

TORSERETIC – 5 mg- 10 mg -20mg -100mg tablet
TORSERETIC – 10mg/1ml injection
TORSERETIC – 20mg/2ml injection

DESCRIPTION

TORSERETIC(torsemide) is a diuretic of the pyridine-sulfonylurea class. **Inactive ingredient of tablet:** lactose monohydrate - Microcrystalline cellulose – povidone - Magnesium stearate – Croscarmellose-(Corspovidone - iron oxide red)TORSERETIC 100 mg only.

Inactive ingredient of ampoule: 400- Tromethamine- Sodium Hydroxide- Water for injection.

CLINICAL PHARMACOLOGY

Mechanism of Action

- Micropuncture studies have shown that torsemide acts from within the lumen of the thick ascending portion of the loop of Henle, where it inhibits the Na⁺/K⁺/2Cl⁻carrier system. Clinical pharmacology studies have confirmed this site of action in humans, and effects in other segments of the nephron have not been demonstrated. - Diuretic activity thus correlates better with the rate of drug excretion in the urine than with the concentration in the blood. - 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.

Pharmacokinetics and Metabolism

-The bioavailability of TORSERETIC tablets is approximately 80%, with little inter subject variation; the 90% confidence interval is 75%to 88%. The drug is absorbed with little first-pass metabolism, and the serum concentration reaches its peak (Cmax) within 1 hour after oral administration. Cmax and area under the serum concentration-time curve (AUC) after oral administration are proportional to dose over the range of 2.5 mg to 200 mg. Simultaneous food intake delays the time to C by about 30 minutes, but overall bioavailability (AUC) and diuretic activity are unchanged.

-The volume of distribution of torsemide is 12 liters to 15 liters in normal adults or in patients with mild to moderate renal failure or congestive heart failure. In patients with hepatic cirrhosis, the volume of distribution is approximately doubled. -In normal subjects the elimination half-life of torsemide is approximately 3.5 hours. Torsemide is cleared from the circulation by both hepatic metabolism and renal excretion. Inadequate oral intake and excretion into the urine (approximately 20% of total clearance inpatients with normal renal function). The major metabolite in humans is the carboxylic acid derivative, which is biologically inactive. Two of the lesser metabolites possess some diuretic activity, but for practical purposes metabolism terminates the action of the drug. -Because torsemide is extensively bound to plasma protein (>99%), very little enters tubular urine via glomerular filtration. Most renal clearance of torsemide occurs via active secretion of the drug by the proximal tubules into tubular urine.

-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. Because of reduced renal clearance, a smaller fraction of any given dose is delivered to the intraluminal site of action, so at any given dose there is less natriuresis in patients with congestive heart failure than in normal subjects. -In patients with renal failure, renal clearance of torsemide is markedly decreased but total plasma clearance is not significantly altered. A smaller fraction of the administered dose is delivered to the intraluminal site of action, and the natriuretic action of any given dose of diuretic is reduced. A diuretic response in renal failure may still be achieved if patients are given higher doses. The total plasma clearance and elimination half-life of torsemide remain, normal under the conditions of impaired renal function because metabolic elimination by the liver remains intact.

-In patients with hepatic cirrhosis, the volume of distribution, plasma half-life, and renal clearance are all increased, but total clearance is unchanged. -The pharmacokinetic profile of torsemide in healthy elderly subjects is similar to that in young subjects except for a decrease in renal clearance related to the decline in renal function that commonly occurs with aging. However, total plasma clearance and elimination half-life remain unchanged.

INDICATIONS AND USAGE

TORSERETIC 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. -TORSERETIC intravenous injection is indicated when a rapid onset of diuresis is desired or when oral administration is impractical. -TORSERETIC is indicated for the treatment of hypertension alone or in combination with other antihypertensive agents.

