SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Crampex Tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Cholecalciferol Ph.Eur. 0.02 mg
Calcium Gluconate Ph.Eur. 200 mg
Nicotinic Acid Ph.Eur. 20 mg

For full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Tablet.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

For night muscle cramp.

4.2 Posology and method of administration

Adults and the Elderly:

One or two tablets with plenty of fluid, preferably before retiring. Attacks of cramp usually occur in bouts which last from a few days to several weeks. Often there are several weeks between each series of attacks. In such cases, it is advisable to take Crampex Tablets at night for a period and then discontinue when the anticipated duration of the attack has passed.

Drink plenty of fluids whilst taking this product.

The product should be used for a maximum of 4 weeks for any one attack of night cramps.

Children:

Not recommended for use in children under 18 years.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

Contraindicated for use in hypercalcaemia, for use in those with, or who have had kidney stones.

4.4 Special warnings and precautions for use

Not recommended for use in children.
Consult a doctor if the tablets have not taken effect within a week of starting treatment.
Do not exceed the stated dose.
Keep all medicines out of the reach and sight of children.
Duration of treatment should be minimised in patients with impaired renal function.
Use with caution in patients with hypertension.
Use with caution in patients with a history of peptic ulcer disease, diabetes mellitus, gout, or impaired liver function.

4.5. Interactions with other medicinal products and other forms of interaction

Use with caution in patients taking Digitalis.

4.6. Pregnancy and lactation

There are no known effects with the use of this product during pregnancy and lactation. This product should be avoided in pregnancy or breast feeding.

4.7. Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Nicotinic acid may cause flushing, pruritus, dizziness, headache, nausea, vomiting and rarely impaired liver function. Calcium supplements may cause mild gastrointestinal disturbances.

Frequency of reports cannot be estimated from the available data.

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

High doses of nicotinic acid may cause hyperpigmentation, abdominal cramps, diarrhoea, nausea and vomiting, anorexia, activation of peptic ulcer, jaundice, impairment of liver function, decrease in glucose tolerance, hyperglycaemia and hyperuricaemia. Excessive intake of calcium salts and vitamin D may lead to hypercalcaemia. Toxic effects should normally subside without treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

A12A X-Calcium, combinations with other drugs.

Crampex Tablets contain three active ingredients, calcium gluconate, nicotinic acid and Cholecalciferol. The inclusion of calcium gluconate is intended to correct any sub-clinical deficiency of calcium that may exist. The vitamin D status of the elderly may border on the deficient and as their vitamin D intake is often inadequate, Cholecalciferol is contained in the formulation to ensure satisfactory calcium absorption. As it is possible that a poor peripheral circulation may be an aggravating factor in the induction of cramps, the formulation includes the vasodilator, nicotinic acid.

5.2. Pharmacokinetic properties

None stated.

5.3. Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium Stearate
Povidone
Sodium Lauryl Sulfate
Starch Maize
Talc (E553 b).
Pre-gelatinised starch

6.2. Incompatibilities

None Stated.

6.3. Shelf life

Three years.

6.4. Special precautions for storage

No special precautions.

6.5 Nature and contents of container

Blisters comprising 20µ Aluminium Foil with 240µ uPVC. The uPVC is principally clear amber but alternatively opaque white. The blisters are contained in printed cartons 12, 24 or 48 tablets.

6.6. Instruction for use, handling and disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Limited
Linthwaite
Huddersfield
West Yorkshire
HD7 5QH
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

PL 00240/0082

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/11/2005

10 DATE OF REVISION OF THE TEXT

18/02/2016