

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nicam 4% w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Nicotinamide 4% w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.

A colourless, translucent gel with an alcoholic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the topical treatment of acne vulgaris.

4.2 Posology and method of administration

Apply to the affected area twice daily after the skin has been thoroughly washed with warm water and soap. Enough gel should be used to cover the affected area.

No difference in dose or dose schedule is recommended for adults, children or the elderly.

For topical administration only.

4.3 Contraindications

Contraindicated in persons who have shown hypersensitivity to any of its components.

4.4 Special warnings and precautions for use

For external use only and to be kept away from the eyes and mucous membranes, including those of the nose and mouth. If excessive dryness, irritation or peeling occurs reduce the dosage to one application per day or every other day.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

4.6 Fertility, pregnancy and lactation

Vitamin B derivative requirements, such as nicotinamide, are increased during pregnancy and infancy. Nicotinamide is excreted in breast milk. As with all medicines, care should be exercised during the first trimester of pregnancy.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

The most frequently encountered adverse effect reported is dryness of the skin. Other less frequent adverse effects include pruritus, erythema, burning sensation and irritation.

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

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

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Niacin (nicotinic acid) is an essential B complex Vitamin (B₃), whose deficiency results in the clinical syndrome known as pellagra. Nicotinic acid is converted in the body to nicotinamide adenine dinucleotide (NAD) or nicotinamide adenine dinucleotide phosphate (NADP), which function as coenzymes for a wide variety of vital oxidation-reduction reactions. Nicotinamide (niacinamide), the active ingredient, is the physiologically active form of niacin and is the chemical form of Vitamin B₃ found in virtually all multivitamin products. Though nicotinic acid and nicotinamide are so closely related chemically, they differ somewhat in pharmacological properties.

Nicotinic acid products exhibit moderately intense cutaneous vasodilation, resulting frequently in mild headaches and flushing or tingling of the skin, but such reactions have not been observed with nicotinamide. Nicotinic acid has also been used for its effects to lower plasma cholesterol, again a property not shared by nicotinamide.

Nicotinamide has demonstrated beneficial effects on inflammatory acne. It is considered that these effects are related to its significant anti-inflammatory activity.

5.2 Pharmacokinetic properties

Following oral administration, nicotinamide is readily absorbed from the gastro-intestinal tract and widely distributed in the body tissues. The main route of metabolism is the conversion to N-methylnicotinamide and the 2-pyridone and 4-pyridone derivatives; nicotinuric acid is also formed. Small amounts of nicotinamide are excreted unchanged in the urine: this amount increases with larger doses.

5.3 Preclinical safety data

Nicotinic acid amide (niacinamide) has been recognised since 1937 as an essential B complex vitamin whose deficiency results in the clinical syndrome known as pellagra. It is widely available, in tablets and in sterile solution in water for intravenous administration, for the prophylaxis and treatment of pellagra and nutritional deficiency.

In the United States, niacinamide is included in the Food and Drug Administration's listing of nutritional agents which are Generally Recognised As Safe (GRAS).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium magnesium silicate

Hypromellose

Citric acid

Macrogol lauryl ether

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Ethanol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years for 60g tube.
2 years for 6 g and 25 g tube.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Low density polyethylene or co-extruded low density polyethylene laminate 6 g, 25 g or 60 g tube with white polypropylene cap.

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

Dermal Laboratories (Ireland) Limited
38 Main Street
Swords
Co Dublin
K67 E0A2
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23128/012/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 October 1992

Date of last renewal: 13 October 2007

10 DATE OF REVISION OF THE TEXT

December 2020