CONTRAINDICATIONS

TORSERETIC is contraindicated in patients with known hypersensitivity to torsemide or to sulfonylureas. TORSERETIC is contraindicated in patients who are anuric. **WARNINGS**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product as it contains lactose as inactive ingredient. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption should not take this medicine

Doses higher than 40mg shouldn't be used for hepatic failure patients and liver cirrhosis

Hepatic Disease with Cirrhosis and Ascites

-TORSERETIC should be used with caution in patients with hepatic disease with cirrhosis and ascites, since sudden alterations of fluid and electrolyte balance may precipitate hepatic coma. In these patients, diuresis with TORSERETIC (or any other diuretic) is best initiated in the hospital. To prevent hypokalemia and metabolic alkalosis, an aldosterone antagonist or potassium-sparing drug should be used concomitantly with TORSERETIC.

Ototoxicity -Tinnitus and hearing loss (usually reversible) have been observed after rapid intravenous injection of other loop diuretics and have also been observed after oral Torsemide. It is not certain that these events were attributable to Torsemide. Administered intravenously, TORSERETIC should be injected slowly over 2 minutes, and single doses should not exceed 200 mg. Volume and Electrolyte Depletion -Patients receiving diuretics should be observed for clinical evidence

of electrolyte imbalance, hypovolemia, or prerenal azotemia. Symptoms of these disturbances may include one or more of the following: dryness of the mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, nausea, and vomiting. Excessive diuresis may cause dehydration, blood-volume reduction, and possibly thrombosis and embolism, especially in elderly patients. In patients who develop fluid and electrolyte imbalances, hypovolemia, or prerenal azotemia, the observed laboratory changes may include hyper- or hyponatremia, hyper- or hypochloremia, hyper- or hypokalemia, acid-base abnormalities, and increased blood urea nitrogen (BUN). If any of these occur, TORSERETIC should be discontinued until the situation is corrected; TORSERETIC may be restarted at a lower dose.

-In patients with cardiovascular hypokalemia, especially those receiving digitalis glycosides, diuretic-induced hypokalemia may be a risk factor for the development of arrhythmias. The risk of hypokalemia is greatest in patients with cirrhosis of the liver. Inpatients experiencing a brisk diuresis, in patients who are receiving inadequate oral intake of electrolytes, and in patients receiving concomitant therapy with corticosteroids or ACTH. -Periodic monitoring of serum potassium and other electrolytes is advised in patients treated with TORSERETIC. -Hypokalemia is dose related.

PRECAUTIONS

Laboratory Values

-Potassium: See WARNINGS.

-Calcium: Single doses of TORSERETIC increased the urinary excretion of calcium by normal subjects, but serum calcium levels were slightly increased in 4- to 6-week hypertension trials.

-Magnesium: Single doses of TORSERETIC caused healthy volunteers to increase their urinary excretion of magnesium, but serum magnesium levels were slightly increased in 4- to 6-week hypertension trials.

-Blood Urea Nitrogen (BUN), Creatinine and Uric Acid: Torsemide produces small dose-related increases in each of these laboratory values. Little further change occurred with long-term treatment, and all changes reversed when treatment was discontinued. -Symptomatic gout has been reported in patients receiving torsemide, but its incidence has been similar to that seen in patients receiving other diuretics. -Glucose: Hypertensive patients who received 10 mg of daily TORSERETIC experienced a mean increase in serum glucose concentration of 5.5 mg/dL (0.3 mmol/L) after 6 weeks of therapy, with a further increase of 1.8 mg/dL (0.1 mmol/L) during the subsequent year. In long-term studies in diabetics, mean fasting glucose values were not significantly changed from baseline. Cases of hyperglycemia have been reported but are uncommon. -Serum Lipids : Daily doses of 5 mg, 10 mg, and 20 mg of Torsemide were associated with increases in total plasma cholesterol of 4, 4, and 8 mg/dL (0.10 to 0.20 mmol/L), respectively. The changes subsided during chronic therapy. daily doses of 5 mg, 10 mg and 20 mg of torsemide were associated with mean increases in plasma triglycerides of 16, 13 and 71 mg/dL (0.15 to 0.80 mmol/L), respectively.

