Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Crampex TabletsCholecalciferol 0.02 mgCalcium Gluconate 200 mgNicotinic Acid 20 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Colecalciferol	20	micrograms
Calcium Gluconate	200	mg
Nicotinic Acid	20	mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet
Flat, circular bevel-edged white tablets with the word 'Crampex' engraved on one face.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For treatment of night muscle cramp.

4.2 Posology and method of administration

Oral.

Adults only (including elderly):
1 or 2 tablets before retiring.

Children:
Not recommended.

4.3 Contraindications

Hypersensitivity to any of the ingredients.
Do not use in patients with hypercalcaemia.

4.4 Special warnings and precautions for use

Duration of treatment should be minimised in patients with impaired renal function or a tendency to form kidney stones.

Use with caution in patients with hypertension, a history of peptic ulcer disease, diabetes mellitus, gout or impaired liver function.

Not recommended for use in children.

Prolonged use is not recommended.

4.5 Interaction with other medicinal products and other forms of interactions

Use with caution in patients taking digitalis.

4.6 Fertility, pregnancy and lactation

This product should not be used during pregnancy or in women breast feeding infants.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Side effects may include erythema, itching or urticaria. Occasionally, hot flushes in sensitive individuals.
Nicotinic acid may cause dizziness, headache, nausea, vomiting and rarely impaired liver function.
Calcium supplements may cause mild gastrointestinal disturbances.

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 of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:
HPRA Pharmacovigilance
Earlsfort Terrace
IRL-Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

4.9 Overdose

Toxic effects should normally subside without treatment.

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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, colecalciferol 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 laurilsulfate
Maize starch
Pregelatinised starch
Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

Blisters comprising 20 µm Aluminium Foil with 240 µm uPVC. The uPVC is principally clear amber but alternatively opaque white. The blisters are contained in printed cartons of 12, 24, 36 or 48 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Clonmel Healthcare Ltd
Waterford Road
Clonmel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0126/318/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 April 1993

Date of last renewal: 23 April 2008

10 DATE OF REVISION OF THE TEXT

May 2019