# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Acnisal 2% w/w Cutaneous Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Salicylic Acid 2.0 %w/w.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Cutaneous Solution
An opaque off-white cutaneous emollient solution.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Acnisal is for the management of acne. It helps prevent new comedones (blackheads and whiteheads) papules and pustules (acne pimples).

### 4.2 Posology and method of administration

For topical administration.

Adults:
Acnisal is used to wash the affected area 2 to 3 times daily. Lather with warm water, massage into skin, rinse and dry.

Children:
As for adults.

Elderly:
As for adults.

### 4.3 Contraindications

Acnisal is contra-indicated in persons with a sensitivity to salicylic acid and its excipients.

### 4.4 Special warnings and precautions for use

For external use only.  Avoid contact with the mouth, eyes and other mucous membranes to avoid irritation.

As with other topical preparations containing salicylic acid, excessive prolonged use may result in symptoms of salicylism (see section 4.9 Overdose).

### 4.5 Interaction with other medicinal products and other forms of interaction

None known.

## 4.6 Fertility, pregnancy and lactation

Whilst there are no known contra-indications to use of Acnisal during pregnancy and lactation, the safety has not been established. Acnisal should therefore be used with caution or following professional advice.

## 4.7 Effects on ability to drive and use machines

None known.

## 4.8 Undesirable effects

Salicylic acid is a mild irritant and may cause skin irritation. If undue skin irritation develops or increases adjust the usage schedule or consult your physician.

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

Symptoms of systemic salicylate poisoning have been reported after the application of salicylic acid to large areas of skin and for prolonged periods. Salicylism may also occur in the unlikely event of large quantities being ingested. Salicylism is unlikely to occur if Acnisal is used as indicated.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Human comedones, naturally or coal tar induced, are firmly anchored and are dislodged with great difficulty. Most classic "peeling" agents are ineffective: they are merely irritants which cause scaling, creating the illusion of comedolysis. While salicylic acid is an irritant its efficacy is dependent on specific pharmacological effects. It seems to detach horny cells from each other by weakening the intercellular cement. As a result, the comedones tend to undergo disorganisation. The effect is probably a good deal more complex. Salicylic acid penetrates skin readily and increases turnover which also favours exfoliation of the comedo. In concentrations of 0.5 to 2% it significantly reduces the formation of microcomedones, which are the precursors of all other acne lesions.

## 5.2 Pharmacokinetic properties

There is no evidence of any systemic absorption from the use of Acnisal.

## 5.3 Preclinical safety data

None presented.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Purified water
Benzyl alcohol
Sodium chloride

Sodium C14-C16 olefin sulphonate
Lauramide DEA
PEG 7 Glyceryl Cocoate
Acrylic styrene copolymer

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf life

3 years.

## 6.4 Special precautions for storage

Store below 25ºC. Store in the original bottle.

## 6.5 Nature and contents of container

Acnisal is supplied in a white HDPE bottle with a white polypropylene screw cap. Each bottle contains either 30 ml or 177 ml of Acnisal.
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

Alliance Pharmaceuticals Limited
Avonbridge House
Bath Road
Chippenham
Wiltshire SN15 2BB
England

# 8 MARKETING AUTHORISATION NUMBER

PA 943/8/1

# 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 December 1992

Date of last renewal: 22 December 2007

# 10 DATE OF REVISION OF THE TEXT

January 2015