DESCRIPTION

The rubefacient Finalgon Cream will provide all the local warmth and create the necessary increased blood circulation to provide relief. Finalgon Cream contains nonivamide and butoxyethyl nicotinate. The cream base is cosmetically acceptable, being without offensive odour and non-staining.

PHARMACOLOGY

Nonivamide is a synthetic capsaicin analogue with analgesic properties, which are assumed to result from depletion of Substance P in the peripheral nociceptive C-fibres and A-delta nerve fibres upon repetitive application on the skin. By stimulating the afferent nerve endings in the skin, nonivamide has a dilatatory effect on the surrounding blood vessels accompanied by an intense, long-lasting feeling of warmth.

Butoxyethyl nicotinate is a B-vitamin which has vasodilating properties mediated by prostaglandin. The hyperaemic effect of butoxyethyl nicotinate has an earlier onset and it is more intense than the nonivamide hyperaemic effect.

The combination of these two agents has complementary vasodilatory properties reducing the time to a hyperaemic skin reaction upon application.

Pharmacokinetics

Finalgon Cream is applied topically and the clinical effect occurs at the application site. Hence, systemic pharmacokinetic data are irrelevant for efficacy. Systemic safety is evident from toxicology studies and extensive clinical experience in man. Pharmacokinetics in the skin is also irrelevant, as the effect occurs with the blood vessels in the skin. The reaction (erythema and increased skin temperature) occurs a few minutes after application, indicating that the active principles penetrate the skin rapidly.

INDICATIONS

For the temporary relief of the pain of rheumatism, arthritis, lumbago, muscular aches, sprains and strains, sporting injuries and other conditions where local warmth is beneficial.

CONTRAINDICATIONS

Finalgon Cream is contraindicated in patients with known hypersensitivity to the active ingredients or excipients in the cream, or with very sensitive skin. Do not apply to wounds (including broken skin surfaces), to inflamed skin or when skin disease is present.
PRECAUTIONS

Due to local skin hyperaemia induced by FINALGON, redness, feeling of warmth, itching and burning sensation at the application site is to be expected. These symptoms may be particularly marked if the amount applied is excessive or FINALGON is intensively rubbed on the skin area. Excessive use or rubbing of FINALGON may cause blisters of the skin. Hands should be washed immediately after application and care should be taken to avoid transferring to unintended areas or to other people.

FINALGON should not be applied to the face, eyes or mouth. This may result in transient face swelling, facial pain, conjunctival irritation, ocular hyperaemia, eye burning, visual disturbance, oral discomfort and stomatitis. Patients should not take a hot bath or shower before or after applying Finalgon Cream. Even hours after FINALGON application, redness of skin and an intensive feeling of warmth can be induced by sweating or application of warming effects.

FINALGON cream contains the excipients cetostearyl alcohol and sorbic acid, which all may cause local skin reactions (e.g. contact dermatitis).

Use in Pregnancy

In the absence of data, Finalgon Cream should not be used during pregnancy.

Use in Lactation

In the absence of data, Finalgon Cream should not be used during lactation.

Drug Interactions

There are no known drug interactions with Finalgon Cream.

Effects on ability to drive or operate machinery

No studies on the effects of FINALGON on the ability to drive or operate machinery have been performed.

ADVERSE REACTIONS

Based on post-marketing experience with FINALGON, the following side effects may occur:

Immune system disorders
- Anaphylactic reaction, hypersensitivity

Nervous system disorders
- Paraesthesia, skin burning sensation

Respiratory, thoracic and mediastinal disorders
- Cough, dyspnoea
Skin and subcutaneous tissue disorders

Application site pustules, blister, localized skin reaction, pruritus, rash, swelling face, urticaria

General disorders and administration site conditions

Feeling hot

Should pain or blistering occur, the application of ice packs or local anaesthetics to the affected area may alleviate these symptoms.

DOSAGE AND ADMINISTRATION

Treatment should always commence with a very small quantity of Finalgon Cream to test personal reaction. Individual response to Finalgon Cream varies greatly and some people need only the slightest smear to generate all the heat required.

No more than 5 mm should be used to cover an area the size of a hand.

The warming reaction to Finalgon Cream occurs within a few minutes after application and reaches its peak within 20-30 minutes. The warmth or heat promoted can persist for up to six hours.

Covering the affected area increases the warmth produced. The application of additional heat, such as by a hot bath, warm bed, hot water bottle or exercise, either before or after application of Finalgon Cream, increases the warming effect both in extent and duration. Often as much as twelve hours later, a hot shower or bath will regenerate the warmth.

Apply thinly on to the skin over the affected area. DO NOT RUB IN.

Hands should be washed thoroughly in soap and cold water after use.

Due to a lack of information, FINALGON is not recommended for use on children.

If too much Finalgon Cream is applied, the excess may be wiped off with cotton wool soaked with a cooking oil (e.g. olive oil, peanut oil) or margarine.

OVERDOSAGE

In case of overdose, immediately call the Poisons Information Centre (telephone 13 11 26).

Symptoms

After excessive sue of FINALGON, the hyperaemic effects may be aggravated and the severity of the described side effects may increase. Excessive use may especially result in the occurrence of blisters in the affected skin area where FINALGON was administered.

Since nicotinic acid esters show a good percutaneous absorption the overdose of FINALGON may result in systemic reactions, e.g. redness of the upper part of the body, increase of body temperature, hot flushes, painful hyperaemia and a decrease in blood pressure.
Therapy

If too much Finalgon Cream is applied, the excess may be wiped off with cotton wool soaked with a cooking oil (e.g. olive oil, peanut oil) or margarine. Symptomatic therapy should be applied.

PRESENTATION

Each gram contains 1.7 mg nonivamide and 10.8 mg butoxyethyl nicotinate. Finalgon Cream also contains sorbic acid as the preservative, decyl oleate, ceteareth-6, cetostearyl alcohol, stearic acid, liquid paraffin, emulgade f, fragrance kraeuter 0/065242 and purified water.

NAME AND ADDRESS OF SPONSOR

Finalgon Cream is supplied in Australia by:

Boehringer Ingelheim Pty Limited
ABN 52 000 452 308
78 Waterloo Road
NORTH RYDE 2113