

Material Safety data sheet

RAMIPRIL CAPSULES

Strength: 1.25/2.5/5/10 mg

Pack Size: Bottles 30/90/100/500 Capsules
Blister 100 Capsules

Revision No: 00

EMERGENCY OVERVIEW

Ramipril capsules intended for oral administration contains 1.25 mg or 2.5 mg or 5 mg or 10 mg of Ramipril and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

Section 1. Identification of the substance

Identification of the product

Product name: Ramipril Capsules
Formula: $C_{23}H_{32}N_2O_5$
Chemical Name: (2S, 3aS, 6aS)-1[(S)-N-[(S)-1-Carboxy-3-phenylpropyl]alanyl] octahydrocyclopenta [b]pyrrole-2-carboxylic acid, 1-ethyl ester
Therapeutic Category ACE Inhibitor

Manufacturer / Supplier Identification

Company: Cadila Healthcare Ltd. Ahmedabad, India
Contact for information: Tel.: +91 79 6868100 Fax: +91 79 3750319
Emergency telephone No. Tel.: +91 79 6868100

Section 2. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Ramipril	Not Found	87333-19-5
Inactive Ingredients :		
Gelatin	Not Found	9000-70-8
Pregelatinized starch	Not Found	NA
Titanium dioxide	Not Found	13463-67-7

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Section 3. Health Hazards Information






Dose and Administration

Hypertension:

2.5 mg once a day. The usual maintenance dosage range is 2.5 to 20 mg per day administered as a single dose or in two equally divided doses.

Instructions for Patients and their Caregivers for Taking Ramipril Capsules:

To Take with Food:

	You may sprinkle the contents of ramipril capsules on a small amount (about 4 oz.) of apple sauce or mixed in 4 oz. (120 mL) of water or apple juice.
	Hold, the capsule upright so that white colored cap portion of the capsule will be at the upper side.
	Carefully twist off the white colored cap of the capsule. You may find it best to do this over the small portion of the food onto which you will be pouring the sprinkles.
	Take care to see that, sprinkle all of the capsule's contents onto a spoonful of apple sauce or in water or in apple juice.
	Be sure the patient swallows entirety the sprinkle/food mixture immediately. It may be helpful to have the patient drink fluids immediately in order to make sure all of the mixture is swallowed. IMPORTANT: The sprinkle/food mixture can be pre-prepared and stored for up to 24 hours at room temperature or up to 48 hours under refrigeration.

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Adverse Effects

Hypertension:

Asthenia.

Body as a whole:

Anaphylactoid Reactions

Cardiovascular:

Symptomatic Hypotension

Hematologic:

Pancytopenia, Hemolytic Anaemia & Thrombocytopenia.

Angioneuritic Edema:

Gastrointestinal :

Hepatic Failure, Hepatitis, Jaundice, Pancreatitis, Abdominal Pain, Anorexia, Constipation, Diarrhoea, Dry mouth, Dyspepsia, Dysphagia, Gastroenteritis, Increase Salivation & Taste Disturbance.

Dermatology:

Hypersensitivity Reactions.

Neurologic & Psychiatric:

Anxiety, amnesia, convulsions, depression, hearing loss, insomnia, nervousness, neuralgia, neuropathy, paresthesia, somnolence, tinnitus, tremor, vertigo, and vision disturbances.

Miscellaneous:

As with other ACE inhibitors, a symptom complex has been reported which may include a positive ANA, an elevated erythrocyte sedimentation rate, arthralgia/arthritis, myalgia, fever, vasculitis, eosinophilia, photosensitivity, rash and other dermatologic manifestations.

Over Dose Effect

Laboratory determinations of serum levels of ramipril and its metabolites are not widely available, and such determinations have, in any event, no established role in the management of ramipril overdose. No data are available to suggest physiological maneuvers (e.g., maneuvers to change the pH of the urine) that might accelerate elimination of ramipril and its metabolites. Similarly, it is not known which, if any, of these substances can be usefully removed from the body by hemodialysis.

Contraindications

Ramipril capsules are contraindicated in patients who are hypersensitive to this product or any other angiotensin converting enzyme inhibitor (e.g., a patient who has experienced angioedema during therapy with any other ACE inhibitor).

Pregnancy Comments

When used in pregnancy during the second and third trimesters, ACE inhibitors can cause injury and even death to the developing fetus. When pregnancy is detected, ramipril capsules should be discontinued as soon as possible

Pregnancy Category

Pregnancy Categories C (first trimester) and D (second and third trimesters)

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Section 4. First aid measures

General	Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive medical attention
Overdose Treatment	Tertiary anticholinergics such as atropine may be used as an antidote for donepezil hydrochloride overdose. Intravenous atropine sulfate titrated to effect is recommended: an initial dose of 1.0 to 2.0 mg IV with subsequent doses based upon clinical response.

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. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build up of static electricity.
Fire Fighting Procedure	As with all fires, evacuate personnel to a safe area. Fire fighter should use self- contained breathing equipment and protective clothing.		

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Section 6. Storage / Spill / Disposal Measures

Storage	Store at 20° to 25°C (68° to 77°F). Protect from light. Dispense in a tight, light resistant container.
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.
Disposal	Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 7. Exposure controls and 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.

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Section 8. Physical and chemical properties

Appearance	White to almost white crystalline powder.	Odour	No Data Available
Solubility in water	It is freely soluble in methanol and sparingly soluble in water..	Melting Point	105°C and 112° C.
Boiling point	No Data Available	Vapour density	No Data Available
Evaporation rate	No Data Available	Evaporation rate	No Data Available
Reactivity in water	No Data Available	Specific gravity	No Data Available
% Volatile by volume	No Data Available	Vapour pressure	No Data Available
Other information	Ramiprilat, the diacid metabolite of ramipril, is a non-sulphydryl angiotensin converting enzyme inhibitor. Ramipril is converted to ramiprilat by hepatic cleavage of the ester group.		

Section 9. Physical Hazards

Condition to avoid	Avoid exposure to extreme heat, light and moisture.	Stable	Stable under normal ambient and anticipated storage and handling conditions.
Decomposition Products	No Data Available	Hazardous Reaction	No data available.
Incompatibilities	No data available.		

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Section 10. Toxicological information

Handling of formulated product is not expected to cause any adverse effects. The data pertains to the ingredient in formulations, rather than this specific formulation.

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

Other No Data Available

Section 11. Ecological information

No data available on Ecotoxicity

Section 12. Other information

None

Date of issue: 14/10/2010

Supersedes edition of: New Edition

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.