-Other: Torsemide has been associated with small mean decreases in hemoglobin, hematocrit, and erythrocyte count and small mean increases in white blood cell count, platelet count, and serum alkaline phosphatase. -This product contains lactose .

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, TORSERETIC has been administered together with digitalis glycosides, ACE inhibitors, and organic nitrates. None of these combined uses was 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, but corresponding increases in the AUC. However, clinical experience indicates that dosage adjustment of either agent is not required. -Because TORSERETIC and salicylates compete for secretion by renal tubules, patients receiving high doses of salicylates may experience salicylate toxicity when TORSERETIC is concomitantly administered. Also, although possible interactions between torsemide and non steroidal anti-inflammatory agents (including aspirin) have not been studied, coadministration of these agents with another loop diuretic (furosemide) has occasionally been associated with renal dysfunction. -The natriuretic effect of TORSERETIC (like that of many other diuretics) is partially inhibited by the concomitant administration of indomethacin. This effect has been demonstrated for torsemide under conditions of dietary sodium restriction (50 mEq/day) but not in the presence of normal sodium intake (150 mEq/day).

-The pharmacokinetic profile and diuretic activity of torsemide are not altered by cimetidine or spironolactone. Coadministration of digoxin is reported to increase the area under the curve for torsemide by 50%, but dose adjustment of TORSERETIC is not necessary. -If TORSERETIC and cholestyramine are used concomitantly, simultaneous administration is not recommended.

-Coadministration of probenecid reduces secretion of Torsemide into the proximal tubule and thereby decreases the diuretic activity of TORSERETIC.

-Other diuretics are known to reduce the renal clearance of lithium, inducing a high risk of lithium toxicity, so coadministration of lithium and diuretics should be undertaken with great caution, if at all. Coadministration of lithium and torsemide has not been studied.

-Other diuretics have been reported to increase the Torsemide potential of aminoglycoside antibiotics and of ethacrynic acid, especially in the presence of impaired renal function.

PREGNANCY:

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

Labor and Delivery

The effect of TORSERETIC on labor and delivery is unknown.

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 TORSERETIC is administered to a nursing woman.

PEDIATRIC USE:

Safety and effectiveness in pediatric patients have not been established.

GERIATRIC USE:

No specific age-related differences in effectiveness or safety were observed between younger patients and elderly patients.

ADVERSE REACTIONS

The most common were (in descending order of frequency) dizziness, headache, nausea, weakness, vomiting, hyperglycemia, excessive urination, hyperuricemia, hypokalemia, excessive urine, hypotension, impotence, esophageal hemorrhage, and dyspepsia. Dropout rates for these adverse events ranged from 0.1% to 0.5%.

The side effects considered possibly in more than 1% of patients on torsemide: Headache, Excessive Urination, Dizziness, Rhinitis, Asthenia,

Diarrhea, ECG Abnormality, Cough Increase, Constipation, Nausea, Arthralgia, Dyspepsia, Sore Throat, Myalgia, Chest Pain, Insomnia,

edema, Nervousness. Serious adverse events reported in the clinical studies for which a drug relationship could not be excluded were atrial fibrillation, chest pain, diarrhea, digitalis intoxication, gastrointestinal hemorrhage, hyperglycemia, hyperuricemia, hypokalemia, hypotension, hyperglycemia, shunt thrombosis, rash, rectal bleeding, syncope, and ventricular tachycardia. Angioedema has been reported in a patient exposed to Torsemide who was later found to be allergic to sulfa drugs. Arthritis and various other nonspecific musculoskeletal problems were reported. Hypokalemia .

OVERDOSAGE

There is no human experience with overdoses of TORSERETIC, but the signs and symptoms of over dosage can be anticipated to be those of excessive pharmacologic effect: dehydration, hypovolemia, hypotension, hyponatremia, hypokalemia, hypochloremic, alkalosis, and hemoconcentration. Treatment of over dosage should consist of fluid and electrolyte replacement.

DOSSAGE AND ADMINISTRATION

General

-TORSERETIC tablets may be given at any time in relation to a meal, as convenient. Special dosage adjustment in the elderly is not necessary.

