RAMIPRIL (CAS number- 87333-19-5)

TAJMTF-LMAERY8972

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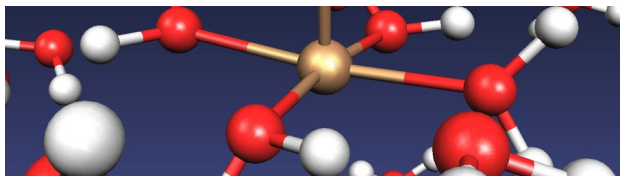
TAJ PHARMACEUTICALS LIMITED INDIA

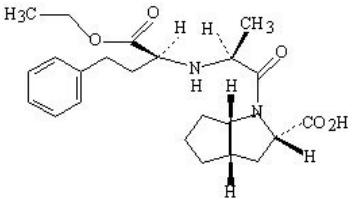
PHARMACEUTICALS INDIA
ACTIVE PHARMACEUTICAL
INGREDIENTS
TAJ GROUP

ACTIVE PHARMACEUTICAL INGREDIENTS

Raw Material / Chemicals Index

Taj Pharmaceuticals Ltd.
RAMIPRIL
(Cas No 87333-19-5)





Systematic (IUPAC) name
(2S,3aS,6aS)-1-[(2S)-2-{[(2S)-1-ethoxy-1-oxo-4-phenylbutan-2-yl]amino}propanoyl]-octahydrocyclopenta[b]pyrrole-2-carboxylic acid

Identifiers
CAS number 87333-19-5
ATC code C09AA05
PubChem 5362129
DrugBank APRD00009
ChemSpider 4514937

Synonyms
(1S,5S,7S)-8-[(2S)-2-[[(1S)-1-Ethoxycarbonyl-3-phenyl-propyl]amino]propanoyl]-8-azabicyclo[3.3.0]octane-7-carboxylic acid
Cyclopenta(b)pyrrole-2-carboxylic acid, octahydro-1-(2-((1-(ethoxycarbonyl)-3-phenylpropyl) amino)-1-oxopropyl), (2S-(1(R*(R*)),2-alpha,3a-beta,6a-beta))
HOE-498
Ramipril

Formula C23H32N2O5

Molecular Weight 416.52

RTECS GY5879600

Merck 12,8283

Physical and Chemical Properties

Solubility in water Insoluble

Melting Point 109

Vapor Pressure 4.9E-16 (25 C)

Density 1.20 g/cm3 (20 C)

pKa/pKb 3.17 (pKa)

Partition Coefficient 3.41

Chemical data
Formula C23H32N2O5
Mol. mass 416.511 g/mol
SMILES eMolecules & PubChem

Pharmacokinetic data
Bioavailability 28%
Protein binding 73% (ramipril)
56% (ramiprilat)
Metabolism Hepatic, to ramiprilat
Half life 2 to 4 hours
Excretion Renal (60%) and fecal (40%)

Ramiprilis an angiotensin-converting enzyme (ACE) inhibitor, used to treat hypertension and congestive heart failure. ACE inhibitors lower the production of angiotensin II, therefore relaxing arterial muscles while at the same time enlarging the arteries, allowing the heart to pump blood more easily, and increasing blood flow due to more blood being pumped into and through larger passageways.

Long-acting angiotensin-converting enzyme inhibitor. It is a prodrug that is transformed in the liver to its active metabolite ramiprilat.

Storage Store in original container in a cool dark place.

Hazards Identification

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

Exposure Controls/Personal Protection
Wear self-contained breathing apparatus, rubber boots & heavy rubber gloves.

Fire Fighting Measures Extinguish with carbon dioxide, dry chemical powder or appropriate foam. Water spray. Wear self-contained breathing apparatus and protective clothing to prevent contact with the skin and eyes.

Accidental Release Measures
Sweep-up/absorb in suitable material, place in a container and hold for disposal. Avoid raising dust. Ventilate area and wash spill site after pickup is complete.

Stability and Reactivity Emits toxic fumes under fire conditions.

Toxicity The most likely clinical manifestations would be symptoms attributable to hypotension. LD50 = 10933 mg/kg (orally in mice).

Protein Binding	Protein binding of ramipril is about 73% and that of ramiprilat about 56%. The absolute bioavailabilities of ramipril and ramiprilat were 28% and 44%, respectively.
Biotransformation	Hepatic. Ramipril is a prodrug and is converted to the active metabolite ramiprilat by liver esterase enzymes.
Effects of Overexposure:	The potential for exposure is reduced in finished pharmaceutical form. Hypotension is the most likely effect of overexposure to Ramipril according to clinical reports.
Hazardous Combustion Products	Carbon dioxide, carbon monoxide, oxides of nitrogen
Hazardous Decomposition	Oxides of carbon, oxides of nitrogen
Hazardous Polymerization	Will not occur.
Regulatory Information	DEA: Ramipril is not a controlled substance. FDA: Ramipril is an approved prescription medication. Inventory Status: 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. This material is not listed on the DSL Inventory but is exempt.
Toxicological Information	Acute Toxicity: Active Ingredient: LD50 Oral (rat): > 10000 mg/kg LD50 Oral (mouse): 10048 mg/kg
Carcinogenicity:	Not listed as a carcinogen by NTP, IARC Monographs or OSHA.

Accidental Release Information

STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT IS SPILLED:

Use appropriate personal protective equipment (see Section 8). Sweep up and containerize spill material in a
compatible container. Dispose according to applicable regulations. Incineration of the waste at an approved facility
is recommended.