

MESSAGE FROM DR PAT TROOP, DEPUTY CHIEF MEDICAL OFFICER
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DEPARTMENT OF HEALTH

30 November 2000

CEM/CMO/2000/17

Dear Colleague

**POTENTIAL FOR ERROR IN PRESCRIBING AND DISPENSING OF
ALFACALCIDOL - ONE-ALPHA DROPS 2 microgram/ml**

I am writing to inform you of the possibility of error in prescribing and dispensing of alfacalcidol, One-Alpha drops 2 micrograms/ml.

Alfacalcidol is indicated for the prevention and treatment of renal bone disease, vitamin D dependent and hypophosphataemic rickets, hypoparathyroidism and neonatal hypocalcaemia.

A new, high-strength formulation of alfacalcidol, One-Alpha drops was introduced in July 2000. It contains alfacalcidol in a concentration 10 times stronger than the former presentation One-Alpha Solution, 0.2 micrograms/ml. One-Alpha solution was discontinued by the company in September 2000. Therefore if the prescription for alfacalcidol is written in MLS rather than MICROGRAMS there is the potential for a patient to be given a dose 10 times that intended.

In neonates, One-Alpha drops is licensed at a dose of 0.05 - 0.1 mcg/kg/day. One Alpha drops, 2 mcg/ml is administered using a dropper. One drop contains 0.1 mcg of alfacalcidol (100 ng). It is therefore not possible to administer this preparation undiluted to those neonates who may require a lower dose than 0.1 mcg (100 ng).

ACTION:

The Medicines Control Agency (MCA) is urgently investigating this issue. In the meantime, the MCA are providing the following advice:

1. Doctors, pharmacists and nurses are advised to be vigilant when prescribing, dispensing and administering alfacalcidol, One-Alpha drops. The dose should be stated in MICROGRAMS and not MLS, and the frequency of administration should also be stated.
2. We advise that all children who have been prescribed alfacalcidol in the last four months should be reviewed.
3. Careful instructions on dosing should be given to parents when prescribing or dispensing One-Alpha drops.
4. Please report any suspected adverse reactions to alfacalcidol, including overdoses through the Yellow Card scheme.

Should you require any further information, please telephone the Medicines Control Agency on 0207 273 0000.

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