

SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

Acne Wash

2 % LIQUID SOAP

1.1 Name of the medicinal product – Acne Wash

1.2 International Non-property name – Salicylic acid

2. Quantitative and Qualitative Composition

Each mL of Acne Wash, 2% liquid soap contains:

active ingredient: salicylic acid - 20 mg;

For a full list of excipients see section 6.1.

3. Pharmaceutical form

A greenish viscous liquid with an apple odor.

4. Clinical particulars

4.1 Therapeutic indications

Acne Wash 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 external use.

Adults:

Acne Wash 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

Acne Wash is contraindicated 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 (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 Acne Wash during pregnancy and lactation, the safety has not been established. Acne Wash 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 "Arpimed" LLC by going to www.arpimed.com and fill out the appropriate form "Report an adverse reaction or inefficiency of drug". Hotline number: (+374 55) 05 79 86. And by using "Centre of Drug and Medical Technology Expertise" SNPO, going to the site: www.pharm.am in "Report about adverse effect of medicine" section and fill out the "Report of adverse reaction or manufacturing problem of medicinal product".

Hotline numbers: +37410200505; +37496220505.

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 Acne Wash is used as indicated.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Dermatological drug.

ATC Code: D02AF

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 Acne Wash.

5.3 Preclinical safety data

None presented.

6. Pharmaceutical particulars

6.1 List of excipients

Cocamidopropyl betaine
Polyquaternium 10
Sodium laureth sulfate
Sodium chloride
Disodium EDTA
Methylparaben
Aroma apple
Color apple green (E 142)
Water purified

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store at temperature below 25°C, protect from light and moisture and out of the reach of children.

6.5 Nature and contents of container

100 mL of liquid soap is filled into plastic container (inside package).
The plastic container packed and inserted with the leaflet into cardboard box (outer package).

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorisation holder

“ARPIMED” LLC

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9. Date of first authorisation/renewal of the authorisation

27.12.2002 (Date of first authorisation).

10. Legal categories

OTC (Over-The-Counter).

11. Date of revision of the text