Tyrodin®

Cinacalcet

Description

Tyrodin® is the preparation of Cinacalcet; it is a calcimimetic agent which lowers parathyroid hormone (PTH) levels by increasing the sensitivity of the calcium sensing receptors of the parathyroid gland. It binds to the transmembrane region of the calcium-sensing receptor, which leads to a different structural configuration that is more sensitive to serum calcium. Cinacalcet works by controlling the levels of parathyroid hormone (PTH), calcium and phosphorus in body.

Indications

Tyrodin® is indicated:

- For the treatment of secondary hyperparathyroidism in patients with chronic kidney disease on dialysis
- For the treatment of hypercalcemia in patients with parathyroid carcinoma
- For the treatment of hypercalcaemia in patients with primary hyperparathyroidism who still have high calcium level after removal of the parathyroid gland

Dosage and administration

Dosage of Tyrodin® must be individualized. Tyrodin® should be taken with food or shortly after a meal.

Secondary hyperparathyroidism in patients with end-stage renal disease on dialysis (Adult over 18 years):

The recommended starting dose of Tyrodin® is 30 mg once daily, adjusted every 2–4 weeks through sequential doses of 60 mg, 90 mg and 120 mg to maximum 180 mg once daily to target PTH consistent with the recommendation for CKD patients on dialysis of 150-300 pg/mL.

Note: Serum calcium and serum phosphorus should be measured within 1 week and PTH should be measured 1 to 4 weeks after initiation or dose adjustment of Tyrodin®. PTH levels should be assessed no earlier than 12 hours after dosing with Tyrodin®.

Hypercalcaemia of primary hyperparathyroidism or parathyroid carcinoma (Adult over 18 years): The recommended starting dose of Tyrodin® is 30 mg twice daily, adjusted every 2–4 weeks according to response through sequential doses of 30 mg twice daily, 60 mg twice daily, 90 mg twice daily and 90 mg three or four times daily (maximum 90 mg 4 times daily) as necessary to normalize serum calcium levels.

Geriatric Use: No dosage adjustment is required for geriatric patients over 65 years of age.

Patients with renal impairment: No dosage adjustment is necessary for renal impaired patients

Patients with hepatic impairment: In patients with moderate and severe hepatic impairment, PTH and serum calcium concentrations should be closely monitored throughout treatment with Cinacalcet.

Pediatric use: The safety and efficacy of Cinacalcet in pediatric patients have not been established

Use in pregnancy & lactation

There are no adequate and well-controlled studies in pregnant women. Cinacalcet should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It

is not known whether this drug is excreted in human milk. Considering the potential for clinically significant adverse reactions in infants from Cinacalcet; it is recommended that breast-feeding be discontinued during treatment with Cinacalcet.

Precautions
Cinacalcet treatment should not be initiated if serum calcium is less than the lower limit of the normal range (8.4 mg/dL). Serum-calcium concentration should be measured before initiation of treatment and within 1 week after starting treatment or adjusting dose, then monthly for secondary hyperparathyroidism and every 2–3 months for primary hyperparathyroidism and parathyroid carcinoma; treatment should not be initiated in patients with hypocalcaemia; in secondary hyperparathyroidism PTH concentration should be measured 1–4 weeks after starting treatment or adjusting dose, then every 1–3 months; dose adjustment may be necessary if smoking started or stopped during treatment; hepatic impairment; pregnancy.

Side effects
The common side effects of Cinacalcet are nausea, vomiting, anorexia; dizziness, paraesthesia, asthenia; reduced testosterone concentrations; myalgia; rash; less commonly dyspepsia, diarrhoea, and seizures; hypotension and heart failure also reported.

Drug interactions
Cinacalcet is metabolized in part by the enzyme CYP3A4. Co-administration of ketoconazole, a strong inhibitor of CYP3A4, caused an approximate 2-fold increase in cinacalcet exposure. Dose adjustment of Cinacalcet may be required and PTH and serum calcium concentrations should be closely monitored if a patient initiates or discontinues therapy with a strong CYP3A4 inhibitor (e.g., ketoconazole, erythromycin, itraconazole).

Contraindications
Cinacalcet is contraindicated in patients with hypersensitivity to any components of this product.

Overdose
Doses titrated up to 300 mg once daily have been safely administered to patients on dialysis. Overdosage of Cinacalcet may lead to hypocalcemia. In the event of overdosage, patients should be monitored for signs and symptoms of hypocalcemia and appropriate measures taken to correct serum calcium levels. Since Cinacalcet is highly protein bound, hemodialysis is not an effective treatment for overdosage of Cinacalcet.

Pharmaceutical precautions
Store in a cool dry place below 30ºC. Protect from light

Presentations
Tyrodin® 30mg tablet: Each tablet contains Cinacalcet hydrochloride INN 30mg

Package quantities
Tyrodin® 30mg tablet: Each box contains Cinacalcet hydrochloride INN 30mg

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ACI Limited
Narayanganj, Bangladesh.