Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Brevoxyl 40mg/g cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 40mg of benzoyl peroxide, as the hydrate.

Excipients with known effects:
Propylene glycol alginate 2.5mg/g
Cetyl alcohol 15mg/g
Stearyl alcohol (present in stearyl alcohol and macrogol cetostearyl alcohol) >48mg/g

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cream
A white to off-white cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Brevoxyl is indicated for the treatment of mild to moderate acne vulgaris.

4.2 Posology and method of administration

Adults and Adolescents
Apply a thin layer to the whole of the affected area once or twice daily. Wash with soap and water prior to application.

Paediatric population
The safety and efficacy of Brevoxyl in children under 12 years of age has not been established since acne vulgaris rarely presents in this age group.

Elderly patients
There are no specific recommendations for use in the elderly. Acne vulgaris does not present in the elderly.

Initial application of the product may be varied at the physician's instructions to reflect the patient's skin type and to avoid undesirable effects.

Improvement can generally be seen after 4-6 weeks of treatment. However, longer use may be necessary.

4.3 Contraindications

Hypersensitivity to the active substance, benzoyl peroxide, or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Contact with the eyes, eyelids, mouth, lips, other mucous membranes and broken skin should be avoided.

Care should be taken when applying the product to the neck and other sensitive areas. Propylene glycol alginate may cause skin irritation. Stearyl alcohol and cetyl alcohol may cause local skin reaction (e.g. contact dermatitis).

Patients should be advised that excessive application will not improve efficacy, but may increase the risk of skin irritation.

As benzoyl peroxide may cause increased sensitivity to sunlight, sunlamps should not be used and deliberate or prolonged exposure to sunlight should be avoided or minimised. When exposure to strong sunlight cannot be avoided, patients should be advised to use a sunscreen product and wear protective clothing.

Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy may occur, which sometimes may be severe, especially with the use of peeling, desquamating, or abrasive agents.

If severe local irritancy occurs (e.g. severe erythema, severe dryness and itching, severe stinging/burning sensation), benzoyl peroxide should be discontinued.

During the first weeks of treatment, a sudden increase in peeling and reddening will occur in most patients; this is not harmful and will normally subside in a day or two if treatment is temporarily discontinued.

The product may bleach hair and coloured or dyed fabrics. Avoid contact with hair, fabrics, furniture or carpeting.

4.5 Interaction with other medicinal products and other forms of interactions

Concomitant application of benzoyl peroxide with tretinoin, isotretinoin and tazarotene should be avoided since it may reduce their efficacy and increase irritation. If combination treatment is required, the products should be applied at different times of the day (e.g. one in the morning and the other in the evening.)

Using topical benzoyl peroxide at the same time as topical sulfonamide-containing products may cause skin and facial hair to temporarily change colour (yellow/orange).

4.6 Fertility, pregnancy and lactation

Pregnancy
There are limited data on the use of topical benzoyl peroxide in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. No effects during pregnancy are anticipated since systemic exposure to benzoyl peroxide is very limited.
However, benzoyl peroxide should be used during pregnancy only if the expected benefit justifies the potential risk to the foetus.

Lactation
Percutaneous absorption of benzoyl peroxide is very limited; however, it is not known whether benzoyl peroxide is excreted in human milk after topical application.
Topical benzoyl peroxide should be used during lactation only if the expected benefit justifies the potential risk to the infant.

If used during lactation, benzoyl peroxide should not be applied to the breast area to avoid ingestion by the infant.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

In normal use, a mild burning sensation will probably be felt on first application and a moderate reddening and peeling of the skin will occur within a few days. During the first few weeks of treatment a sudden increase in peeling will occur in most patients; this is not harmful and will normally subside in a day or two if treatment is temporarily discontinued. The patient may also experience temporary pruritus, facial oedema, dermatitis or rash.

The following convention has been used for the classification of adverse reactions:

Very common ≥1/10
Common ≥1/100 to <1/10

Uncommon ≥1/1000 to <1/100
Rare ≥1/10000 to <1/1000
Very rare <1/10000
Not known* (cannot be estimated from the available data).

Clinical trial data
Skin and subcutaneous tissue disorders

Very Common: Peeling, application site erythema
Common: Dryness, pruritus and contact sensitisation reactions
Uncommon: Burning sensation

Post-marketing data
The following post-marketing data come from published studies and the Company in-house adverse event reporting database.

General Disorders and Administration Site Conditions
Rare: Application site discoloration and application site reactions such as irritation and pain

Immune System Disorders
Rare: Allergic reactions, including application site hypersensitivity and anaphylaxis

Skin and Subcutaneous Tissue Disorders
Rare: Application site rash

4.9 Overdose

Symptoms
Topically applied benzoyl peroxide is not generally absorbed in sufficient amounts to produce systemic effects.

Excessive application may result in severe irritation. In this event, discontinue use and wait until the skin has recovered.

Management
Cold compresses can provide relief from irritation due to excessive application.

Accidental ingestion of topical benzoyl peroxide should be managed as clinicallyindicated or as recommended by the National Poisons Information Centre of Ireland.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Peroxides, benzoyl peroxides.
ATC code: D10AE01.

Benzoyl peroxide has antibacterial activity against Propionibacterium acnes, the organism implicated in acne vulgaris. It has keratolytic activity and is sebostatic, counteracting the hyperkeratinisation and excessive sebum production associated with acne.

5.2 Pharmacokinetic properties

After topical application, benzoyl peroxide is absorbed in varying quantities through the skin of man and animals.

Radio-labelled studies have shown that absorption of benzoyl peroxide through the skin can only occur following its conversion to benzoic acid. Benzoic acid is mostly conjugated to form hippuric acid which is excreted via the kidneys.

5.3 Preclinical safety data

Animal toxicity studies of benzoyl peroxide have shown that the compound is non-toxic when applied topically.

Benzoic acid, to which benzoyl peroxide is converted prior to absorption, has a wide margin of safety. Benzoic acid is an approved food additive.

Benzoyl peroxide is a free radical generating compound. The release of oxygen during its conversion to benzoic acid may be implicated in a tumour promoting effect seen in mouse skin.

Benzoyl peroxide at high doses (>20 times the normal human dose), has been shown to increase the tumour growth initiated by dimethyl benzanthracene (DMBA) in mice. DMBA is a powerful chemical carcinogen to which patients are unlikely to be exposed. The relevance of these results to man is limited. Studies in mice have also shown that benzoyl peroxide does not increase the growth of tumours initiated by ultra violet light.

No reproductive toxicology studies have been performed. Up to date there are no indications that the topical use of Brevoxyl causes damage to the unborn child.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetyl alcohol
Stearyl alcohol and Macrogol cetostearyl ether
Simethicone emulsion
Propylene glycol alginate
Dimethyl isosorbide
Fragrance X-23304
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

Lacquered aluminium or laminated tubes with white polypropylene or polyethylene screw caps
Pack size: 40g

and/ or

Membrane sealed polyethylene/ ethylene vinyl alcohol co-polymer (EVOH)/ polyethylene laminate tubes with a polyethylene shoulder and polypropylene screw caps.
Pack sizes: 5g, 15g, 30g and 50g

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Avianta Pharma EU Limited
Inniscara
Main Street
Rathcoole
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23354/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 November 1995

Date of last renewal: 13 November 2005

10 DATE OF REVISION OF THE TEXT

June 2022