-Because of the high bioavailability of TORSERETIC, oral and intravenous doses are therapeutically equivalent, so patients may be switched to and from the intravenous form with no change in dose. -TORSERETIC intravenous injection should be administered either slowly as a bolus over a period of 2 minutes or administered as a continuous infusion.

-If TORSERETIC is administered through an IV line, it is recommended that, as with other IV injections, the IV line be flushed with Normal Saline (Sodium Chloride Injection, USP) before and after administration. TORSERETIC injection should be used with caution.

8.3.Flushing the line is recommended to avoid the potential for incompatibilities caused by differences in pH which could be indicated by color change, haziness or the formation of a precipitate in the solution.

-If TORSERETIC is administered as a continuous infusion, stability has been demonstrated through 24 hours at room temperature: in plastic containers for the following fluids and concentrations:

200 mg TORSERETIC (10 mg/mL) added to: 250 mL Dextrose 5% in water 250 mL 0.9% Sodium Chloride 500 mL 0.45% Sodium Chloride 50 mg TORSERETIC (10 mg/mL) added to: 500 mL Dextrose 5% in water 500 mL 0.9% Sodium Chloride 500 mL 0.45% Sodium Chloride

**Before administration, the solution of TORSERETIC should be visually inspected for discoloration and particulate matter. If either is present, the ampoule should not be used.

Congestive Heart Failure

The usual initial dose is 10 mg or 20 mg of once-daily oral or intravenous TORSERETIC. 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

The usual initial dose of TORSERETIC is 20 mg of once-daily oral or intravenous TORSERETIC. If the response is inadequate, the dose should be titrated upward by approximately doubling until the desired diuretic response is obtained. Single doses higher than200 mg have not been adequately studied.

Hepatic Cirrhosis

The usual initial dose is 5 mg or 10 mg of once-daily oral or intravenous TORSERETIC, 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.

Hypertension

The usual 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.

PACKAGE:

For TORSERETIC 5mg &100mg Tablets :Carton box containing 1,2 or 3 transparent colorless PVCDC/AL strips, each strip of 10 tablets + insert leaflet

For TORSERETIC 10 mg & 20 mg Tablets :Carton box containing 1 or 3 transparent colorless PVCDC/AL strips, each strip of 10 tablets + insert leaflet

For TORSERETIC 20 mg/2ml ampoule :Carton box containing 3, 5, 10, 50 clear colorless glass ampoules type I of 2 ml solution with an insert leaflet.

For TORSERETIC 10mg/1ml ampoule :Carton box containing 3, 5, 10, 50 clear colorless glass ampoules type I of 1ml solution with an insert leaflet.

Keep out of reach of children .

PRODUCED BY:

Tablets: Future Pharmaceutical Industries for Utopia pharmaceuticals

Ampoules: Global pharmaceutical industries 2 for Utopia pharmaceuticals



الحوي العالي للتورسيبتك ، لذلك يمكن أن يغير المريض كيفية تناول تورسيبتك من الملم إلى الوريد أو العكس دون تغير الجرعة . ستعطى حقن تورسيبتك إما في الوريد ببطء على مدى دقيقتين أو بالتقطيط الوريدي.

- من المستحسن أن يحقن الوريد بحلول كلوريد الصوديوم قبل وبعد الحقن ب تورسيبتك حقن.

- عند أخذ تورسيبتك بالتقطيط الوريدي المستمر فيمكن حفظه في درجة حرارة الغرفة لمدة ٢٤ ساعة في حاويات بلاستيكية للنسائل وتركيزات الوريدية.

٢٠٠ مجم (تورسيبتك ١٠٠مجم/ملي) تصاف إلى: ٢٥٠ مللى دكستروز ٥٪ في الماء ٢٥٠ مللى ٢٠٠ ٪ كلوريد الصوديوم ٥٠٠ مللى ٥٠ ٪ كلوريد الصوديوم ٥٠٠ مجم (تورسيبتك ١٠٠مجم/ملي) تصاف إلى: ٥٠٠ مللى دكستروز ٥٪ في الماء ٥٠٠ مللى ٥٠ ٪ كلوريد الصوديوم ٥٠٠ مللى ٥٠ ٪ كلوريد الصوديوم ** ٢٠٠ مجم بشكل كاف.

