

ABSTRACT

Safety Aspects of Calcipotriol Treatment

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When excessive doses of vitamin D – including calcipotriol – are used, there is a risk of D hypervitaminosis. In cases of mild overdosage, the physiological control mechanisms cause compensatory hypercalciuria, whereas with true overdosage, hypercalcaemia develops.

Hypercalcaemia is a result of increased calcium absorption from the gut and resorption of bone. Symptoms which may arise include malaise, headache, drowsiness, constipation, polydipsia, polyuria, muscle weakness, fatigue, irritability, nausea and vomiting. Chronic hypercalcaemia can result in urinary stones, soft tissue calcification in blood vessels, myocardium and cornea, nephrocalcinosis, and renal failure. Furthermore, hypercalciuria alone can cause urinary stones.

The extensive clinical research performed on topical calcipotriol has indicated a high degree of safety. Serum calcium was monitored during all the clinical studies performed on this compound, and none has shown a significant rise in the mean level, even in long-term use. Fewer data are available regarding urine calcium excretion during calcipotriol treatment.

Three studies have failed to demonstrate any increase in 24-hour calcium excretion in patients using up to 100 g of ointment weekly. Furthermore, no changes have been detected in other biochemical markers of calcium and vitamin D₃ metabolism.

As of today there are 4 cases of hypercalcaemia during calcipotriol treatment of psoriasis. These patients used, against the guidelines, between 150 g and 490 g of calcipotriol ointment per week. Symptoms of hypercalcaemia developed in only 1 of the 4 patients. In all cases the hypercalcaemia disappeared within a few days of discontinuing treatment. Three further cases of marginally increased serum calcium have been observed after use of between 70 g and 83 g of calcipotriol ointment per week.

Of the 7 patients with marginal or frank hypercalcaemia, 3 had renal impairment or previous urinary stones.

On current evidence, monitoring of serum or urine calcium does not appear necessary, provided less than 100 g of calcipotriol ointment is used weekly.

However, if quantities above this limit are required, it is essential to monitor the serum calcium closely.

REFERENCES

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