SUMMARY PRODUCT CHARACTERISTIC (SPC)

ERYTHROMYCIN OINTMENT

1.1. NAME OF THE MEDICINAL PRODUCT – ERYTHROMYCIN OINTMENT
1.2. INTERNATIONAL NON-PROPERTY NAME – Erythromycin

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of ERYTHROMYCIN OINTMENT contains:
active ingredient: erythromycin - 10 mg;
For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

A white, homogenous ointment, odorless.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

- Treatment of acne vulgaris (mainly papular and pustular).
- Purulent-inflammatory skin diseases.

4.2. Posology and method of administration

Topical, on previously cleaned skin lesions, two times a day, morning and evening. Treatment continued until clinical improvement, on average 1-3 months.

4.3. Contraindications

Patients with known hypersensitivity to erythromycin, other macrolide antibiotics or to any of the excipients listed in section 6.1.

4.4. Special warnings and precautions for use

This medicine is for external use only.
Avoid getting this medicine in contact with mucous membranes and sensitive skin. If accidental contact does occur, the area should be washed with lukewarm water.
Cross-resistance with other antibiotics of the macrolide group and with clindamycin, lincomycin may occur.
Patient should avoid using any other anti-acne preparations for external use on the same area within 1 hour after using ERYTHROMYCIN 1% OINTMENT. Wash your hands thoroughly after applying. In cases of complications of infection ERYTHROMYCIN should be discontinued.
Generalized urticarial reactions possibly related to the use of ERYTHROMYCIN, which required systemic steroid therapy have been reported.
The *Propionibacterium* is becoming more resistant to antibiotics. To help avoid the development of resistance, your doctor should avoid prescribing different antibiotics for you to take by mouth while you are using this antibiotic on your skin.
If acne does not improve within 3-4 weeks, you should consult a doctor (it may take 2-3 months to achieve the full therapeutic effect).
With prolonged use, superinfection may develop.
Carefully consider the balance of benefits and risks before prescribing erythromycin for any patients taking hydroxychloroquine or chloroquine, because of the potential for an increased risk of cardiovascular events and cardiovascular mortality (see section 4.5).
<u>Paediatric use</u>
Safety and effectiveness of ERYTHROMYCIN 1% OINTMENT for external use in children have not been established.

Information about Propylparaben
ERYTHROMYCIN OINTMENT contains propylparaben, which may cause allergic reactions (possibly delayed).

4.5. Interaction with other medicinal products and other forms of interaction
Your skin may be more likely to get dry or irritated if you are use other external preparations on your skin, for example , drugs that causes desquamation of skin , medicated cosmetics, soaps, toiletries or other anti-acne preparations, in combination with this medicine. Concurrent administration of drugs that cause desquamation of skin (benzoyl peroxide, resorcinol, sulfur, or tretinoin) with ERYTHROMYCIN may increase the risk of adverse effects.
Concurrent administration of ERYTHROMYCIN with other antibacterial drugs is contraindicated.
The drug is incompatible with lincomycin, clindamycin, chloramphenicol (antagonism).
Reduces the bactericidal effect of beta-lactam antibiotics (penicillins, cephalosporins, carbapenems).
Concomitant use with hydroxychloroquine and chloroquine
Observational data have shown that co-administration of azithromycin with hydroxychloroquine in patients with rheumatoid arthritis is associated with an increased risk of cardiovascular events and cardiovascular mortality. Because of the potential for similar risks with other macrolides in combination with hydroxychloroquine or chloroquine the benefits and risks should be carefully weighed before prescribing erythromycin to any patient taking hydroxychloroquine or chloroquine.

4.6. Pregnancy and lactation
Certain medicines should not be used during pregnancy or breastfeeding. However, other medicines may be safely used in pregnancy or breastfeeding providing the benefits to the mother outweigh the risks to the unborn baby. Always inform your doctor if you are pregnant or planning a pregnancy, before using any medicine.
There are no known harmful effects when this medicine is used by pregnant or breastfeeding mothers. However, if used by breastfeeding mothers it should not be applied to the chest to avoid the child accidentally ingesting it while feeding.
This drug should be used during pregnancy and breastfeeding only if it is clearly needed and the potential benefit justifies the potential risk to the fetus.

4.7. Effects on ability to drive and use machines
During the period of use of the drug, it is possible to drive vehicles, operate machinery and perform other potentially dangerous activities that require increased concentration and speed of psychomotor reactions.

4.8. Undesirable effects
External reaction: Dryness, irritation and burning sensation have been reported following external application of erythromycin. Generally these effects are mild and transient generally do not require discontinuation of therapy.
Allergic reactions: Generalized urticaria, irritation, redness, desquamation of the epidermis, the skin erythema, irritation of the eyes.

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 online to the Center of Drug and Medical Technologies Expertise of MoH of RA viawww.pharm.am or call the hotline numbers: (+374 0) 20 05 05 and (+374 96) 22 05 05.

4.9. Overdose
Accidental overdose is unlikely because of features of the external use of the drug.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Anti-acne preparations. Anti-acne preparations for topical use. Antiinfectives for treatment of acne.

ATC code: D10AF02.

ERYTHROMYCIN 1% OINTMENT contains the active ingredient erythromycin, which is a type of medicine known as a macrolide antibiotic.

Erythromycin is a macrolide antibiotic. It interferes with bacterial protein synthesis by binding to the 50S subunit of ribosomes of sensitive organisms.

ERYTHROMYCIN 1% OINTMENT is applied to the skin to treat acne. The erythromycin works by attacking the bacteria associated with acne, *Propionibacterium acnes*. This is a common type of bacteria that feeds on sebum produced by the sebaceous glands in the skin. Although the mechanism of action of Erythromycin in reducing inflammatory lesions of acne vulgaris has not been conclusively shown, it is presumably due to its antibiotic action on sensitive bacteria, and in reducing follicular porphyrin fluorescence and free fatty acid levels of skin lipids.

Erythromycin prevens these bacteria from producing proteins that are essential to them. Without these proteins the bacteria cannot grow, replicate and increase in numbers. Erythromycin doesn't directly kill the bacteria, but leaves them unable to increase in numbers. The remaining bacteria eventually die or are destroyed by the immune system.

By controlling bacterial numbers, erythromycin brings the inflammation of the sebaceous glands under control, and allows the skin to heal.

The application of high doses, depending on the type of agent may also exhibit bactericidal effect.

5.2. Pharmacokinetic properties

Only very small amounts of erythromycin appear to be absorbed systemically following external application to the skin. Which subsequently excreted in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

liquid paraffin,
propylparaben,
white soft paraffin (vaseline),
ethanol 96%.

6.2. Incompatibilities

The drug is incompatible with lincomycin, clindamycin, chloramphenicol (antagonism).

6.3. Shelf life

3 years.

6.4. Special precautions for storage

Store out of the reach of children, protected from moisture and light at a temperature not higher than 25°C.

6.5. Presentation

1% ointment for external use in aluminum tubes of 20 and 25 g with a leaflet in a cardboard box.

6.6. Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORIZATION HOLDER

"ARPIMED" LLC

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8. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12.11.2004

9. LEGAL CATEGORIES

POM (Prescription Only Medicine)

10. DATE OF REVISION OF THE TEXT