 mg are enteric-coated pellets filled in size '3' hard gelatin capsules with standard pink opaque colored cap printed with "ZA -50" in black ink and white opaque body printed with "15mg" in black ink. Lansoprazole Delayed-release Capsules USP, 30 mg are enteric-coated pellets filled in size '1' hard gelatin capsules with standard pink opaque colored cap printed with "ZA -51" in black ink and white opaque body printed with "30 mg" in black ink.		
Solubility	Freely soluble in dimethylformamide, insoluble in hot and cold water.	**Odour**	Odorless
Boiling point	Not available.	**Melting Point**	152 to 162° C
Evaporation rate	Not available.	**Vapour density**	Not available.
Reactivity in water	Not available.	**Vapour pressure**	Not available.
Percentage Volatile by volume	Not available.	**Specific gravity**	Not available.
Vapour pressure	Not available.		

Section 10. Stability and Reactivity

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	**Stable**	Product is stable.
Incompatibilities	Reacting with oxidizing substance.	**Hazardous Reaction**	No data 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.

Target organ Eye contact, Skin contact and inhalation is not great risk as this product is capsule.

Other Oral lansoprazole doses up to 5000 mg/kg in rats [approximately 1300 times the 30 mg human dose based on body surface area (BSA)] and in mice (about 675.7 times the 30 mg human dose based on BSA) did not produce deaths or any clinical signs.

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 202366

Section 16. Other information

None

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