

Trandolapril Cas No. : 87679-37-6

This drug belongs to a group of medications called ACE inhibitors. It is used to treat high blood pressure (hypertension). It works by relaxing blood vessels, causing them to widen. Lowering high blood pressure helps prevent strokes, heart attacks and kidney problems.

Active Pharmaceuticals Ingredients Manufacturers

Taj Pharmaceuticals Ltd.**Trandolapril****CAS No. : 87679-37-6****Synonyms:**

(2S,3aR,7aS)-1-[(2S)-2-[[[(2S)-1-ethoxy-1-oxo-4-phenylbutan-2-yl]amino} propanoyl]-octahydro-1H-indole-2-carboxylic acid

Identifiers

CAS number 87679-37-6

ATC code C09AA10

PubChem 5484727

DrugBank APRD01269

Chemical dataFormula C₂₄H₃₄N₂O₅

Mol. mass 430.537 g/mol

Pharmacokinetic data**Bioavailability**

Protein binding Trandolapril 80%

(independent of concentration)

Trandolaprilat 65 to 94%

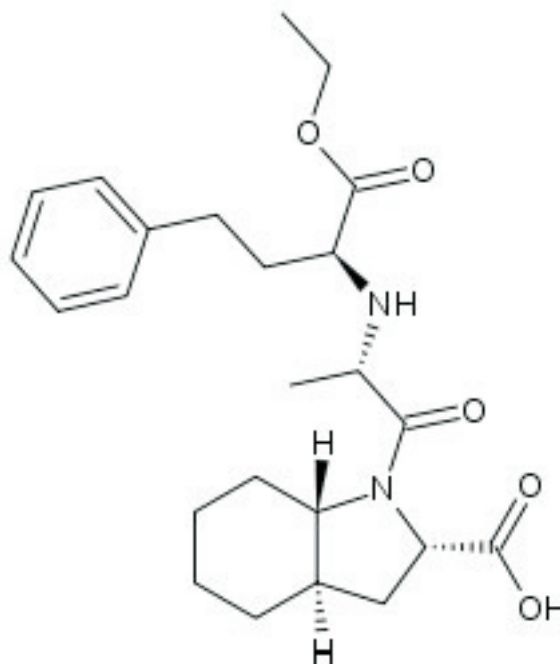
(concentration-dependent)

Metabolism Hepatic

Half life 6 hours (trandolapril)

10 hours (trandolaprilat)

Excretion Fecal and renal



Trandolapril is the ethyl ester prodrug of a nonsulfhydryl angiotensin converting enzymeinhibitor, trandolaprilat. Trandolapril is chemically described as (2S, 3aR, 7aS)-1-[(S)-N-[(S)-1-Carboxy-3-phenylpropyl]alanyl] hexahydro-2-indo-linecarboxylic acid, 1-ethyl ester. Its empirical formula is C₂₄H₃₄N₂O₅and M.W.= 430.54
Melting Point = 125°C

Trandolapril is used alone or in combination with other medications to treat high blood pressure. It is also used to improve survival in patients with heart failure after a heart attack. Trandolapril is in a class of medications called angiotensin-converting enzyme (ACE) inhibitors. It works by decreasing certain chemicals that tighten the blood vessels, so blood flows more smoothly and the heart can pump blood more efficiently.

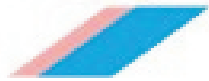
WARNING

This drug can cause serious (possibly fatal) harm to an unborn baby if used during pregnancy. Therefore, it is important to prevent pregnancy while taking this medication. Consult your doctor for more details and to discuss the use of reliable forms of birth control while taking this medication. If you are planning pregnancy, become pregnant, or think you may be pregnant, contact your doctor immediately.



Taj Pharmaceuticals Ltd.
Trandolapril

CAS No 87679-37-6



USES

This drug belongs to a group of medications called ACE inhibitors. It is used to treat high blood pressure (hypertension). It works by relaxing blood vessels, causing them to widen. Lowering high blood pressure helps prevent strokes, heart attacks and kidney problems. This medication is also used to improve survival after an acute heart attack and with other drugs (e.g., "water pills"/diuretics, digoxin) to treat congestive heart failure.

HOW TO USE

Take this medication by mouth, usually once or twice a day; or as directed by your doctor. You may take this drug with or without food. Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time(s) each day. The dosage is based on your medical condition and response to therapy. For the treatment of high blood pressure, it may take 1 week before the full benefit of this drug occurs or several weeks to months when used for congestive heart failure.

SIDE EFFECTS

You may experience dizziness, light-headedness, diarrhea, dry cough or blurred vision as your body adjusts to the medication. If any of these effects persist or worsen, notify your doctor. This drug may rarely cause serious (possibly fatal) liver problems. If you notice any of the following highly unlikely but very serious side effects, seek immediate medical attention: yellowing eyes or skin, dark urine, stomach/abdominal pain, persistent fatigue, persistent nausea. A serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction include: rash, itching, swelling (especially of the face, lips, tongue, or throat), severe dizziness, trouble breathing.

PRECAUTIONS

Before taking trandolapril, tell your doctor or pharmacist if you are allergic to it; or to other ACE inhibitors (e.g., benazepril, captopril); or if you have any other allergies (including exposure to certain membranes used for blood filtering).

This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: history of an allergic reaction which included swelling of the face/lips/tongue/throat (angioedema).

Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease, liver disease, high blood levels of potassium, heart problems, severe dehydration (and loss of electrolytes such as sodium), diabetes (poorly controlled), strokes, blood vessel disease (e.g., collagen vascular diseases such as lupus, scleroderma).





MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store the US product at room temperature between 68-77 degrees F (20-25 degrees C) away from light and moisture. Do not store in the bathroom.

Store the Canadian product at room temperature between 59-77 degrees F (15-25 degrees C) away from light and moisture. Do not store in the bathroom.
Keep all medicines away from children

DOSAGE

Trandolapril comes as a tablet to take by mouth. It is usually taken once or twice a day with or without food.

To help you remember to take trandolapril, take it around the same time every day.

Follow the directions on your prescription label carefully, and ask your doctor to explain any part you do not understand.

Take trandolapril exactly as directed.

Do not take more or less of it or take it more often than prescribed by your doctor.

Trandolapril is taken once or twice daily. African-American patients generally require higher doses than do Caucasians.

Food reduces the amount of trandolapril that is absorbed, so it is best to take this medication one hour before or two hours after meals.

Patients with advanced renal or liver diseases may need to take lower doses.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.

This leaflet was prepared by
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