

SUMMARY OF PRODUCT CHARACTERISTICS

Erythromycin **2% solution for topical use**

1.1 BRAND NAME – Erythromycin

1.2 INTERNATIONAL NON-PROPERTY NAME – Erythromycin

2. Qualitative and quantitative composition

Each mL contains:

Active ingredient: erythromycin – 20 mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for topical use.

A transparent, odorless liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Erythromycin is indicated for use in the treatment of acne vulgaris.

4.2 Posology and method of administration

• Adults and adolescents

To be applied in a thin film to the affected area twice daily after washing and drying the skin. Hands should be washed after application.

Patients should be advised that a therapeutic effect may not be seen until after 6-8 weeks of treatment. Treatment may be continued for up to a maximum of 6 months. If there has been no improvement after 6 to 8 weeks, or if the condition becomes worse, treatment should be discontinued.

Owing to the flammable nature of the product, Erythromycin solution should be kept away from open fire and flames and all sources of ignition, including smoking, during and immediately after use.

• Paediatric population

Safety and effectiveness of topical erythromycin in children under the age of 12 have not been established.

• Elderly

There are no specific recommendations for use in the elderly.

• Renal impairment

No dosage adjustment is necessary.

• Hepatic impairment

No dosage adjustment is necessary.

4.3. Contraindications

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

4.4 Special warnings and precautions for use

Erythromycin should be used with caution in patients with a known sensitivity or allergy to any ingredients. Erythromycin contains propylene glycol which may cause skin irritation.

Concomitant topical acne therapy should be used with caution because a cumulative irritancy effect may occur, especially with the use of peeling, desquamating or abrasive agents. If irritancy or dermatitis occurs, erythromycin should be discontinued.

Contact with the mouth, eyes, lips, other mucous membranes or areas of broken skin should be avoided.

Resistance to erythromycin

Cross-resistance and cross-sensitivity with other antibiotics of the macrolide group and with clindamycin may occur.

The use of antibiotic agents may be associated with the overgrowth of antibiotic-resistant organisms. If this occurs, discontinue use.

Pseudomembranous colitis

Erythromycin should be used with caution in patients with a history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis (including pseudomembranous colitis).

Pseudomembranous colitis has been reported with nearly all antibacterial agents, including erythromycin, and may range in severity from mild to life-threatening.

Although this is unlikely to occur with topically applied erythromycin, if prolonged or significant diarrhoea occurs or the patient suffers from abdominal cramps, treatment should be discontinued immediately and the patient investigated further, as the symptoms may indicate antibiotic-associated colitis.

As with other macrolides, rare serious allergic reactions, including acute generalised exanthematous pustulosis (AGEP) have been reported. If an allergic reaction occurs, the drug should be discontinued and appropriate therapy should be instituted. Physicians should be aware that reappearance of the allergic symptoms may occur when symptomatic therapy is discontinued.

4.5 Interaction with other medicinal products and other forms of interaction

Clindamycin and erythromycin have been shown to be antagonistic *in vitro*.

No clinical data is available.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are limited data on the use of topical erythromycin in pregnant women. No effects during pregnancy are anticipated since systemic exposure to erythromycin is very limited. However, topical erythromycin should be used during pregnancy only if the expected benefit justifies the potential risk to the foetus.

Breast-feeding

Percutaneous absorption of erythromycin is very limited, however, it is not known whether erythromycin is excreted in human milk after topical application.

Erythromycin is excreted in human milk following oral and parenteral administration.

Topical erythromycin should be used during lactation only if the expected benefit justifies the potential risk to the infant. If used during lactation, erythromycin should not be applied to the breast area to avoid accidental ingestion by the infant.

Fertility

There are no data on the effect of topical erythromycin on fertility in humans.

4.7 Effects on ability to drive and use machines

Erythromycin solution has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The following convention has been used for the classification of frequency:

Very common: $\geq 1/10$

Common: $\geq 1/100$ to $< 1/10$

Uncommon: $\geq 1/1000$ to $< 1/100$

Rare: $\geq 1/10000$ 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: Skin burning sensation, skin irritation, dry skin, especially on initiation of treatment, application site erythema, especially on initiation of treatment.

Not known: acute generalised exanthematous pustulosis (AGEP)

Post-marketing data

The following adverse drug reactions are based on post-marketing reports. Since these reports are from a population of uncertain size and are subject to confounding factors, it is not possible to reliably estimate their frequency, however in reality systemic reactions are rarely seen.

Immune system disorders

Not known: Allergic reaction

Gastrointestinal disorders

Not known: Diarrhoea, abdominal discomfort, upper abdominal pain

Skin and subcutaneous disorders

Not known: Rash, urticaria, pruritus.

General disorders and administration site conditions

Not known: Facial oedema

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

Symptoms and signs

In the event of accidental ingestion, the same gastrointestinal adverse reactions as those seen with orally administered erythromycin may be seen.

The formulation contains a significant quantity of ethanol. Systemic absorption of this should be considered a possibility in the event of overdosage.

Treatment

Further management should be as clinically indicated or as recommended by the National Poisons Centre, where available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Erythromycin, ATC code: D10AF02

Erythromycin suppresses *propionibacterium acnes*, a resident bacterial of sebaceous follicles, and as a result of this organism's role in the hydrolysis of triglycerides to free fatty acids, administration decreases fatty acid formation.

This is thought to be responsible for its effectiveness in reducing acne lesion counts and the fatty acid to fatty ester ratios in acne patients.

5.2 Pharmacokinetic properties

Percutaneous absorption of erythromycin from Erithromycin solution is negligible.

5.3 Preclinical safety data

The preclinical and clinical safety of erythromycin is well established.

Erythromycin has been in widespread use for many years.

6 PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Propylene Glycol

Ethanol

6.2 Incompatibilities

None.

6.3 Shelf life

36 months.

Use till expiration date after opening.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

30 ml of 2% topical solution is filled into glass bottle (inside package).

The bottle inserted with the leaflet in cardboard box (outer package).

6.6 Special precautions for disposal

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

7. Manufacturer

“Arpimed” LLC

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

Tel.: (374) 222 21703 Fax: (374) 222 21924

8. Marketing authorisation holder

“Arpimed” LLC

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

Tel.: (374) 222 21703 Fax: (374) 222 21924

9. Date of first authorisation

16.12. 2002

10. Date of revision of the text