TANATRIL®

(Imidapril)

ACTION

Tanatril (Imidapril) is an oral long-acting sulfhydryl-free angiotensin converting enzyme (ACE) inhibitor originally developed by Mitsubishi Tanabe Pharma Corporation, Osaka - Japan.

Imidapril is metabolized into the active metabolite imidaprilat which inhibits the formation of angiotensin II (strong vasopressor) and the degradation of bradykinin (vasodepressor); resulting in an antihypertensive effect.

INDICATIONS

Tanatril is indicated for the treatment of essential hypertension.

DOSAGE AND ADMINISTRATION

Adults: Usual initial dose is 5 mg once daily; the dose should be adjusted according to response. The usual maintenance dose is 10 mg/day with the maximum recommended dose being 20 mg once a day.

Elderly: Initial dose is 2.5 mg once daily with the dose being adjusted according to response. The maximum dose is 10 mg once a day.

Additionally, 2.5 mg once daily is recommended as a starting dose in:

Severe renal impairment (CrCl<30ml/min).

Hepatic impairment

Patients with previous experience of syncope. Salt and/or body fluid deficiencies should be corrected before initiating Tanatril.

Diurectic therapy should be discontinued 2-3 days before initiating Tanatril treatment.

Children: not recommended.

CONTRAINDICATIONS

Hypersensitivity to Imidapril. Patients with a history of angioedema due to another ACE inhibitor. Pregnancy and lactation. Renal failure (CrCl < 10ml/min) with or without hemodialysis. Renovascular hypertension.

PRECAUTIONS

Renal function should be assessed before use. Symptomatic hypotension may occur, particularly in volume-depleted patients and cardiac failure. To be used with caution in the elderly, bilateral renal arterial stenosis, cerebrovascular impairment, angina pectoris, and in aortic stenosis. Hypotension may occur during surgery or anesthesia.

Tanatril should be avoided in patients using polyacrylonitrite dialysis membranes, and during LDL lipid apheresis with dextran sulphate.

Drug Interactions

The combination of Tanatril with the following may result in:

Other antihypertensives, narcotics, or antipsychotics -increased hypotensive effect.

Potassium supplements, potassium-sparing diuretics -not recommended.

Lithium - increased serum concentrations of lithium.

Antidiabetics - enhanced antidiabetic effect.

Sympathomimetics, NSAIDs, or rifampicin - reduced hypotensive effect.

Allopurinol, cytostatics, or immunosuppressive agents, systemic corticosteroids , procainamide - increased risk of leucopenia.

Antacids - decreased bioavailability of imidapril.

WARNINGS

Use in pregnancy: There are no adequate and well-controlled studies of imidapril in pregnant women. Therefore, the use of imidapril in pregnancy is not recommended.

Nursing mothers: It is not known whether Imidapril is secreted in human breast milk; However, in animal experimental studies (rats), Imidapril was secreted in breast milk. Therefore, the use Imidapril in nursing mothers is not recommended.

Pediatric use: Safety and efficacy in children have not been established. Therefore the use of imidapril in children is not recommended.

SIDE EFFECTS

Most common: nausea, dizziness, headache, diarrhea, cough, fatigue, hypotension.

Less commonly : angioedema, hypersensitivity reactions, renal failure, severe hypotension, hyperkalemia, increases in liver enzymes and serum bilirubin, palpitations, tachycardia, abdominal pain, impotence, blurred vision, taste disturbances, dry mouth, glossitis, bronchitis, dyspnoea, sleep disturbances, confusion, tinnitus.

Decreases in hemoglobin and hematocrit have occurred.

A symptom complex which may include fever, myalgia, arthralgia/arthritis, increased ANA, eosinophilia, rash or other dermatological manifestations may occur.

Rarely: agranulocytosis or pancytopenia.

OVERDOSAGE

There are no data on overdosage in humans. Symptoms of overdosage may be severe hypotension, shock, syncope, stupor, bradycardia, electrolyte imbalance and renal failure. Measures to be taken should be the same as those suggested for ACE inhibitors in general. Imidapril and imidaprilat are removable by hemodialysis.

STORAGE

Store between 15-30°C, away from light.

PRESENTATION

Tablets:

TANATRIL 5:	Imidapril hydrochloride 5 mg/tablet
TANATRIL 10:	Imidapril hydrochloride 10 mg/tablet
TANATRIL 20:	Imidapril hydrochloride 20 mg/tablet

Excipients: Lactose, Calcium hydrogen phosphate anhydrous Starch, Carmellose sodium, Glycerol palmitostearate

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous.
- Follow the doctor's prescription strictly, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Under license of:

Mitsubishi Tanabe Pharma Corporation
Osaka, Japan

Manufactured by Hikma Pharmaceuticals,
Amman- Jordan

HIKMA

Keep medicament out of the reach of children

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