



רופאה נכבד/ה,
רוקח/ת נכבד/ה,

אבוט מעבדות רפואית בע"מ מודיעה כי העלון לרופא של התכשירים הבאים עודכנו. בהודעה זו מצוינים סעיפים בהם נעשה שינוי אשר מהווה החמרה או שינוי מהותי. עדכונים נוספים אשר אינם מהווים החמרה או שאינם מהותיים, אינם נכללים בהודעה זו (שינוי שהינו הוספה מסומן בקו תחתון, מחיקה מסומנת בקו אמצעי).

Zemplar 5 mcg/ml Solution for Injection
זמפאר 5 מק"ג/מ"ל תמיסה להזרקה
Solution for Injection
Paricalcitol 5 mcg/ml

ההתוויות המאושרות לתכשיר:
Paricalcitol is indicated for the prevention and treatment of secondary hyperparathyroidism associated with chronic renal failure.

העלון לרופא עודכן בסעיפים:

4. Clinical Particulars

מהות השינוי:

4.2 Posology and method of administration

Suggested Dosing Guidelines (Dose adjustments at 2 to 4 week intervals)	
iPTH Level Relative to Baseline	Paricalcitol Dose Adjustment
Same or increased	Increase by 2 to 4 micrograms
Decreased by < 30%	
Decreased by $\geq 30\%$, $\leq 60\%$	Maintain
Decreased > 60%	Decrease by 2 to 4 micrograms
iPTH < 15.9 pmol/l (150 pg/mL)	

4.4 Special warnings and precautions for use

Over suppression of parathyroid hormone may result in elevations of serum calcium levels and may lead to metabolic bone disease. Patient monitoring and individualised dose titration are required to reach appropriate physiological endpoints.

Chronic hypercalcaemia may be associated with generalized vascular calcification and other soft tissue calcification.

4.5 Interaction with other medicinal products and other forms of interaction

Ketoconazole is known to be a non-specific inhibitor of several cytochrome P450 enzymes. The available in vivo and in vitro data suggest that ketoconazole may interact with enzymes that are responsible for the metabolism of paricalcitol and other vitamin D analogs. Caution should be taken while dosing paricalcitol with ketoconazole. The effect of multiple doses of ketoconazole administered as 200 mg, twice daily (BID) for 5 days on the pharmacokinetics of paricalcitol capsule has been studied in healthy subjects. The C_{max} of paricalcitol was minimally affected, but AUC_{0-∞} approximately doubled in the presence of ketoconazole. The mean half-life of paricalcitol was 17.0 hours in the presence of ketoconazole as compared to 9.8 hours, when paricalcitol was administered alone. The results of this study indicate that following oral administration of paricalcitol the maximum amplification of the paricalcitol AUC_∞ from a drug interaction with ketoconazole is not likely to be greater than about two-fold.



4.6 Pregnancy and lactation

Lactation:

Animal studies have shown excretion of paricalcitol or its metabolites in breast milk, in small amounts. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with paricalcitol should be made taking into account the benefit of breast-feeding to the child and the benefit of paricalcitol therapy to the woman.

4.8 Undesirable effects

System Organ Class	Preferred Term	Frequency
Investigations	Bleeding time prolonged, aspartate aminotransferase increased, <u>laboratory test abnormal</u> , weight decreased	Uncommon
Gastrointestinal disorders	Rectal haemorrhage, colitis, diarrhoea, gastritis, dyspepsia, dysphagia, <u>abdominal pain</u> , constipation, nausea, vomiting, dry mouth, gastrointestinal disorder	Uncommon
	<u>Gastrointestinal haemorrhage</u>	unknown
Metabolism and nutrition disorders	Hypercalcaemia, Hyperphosphataemia	Common
	<u>Hyperkalaemia, hypocalcemia, anorexia</u>	Uncommon
General disorders and administration site conditions	Gait disturbance, oedema, Peripheral oedema , pain, injection site pain, pyrexia, chest pain, <u>condition aggravated</u> , asthenia, malaise, thirst	Uncommon

4.9 Overdose

Overdosage of paricalcitol may lead to hypercalcaemia , hypercalciuria, hyperphosphatemia, and over suppression of PTH .

6. Pharmaceutical particulars

מהות השינוי:

6.4 Special precautions for storage

Below 30°C.

העלון המעודכן לרופא נשלח למאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום, אבט מעבדות בע"מ, קריית עתידים בניין 4, ת.ד. 58099 תל אביב או בטלפון 03-7691037.

בברכה,

נעמי רביב
רוקחת ממונה