

SUMMARY PRODUCT CHARACTERISTIC (SPC)

ANTI-ACNE[®]

Suspension for external use

1. Name of the medicinal product – Anti-Acne

International non-property or generic name – Salicylic acid, Sulfur precipitated, Zinc oxide

2. Quantitative and Qualitative Composition

Each mL contains:

active ingredients: salicylic acid – 20 mg, sulfur precipitated – 50 mg, zinc oxide – 150 mg;

For a full list of excipients see section 6.1.

3. Pharmaceutical form

Suspension for external use.

Milky-white colored suspension.

4. Clinical Particulars

4.1 Therapeutic indications

- Acne vulgaris.

4.2 Posology and Method of Administration

Shake well before use.

Anti-Acne is applied topically for the treatment of acne vulgaris. The frequency with which Anti-Acne is applied should be determined by the severity of the acne and patient response. Generally, Anti-Acne intended to be applied and left on the skin are applied to thoroughly cleansed skin, covering the entire affected area with a thin layer of the preparation 1–3 times daily or as directed by a physician. To avoid excessive drying, therapy generally is initiated with a single application daily and then the frequency is increased gradually if necessary.

4.3 Contraindications

- Anti-Acne is contraindicated in patients with hypersensitivity to ingredients of preparation.
- Children up to age 12 years.

4.4 Precautions for Use and Special Warnings

To minimise absorption after topical application salicylic acid should not be used for prolonged periods, in high concentrations, on large areas of the body, or on inflamed or broken skin. Contact with mouth, eyes, and other mucous membranes should be avoided; if contact with the eyes occurs, the affected eyes should be rinsed thoroughly with water. It should also be used with care on the extremities of patients with impaired peripheral circulation or diabetes; caution has also been suggested for the use of caustic preparations in patients with significant peripheral neuropathy.

It should be considered, that skin diseases that occur with hyperemia and inflammation or weeping lesions, also may increase the absorption of salicylic acid.

Contact with sulfur can discolour certain metals such as silver, and application of sulfur with topical mercurial compounds can lead to the generation of hydrogen sulfide which has a foul odor and may stain the skin black.

If excessive skin irritation develops or increases during self-medication with a Anti-Acne, the drug should be discontinued and physician or pharmacist consulted.

When used for self-medication of acne, Anti-Acne generally should not be used concurrently with other topical acne medications unless otherwise directed by a physician.

Pediatric precautions

Anti-Acne should not be used in children younger than 12 years of age.

4.5 Drug interactions

Salicylic acid can increase the permeability of the skin to other drugs for topical use and thereby increase their absorption.

Absorbed salicylic acid can increase the side effects of methotrexate and oral hypoglycemic drugs, sulfonylurea derivatives.

Solution pharmaceutically incompatible with resorcinol (form melted mixture).

4.6 Pregnancy and Breast-Feeding

It should be avoided to use **Anti-Acne** in pregnancy and breast feeding.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Possible Side Effects

Salicylic acid

Salicylic acid is a mild irritant and application of salicylic acid preparations to the skin may cause dermatitis. It is readily absorbed through the skin and symptoms of acute systemic salicylate poisoning have been reported after excessive use; deaths have occurred, mainly in children.

Sulfur

When used in appropriate dosage, topically applied Sulfur preparations have a low order of toxicity. Topical preparations containing 5% Sulfur generally are well tolerated. Local irritation of the skin, eyes, or respiratory tract may occur and, therefore, contact with eyes should be avoided. Allergic reactions to sulfur occur rarely. Repeated applications may cause dermatitis, sometimes severe.

There have been no reports of systemic toxicity to date following topical application of preparations containing 5% Sulfur, and such concentrations are generally considered safe for topical use.

Zinc oxide

There have been no side effects reported with topical zinc oxide.

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 Scientific Centre of Drug and Medical Technology Expertise after academician E. Gabrielyan "CJSC", 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

In connection with low absorption of the drug overdose is not described.

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacological group and ATC code:

Not available.

Dermatologicals. Emollients and protectives. Salicylic acid preparations.

Anti-Acne preparations. Anti-Acne preparations for topical use. Preparations containing Sulfur. Combined preparation for topical use. Salicylic acid suppressed the secretion of the sebaceous and sweat glands. It's has a potent keratolytic action and a slight antiseptic action when applied topically to the skin. In low concentrations, the drug has keratoplastic activity (correction of abnormal keratinization) and in higher concentrations (i.e., 1% or higher, depending on the vehicle), the drug has keratolytic activity (causes peeling of skin). Salicylic acid softens and destroys the stratum corneum by increasing endogenous hydration (water concentration), probably because of decreased pH, which causes the cornified epithelium (horny layer) of the skin to swell, soften, and then desquamate. Necrosis of normal skin has been associated with overuse of the drug. At high concentrations (e.g., 20%), Salicylic acid has a caustic effect. Moisture is essential for Salicylic acid to exert its action on the skin and for maceration and desquamation of epidermal tissue to occur. The drug has weak antifungal and antibacterial activity. When combined, Salicylic acid and sulfur may produce a synergistic keratolytic effect. Topically applied sulfur is a keratolytic agent. Sulfur has keratoplastic activity at low concentrations, correcting abnormal keratinization, and keratolytic activity at high concentrations, causing peeling of skin. Although the mechanism of sulfur's keratolytic action has not been determined, this action may depend on formation of hydrogen sulfide when the drug comes in contact with skin; the production of the characteristic odor of rotten eggs when sulfur comes in contact with skin results from hydrogen sulfide formation. Hydrogen sulfide may be formed within the epidermis by sulfur reacting with cysteine.

Topically applied sulfur has mild antifungal and antibacterial activity. It has been suggested that when applied topically to the skin, sulfur forms hydrogen sulfide and/or polythionic acid, which may exert germicidal activity. Therefore, sulfur's antifungal activity probably results largely from its keratolytic action, causing shedding of fungal spores and hyphae embedded within the stratum corneum. The exact mechanism(s) of action of sulfur in the treatment of acne is not fully understood but is presumed to involve the drug's keratolytic and antibacterial effects. Although some studies indicate that sulfur may also be comedogenic, other studies have been unable to substantiate this effect and the drug generally is considered effective in the topical treatment of acne.

Zinc oxide has mild astringent, drying and adsorbent actions, reduces exudation which relieves the local occurrences of inflammation and irritation.

5.2 Pharmacokinetic properties

Topically applied Sulfur reportedly penetrates the skin and is detectable in the epidermis within 2 hours after application and throughout the skin within about 8 hours; the drug is not detectable in skin 24 hours after application.

Distribution: With intact skin zinc oxide and sulfur penetrated the skin, but don't accumulate in the serum. Salicylic acid absorbed in a small amount.

Metabolism: Salicylic acid metabolized partially in dihydroxybenzoic acid.

Elimination: Salicylic acid and its metabolites are excreted mainly by the kidneys.

6. Pharmaceutical Particulars

6.1 List of Excipients:

- ethanol
- camphora
- water purified

6.2 Special precautions for storage

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

6.3 Shelf life

3 years. Do not use the medicine after the expiry date. Do not use the medicine for more than 6 months after opening.

6.4 Nature and content of container

30ml suspension for external use in the bottle with leaflet inserted in the cardboard box.

7. Manufacturer

“ARPIMED” LLC

Bldg. 19, mcr 2-nd, Abovyan, Kotayki Marz, Republic of Armenia.

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8. 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).

Date of revision of the text