

IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0610/011/001
Case No: 2035670

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Thornton & Ross Limited

Linthwaite, Huddersfield, HD7 5QH, England

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Transvasin Heat Rub Cream

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **09/05/2007**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Transvasin Heat Rub Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ethyl nicotinate	2	% w/w
Hexyl nicotinate	2	% w/w
Tetrahydrofurfuryl salicylate	14	% w/w

Excipients: contains 8.25% w/w cetostearyl alcohol and 0.10% w/w methylparahydroxybenzoate

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cream

A white to pale cream coloured cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief of rheumatic and muscular pain and the symptoms of sprains and strains.

4.2 Posology and method of administration

Adults, children and elderly

Quantities are not critical and are not specified on the data sheet. The amount used should be consistent with the directions for use, and will vary with the size of the treated area.

Massage gently into the affected area until the cream is entirely absorbed. Apply at least twice daily until the symptoms abate.

4.3 Contraindications

Promotion to doctors

Transvasin should not be used by patients with known hypersensitivity to the product or any of its ingredients.

Labelling (sold direct to the public)

Not to be used by patients with known hypersensitivity to the product or any of its ingredients.

4.4 Special warnings and precautions for use

Promotion to doctors

Transvasin should not be applied to broken or sensitive skin, for example around the eyes or scrotal skin. Avoid use on mucous membranes.

Labelling (sold direct to the public)

Not to be used on broken or sensitive skin. For external use only.
Not suitable for use in children under 12 years except under medical advice.
If symptoms persist consult your doctor.
Discontinue use if excessive irritation occurs.

Transvasin is a rubefacient, and within a few minutes of application a sensation of warmth is felt, followed by a reddening of a skin. This erythema does not indicate intolerance.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Although there have been no reports of any adverse effects, as with all other medicines, care should be taken when administering to pregnant or lactating women.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Reported effects have taken the form of localised sensitisation reactions and have invariably subsided following withdrawal of medication.

4.9 Overdose

Overdose is unlikely when applied externally. Ingestion of very large amounts may result in symptoms of salicylate toxicity e.g. dizziness, tinnitus, deafness, nausea, vomiting, headache and mental confusion. No special measures are necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ethyl nicotinate, hexyl nicotinate and tetrahydrofurfuryl salicylate are all counter irritants.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl alcohol
Stearic acid
Polysorbate 20 (E432)
Sorbitan stearate (E491)
Methyl parahydroxybenzoate (E218)
Perfume (perfume 3679E, *consisting of* terpineol, phenylethyl alcohol, spike lavender oil)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Collapsible aluminium tubes with membrane. Polyamide-imide lacquer internal coating. Polypropylene piercer cap packed in a cardboard outer. Contains 40g or 80g of cream.

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

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

8 MARKETING AUTHORISATION NUMBER

PA 610/11/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1984
Date of last renewal: 27 November 2006

10 DATE OF REVISION OF THE TEXT

May 2007