

Torseretic 10mg

Torsemide 10mg Tablets

Company Name:

Utopia Pharmaceuticals.

Trade Name:

Torseretic 10 mg.

Generic Name:

Torsemide 10 mg.

Composition:

Each tablet contains:

Active ingredients:

Torsemide 10 mg.

Inactive ingredients:

- Anhydrous lactose
- Microcrystalline cellulose
- Povidone
- Magnesium stearate
- Croscarmellose

Pharmaceutical Form:

Tablets.

Properties:

Torsemide is a diuretic of the pyridine – sulphonyl urea class. Its chemical name is 1- isopropyl-3-[(4-m-toluidino-3-pyridyl)sulphonyl] urea. It acts as a loop diuretic.

Clinical Pharmacology:

Mechanism of Action:

Torsemide acts within the lumen of the thick ascending portion of the loop of Henle where it inhibits the $\text{Na}^+/\text{K}^+/\text{2Cl}^-$ -carrier system and effects in other segments of the nephron have not been demonstrated. Torsemide increases the urinary excretion of sodium, chloride and water, but it does not significantly alter glomerular filtration rate, renal plasma flow or acid-base balance.

Systolic and diastolic supine and standing blood pressure are all reduced.

There is no significant orthostatic effect and there is only a minimal peak-trough difference in blood pressure reduction.

When Torsemide is first administered, daily urinary sodium excretion increases for at least a week.

With chronic administration, however, daily sodium loss comes into balance with dietary sodium intake. If the administration of torsemide is suddenly stopped, blood pressure returns to pretreatment levels over several days without overshoot.

Pharmacokinetics & Metabolism:

The bioavailability of torsemide is approximately 80%. The drug is absorbed with little first-pass metabolism, and the serum concentration reaches its peak (C_{max}) within 1 hour after oral administration. C_{max} and area under the serum concentration-time curve (AUC) after oral administration are proportional to a dose over the range of 2.5 mg to 200 mg. Simultaneous food intake delays the time to C_{max} by about 30 minutes but overall bioavailability (AUC) and diuretic activity are unchanged. Absorption is essentially unaffected by renal or hepatic dysfunction. The peak effect occurs during the first or second hour. Independent of the route of administration, diuresis lasts about 6 to 8 hours. The elimination half-life of torsemide is approximately 3.5 hours. Torsemide is cleared from the circulation by both hepatic metabolism (approximately 80% of total clearance) and excretion into the urine (approximately 20% of total clearance in patients with normal renal function).

In patients with decompensated congestive heart failure:

Hepatic and renal clearance are both reduced, probably because of hepatic congestion and decreased renal plasma flow, respectively. The total clearance of torsemide is approximately 50% of that seen in healthy volunteers, and the plasma half-life and AUC are correspondingly increased.

In patients with renal failure:

Renal clearance of torsemide is markedly decreased but total plasma clearance is not significantly altered.

In patients with hepatic cirrhosis:

The volume of distribution, plasma half-life and renal clearance are all increased but total clearance is unchanged.

Indications:

Torsemide is indicated for the treatment of edema associated with congestive heart failure, renal disease, or hepatic disease. Use of torsemide has been found to be effective for the treatment of edema associated with chronic renal failure. Chronic use of any diuretic in hepatic disease has not been studied in adequate and well-controlled trials.

Torsemide is indicated for the treatment of hypertension alone or in combination with other antihypertensive agents.

Dosage and Administration:

Torsemide tablets may be given at any time regardless to food, as convenient. Special dosage adjustment in the elderly is not necessary because of the high bioavailability of torsemide.

Essential Hypertension:

In patients with essential hypertension, torsemide has been shown to lower blood pressure when administered once a day at doses of 5 mg to 10 mg. The antihypertensive effect is near maximal after 4 to 6 weeks of treatment, but it may continue to increase for up to 12 weeks.

Torsemide has been administered together with (beta)-adrenergic blocking agents, ACE inhibitors, and calcium-channel blockers. Adverse drug interactions have not been observed, and special dosage adjustment has not been necessary.

Torsemide initial dose is 5 mg once daily. If the 5 mg dose does not provide adequate reduction in blood pressure within 4 to 6 weeks, the dose may be increased to 10 mg once daily. If the response to 10 mg is insufficient, an additional antihypertensive agent should be added to the treatment regimen.

Congestive Heart Failure:

Torsemide initial dose is 10 mg or 20 mg once daily. If the diuretic response is inadequate, the dose should be titrated upward by approximately doubling until the desired diuretic response is obtained. Single doses higher than 200 mg have not been adequately studied.

Chronic Renal Failure:

Torsemide initial dose is 20 mg once daily. If the diuretic response is inadequate, the dose should be titrated upward by approximately doubling until the desired diuretic response is obtained. Single doses higher than 200 mg have not been adequately studied.

Hepatic Cirrhosis:

Torsemide initial dose is 5 mg or 10 mg once daily administered together with an aldosterone antagonist or a potassium-sparing diuretic. If the diuretic response is inadequate, the dose should be titrated upward by approximately doubling until the desired diuretic response is obtained. Single doses higher than 40 mg have not been adequately studied.

Contraindications:

-Torsemide is contraindicated in patients with known hypersensitivity to sulfonylureas.

-Torsemide is contraindicated in patients who are anuric.

Side Effects:

The reported side effects of torsemide were generally transient and there was no relationship between side effects and age, sex, race or duration of therapy. The most common side effects (in descending order of frequency) dizziness, headache, nausea, weakness, vomiting, hyperglycemia, excessive urination, hyperuricemia, hypokalemia, excessive thirst, hypovolemia, impotence, esophageal hemorrhage and dyspepsia. Drop out rates for these adverse events ranged from 0.1% to 0.5%.

Drug Interactions:

-In patients with essential hypertension, torsemide has been administered together with beta-blockers, ACE inhibitors and calcium-channel blockers. In patients with congestive heart failure, torsemide has been administered together with digitalis glycosides, ACE inhibitors and organic nitrates. None of these combined uses were associated with new or unexpected adverse events.

-Torsemide does not affect the protein binding of glyburide or of warfarin, the anticoagulant effect of phenprocoumon (a related coumarin derivative), or the pharmacokinetics of digoxin or carvedilol (a vasodilator/beta-blocker). In healthy subjects, coadministration of torsemide was associated with significant reduction in the renal clearance of spironolactone with corresponding increases in the AUC. However, clinical experience indicates that dosage adjustment of either agent is not required. Possible interaction with high doses of salicylates may occur.

Pregnancy:

This drug should be used during pregnancy only if clearly needed.

Nursing mothers:

It is not known whether torsemide is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when administered to a nursing woman.

Warnings & Precautions:

Hepatic coma, pediatric use, hypokalemia.

Package:

Carton box containing 3 pvdc/aluminum strips. Each strip is 10 tablets with insert leaflet.

Storage:

keep out of reach of children.

keep at a temperature not exceeding 30°C in a dry place.

Information for Patients:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others; it may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- Don't stop toremide suddenly, blood pressure will return to pretreatment levels.

Produced by Medizen Pharmaceutical Industries for Utopia Pharmaceuticals.