SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

AT10

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Dihydrotachysterol BP 0.025% w/v

3. PHARMACEUTICAL FORM

Oily solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

AT10 is recommended for use in acute, chronic and latent forms of hypocalcaemic tetany due to hypoparathyroidism where its action is to increase the rate of absorption and utilisation of calcium.

4.2 Posology and method of administration

Adults (and the elderly):
In acute cases 3-5ml may be given on each of the first three days of treatment, followed two to three days later by blood and urinary calcium estimations. The maintenance dose of AT10 is usually within the range of 1-7ml each week, but the precise amount depends on the results of serum and urinary calcium determinations. In chronic cases an initial dose of 2ml of AT10 daily, or on alternate days, may be sufficient to maintain normocalcaemia in moderate cases. The dose of AT10 usually has to be increased during menstruation and periods of unusual activity.

Children
No specific dosage recommendations.
Route of Administration
Oral.

4.3 Contraindications
Hypersensitivity to dihydrotachysterol.
Hypercalcaemia.
Hypervitaminosis D.
Allergy to nuts (including peanuts).

4.4 Special warnings and special precautions for use
AT10 contains Arachis oil (peanut oil) and should not be taken by patients known to be allergic to peanut. As there is a possible relationship between allergy to peanut and allergy to Soya, patients with Soya allergy should also avoid AT10.
As with calciferol, uncontrolled prolonged administration of AT10 can result in hypercalcaemia which may lead to nephrocalcinosis. Therefore accurate blood calcium determinations must be made at the beginning of treatment and then periodically until the required maintenance dose has been established. The serum calcium level should subsequently be kept between 2.25-2.5mmol/litre. Serum phosphate, magnesium, and alkaline phosphatase should also be measured periodically to monitor progress.
If nausea and vomiting are present, serum calcium level should be checked.
Monitoring of calciuria is a convenient supplement to blood calcium determinations, but it should not be regarded as a substitute because in hypoparathyroid patients treated with AT10 hypercalciuria can occur in the presence of hypocalcaemia.
Certain individuals, particularly those suffering from sarcoidosis, are very sensitive to the effect of Vitamin D and it is advisable to consult a physician in cases of doubt.

4.5 Interactions with other medicinal products and other forms of interaction
Several classes of medicine interact with Vitamin D analogues calling for adjustment in the dosage of AT10. Thyroid replacement therapy may increase clearance of dihydrotachysterol; cholestyramine may impair its absorption; thiazide diuretics may enhance the calcaemic response leading to hypercalcaemia; barbiturates, anticonvulsants, rifampicin and isoniazid may reduce the effectiveness of AT10. Hypercalcaemia induced by excessive dosaging of AT10 may enhance the toxic effects of cardiac glycosides.
4.6 Fertility, pregnancy and lactation

The safety of dihydrotachysterol in pregnancy is not established. Since there is some evidence that use during pregnancy could lead to foetal damage and hypercalcaemia in the newborn, treatment with AT 10 is only justified if potential benefits outweigh possible risks. Dihydrotachysterol is excreted in breast milk and may cause hypercalcaemia in the suckling infant. AT 10 is contraindicated in breast feeding mothers.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Side effects are most likely to be due to hypercalcaemia, the first signs of which are loss of appetite, listlessness and nausea.

More severe manifestations include vomiting, urgency of micturition, polyuria, dehydration, thirst, vertigo, stupor, headache, abdominal cramps and paralysis.

The calcium and phosphorus concentrations of serum and urine are increased.

With chronic overdosage, calcium may be deposited in many tissues, including arteries and the kidneys, leading to hypertension and renal failure. Plasma cholesterol may also be increased.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Treatment
The symptoms of hypercalcaemia in chronic overdosage will usually respond to withdrawal of medication, bed rest, liberal fluid intake and the use of laxatives.

In acute overdosage, consideration should be given to recovery of AT10 by emesis or gastric lavage if ingestion is recent. Serum calcium estimations should be helpful in determining management.

In massive overdosage of Vitamin D, corticosteroids have been found useful and also neutral phosphate in resistant cases. Several months management may be needed in such cases.
5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Dihydrotachysterol is a synthetic analogue of Vitamin D and is used in the treatment of hypoparathyroidism. However, it is not useful in the treatment of rickets since its antirachitic activity is considerably weaker than that of Vitamin D. The actions of dihydrotachysterol resemble those of calciferol and Vitamin D₃. It promotes the absorption of calcium from the intestine and the mobilisation of calcium from bone as effectively as calciferol. Dihydrotachysterol acts more rapidly and is more rapidly eliminated than calciferol and its action is therefore more readily controlled; in practice, calciferol is generally used for the treatment of Vitamin D deficiency and dihydrotachysterol for other conditions.

5.2 Pharmacokinetic properties

Vitamin D substances are well absorbed from the gastro-intestinal tract. The presence of bile is essential for adequate intestinal absorption; absorption may be decreased in patients with decreased fat absorption. Vitamin D compounds and their metabolites are excreted mainly in the bile and faeces with only small amounts appearing in urine.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Arachis oil, Sodium sulphate anhydrous.
6.2 Incompatibilities

None.

6.3 Shelf life

48 months.
Use within 4 months after first opening.

6.4 Special precautions for storage

Store in well-closed containers protected from heat and light.

6.5 Nature and contents of container

15ml bottles with a 1ml dropper.
Pack size: 15ml.

6.6 Instructions for use/handling

None.

Administration Details

7 MARKETING AUTHORISATION HOLDER

Intrapharm Laboratories Limited
The Courtyard Barns
Choke Lane
Maidenhead
Berkshire SL6 6PT
United Kingdom

8. MARKETING AUTHORISATION NUMBER
9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/04/1999

10 DATE OF REVISION OF THE TEXT

23/06/2014