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٢٠٠ مجم بشكل كاف.

٢٠٠ مجم (تورسيبتك ١٠٠مجم/ملي) تصاف إلى: ٢٥٠ مللى دكستروز ٥٪ في الماء ٢٥٠ مللى ٢٠٠ ٪ كلوريد الصوديوم ٥٠٠ مللى ٥٠ ٪ كلوريد الصوديوم ٥٠٠ مجم (تورسيبتك ١٠٠مجم/ملي) تصاف إلى: ٥٠٠ مللى دكستروز ٥٪ في الماء ٥٠٠ مللى ٥٠ ٪ كلوريد الصوديوم ٥٠٠ مللى ٥٠ ٪ كلوريد الصوديوم

٢٠٠ مجم بشكل كاف.

٢٠٠ مجم (تورسيبتك ١٠٠مجم/ملي) تصاف إلى: ٢٥٠ مللى دكستروز ٥٪ في الماء ٢٥٠ مللى ٢٠٠ ٪ كلوريد الصوديوم ٥٠٠ مللى ٥٠ ٪ كلوريد الصوديوم ٥٠٠ مجم (تورسيبتك ١٠٠مجم/ملي) تصاف إلى: ٥٠٠ مللى دكستروز ٥٪ في الماء ٥٠٠ مللى ٥٠ ٪ كلوريد الصوديوم ٥٠٠ مللى ٥٠ ٪ كلوريد الصوديوم

٢٠٠ مجم بشكل كاف.

٢٠٠ مجم (تورسيبتك ١٠٠مجم/ملي) تصاف إلى: ٢٥٠ مللى دكستروز ٥٪ في الماء ٢٥٠ مللى ٢٠٠ ٪ كلوريد الصوديوم ٥٠٠ مللى ٥٠ ٪ كلوريد الصوديوم ٥٠٠ مجم (تورسيبتك ١٠٠مجم/ملي) تصاف إلى: ٥٠٠ مللى دكستروز ٥٪ في الماء ٥٠٠ مللى ٥٠ ٪ كلوريد الصوديوم ٥٠٠ مللى ٥٠ ٪ كلوريد الصوديوم

٢٠٠ مجم بشكل كاف.

٢٠٠ مجم (تورسيبتك ١٠٠مجم/ملي) تصاف إلى: ٢٥٠ مللى دكستروز ٥٪ في الماء ٢٥٠ مللى ٢٠٠ ٪ كلوريد الصوديوم ٥٠٠ مللى ٥٠ ٪ كلوريد الصوديوم ٥٠٠ مجم (تورسيبتك ١٠٠مجم/ملي) تصاف إلى: ٥٠٠ مللى دكستروز ٥٪ في الماء ٥٠٠ مللى ٥٠ ٪ كلوريد الصوديوم ٥٠٠ مللى ٥٠ ٪ كلوريد الصوديوم

٢٠٠ مجم بشكل كاف.

٢٠٠ مجم (تورسيبتك ١٠٠مجم/ملي) تصاف إلى: ٢٥٠ مللى دكستروز ٥٪ في الماء ٢٥٠ مللى ٢٠٠ ٪ كلوريد الصوديوم ٥٠٠ مللى ٥٠ ٪ كلوريد الصوديوم ٥٠٠ مجم (تورسيبتك ١٠٠مجم/ملي) تصاف إلى: ٥٠٠ مللى دكستروز ٥٪ في الماء ٥٠٠ مللى ٥٠ ٪ كلوريد الصوديوم ٥٠٠ مللى ٥٠ ٪ كلوريد الصوديوم

٢٠٠ مجم بشكل كاف.

٢٠٠ مجم (تورسيبتك ١٠٠مجم/ملي) تصاف إلى: ٢٥٠ مللى