

## 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 excipients, see 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.

#### **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.

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

None known.

#### **4.6 Pregnancy and lactation**

No limitations to the use of Acnival during pregnancy or lactation are known.

#### **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.

#### **4.9 Overdose**

Not applicable.

### **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 Acnival.

#### **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 (monoamide 716)  
PEG-7 Glyceryl cocoate  
Acusol OP301 (styrene/acrylate copolymer)

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

3 years.

### **6.4 Special precautions for storage**

Store below 25°C.

### **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 30ml or 177ml of Acnisal.

### **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 Ltd  
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## **8. MARKETING AUTHORISATION NUMBER**

PL 16853/0070

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

11<sup>th</sup> September 1998.

**10. DATE OF REVISION OF THE TEXT**

July 2008