125X146mm

E-Sol Gel

■ **Name and Strength of Active Substance(s)**

Erythromycin ·····4.0% w/w
Tretinoin·····0.025% w/w

■ **Product description**

Homogeneous opaque gel

■ **Pharmacodynamics / Pharmacokinetics**

•Pharmacodynamics

Erythromycin is a macrolide antibiotic with bacteriostatic action on all pathogens involved in the development of acne. When applied topically it also effects a reduction in the concentration of skin surface lipids and shows a direct anti-inflammatory effect. The retinoid tretinoin acts topically as keratolytic agent by markedly increasing cell turnover in the cornified epithelium including epithelium of the follicular ducts and comedones. In the first instance, skin irritation, erythema and increased vascularization occur followed by thickening and desquamation of the epithelium. The renewal time of the cornified epithelium is therefore shortened.

•Pharmacokinetics

Percutaneous absorption or erythromycin is negligible following topical application of E-Sol Gel for several to large areas of skin. After topical application, up to 6% of the applied dose of tretinoin is recovered in the urine within 50-60 hours, indicating some absorption. The ratio of renal to biliary excretion is approximately 1:3, therefore the maximum likely total absorption is 24%

■ **Indication**

E-Sol Gel is indicated for topical application in the treatment of all forms of acne, both non-inflammatory forms with comedones and inflammatory forms with papules and pustules particularly those associated with a very oily skin.

■ **Recommended Dosage and Administration**

The dosage is the same for all ages. The duration of use depends on the condition of the skin and should not exceed 12 weeks.
E-Sol gel should be applied once a day, in the evening, to the skin where acne lesions appear, using enough to cover the entire affected area lightly. Application may cause a transient feeling of warmth or slight stinging. In cases where it has been necessary to temporarily discontinue therapy or reduce the frequency of application, therapy may be resumed or frequency of application increased when the patients become able to tolerate the treatment. Alterations of dose frequency should be closely monitored by careful observation of the clinical therapeutic response and skin tolerance. Efficacy has not been established for less than once daily dosing frequencies. During the early weeks of therapy, an apparent increase in number and exacerbation of inflammatory acne lesions may occur. This is due in part to the action of the medication on deep, previously unseen lesions and should not be considered a reason to discontinue therapy. Therapeutic results should be noticed after two or three weeks, but more than six weeks of therapy may be required before definite beneficial effects are seen. Patients treated with E-Sol gel may use cosmetics, but the areas to be treated should be cleansed thoroughly before the medication is applied.

■ **Contraindication**

- Hypersensitivity to the active ingredients or to any of the excipients (Ethanol, glycerol, copolyvidone)
- A family history of cutaneous epithelioma.
- In acute eczemas, rosacea and acute inflammatory conditions of the skin, especially around the mouth.
- When underlying sunburn is present
- Concomitant use with other skin medications particularly those containing keratolytic agents.
- Pregnancy (see Section Pregnancy and Lactation)
- Women planning a pregnancy

■ **Warning and Precautions**

Photosensitivity may occur during treatment with E-Sol gel. Exposure to sunlight should be minimized and use of sun lamps or sun beds avoided during treatment. Patients with sunburn should not use this product until recovered because of the increased susceptibility to sunlight whilst using tretinoin. Wind and rain may be unusually irritating to patients under treatment.
Accumulation of the product in skin folds or in the angles of the nose should be avoided.
The product should not be allowed to come into contact with the eyes or eyelids - if this occurs, thorough rinsing with water is recommended.
In the event of severe acute hypersensitivity reactions, such as anaphylaxis, severe cutaneous adverse reactions (SCARs) [e.g. Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) & acute generalised exanthematous pustulosis (AGEP)], E-Sol gel should be discontinued immediately and appropriate treatment should be urgently initiated.

■ **Interactions with Other Medicaments**

Skin irritation may be enhanced by UV rays (natural sunlight, sun lamps, sun beds), X-rays or by bathing in chlorinated or salt water.
Any sunburn should be allowed to heal before the start of treatment with E-Sol gel.
E-Sol gel should not be used concomitantly with other skin medications particularly those containing keratolytic agents, as this may exacerbate any skin irritation that is present

■ **Pregnancy and Lactation**

Orally administered retinoids have been associated with congenital abnormalities. When used in accordance with the prescribing information, topically administered retinoids are generally assumed to result into low systemic exposure due to minimal dermal absorption. However, there could be individual factors (e.g. damaged skin barrier, excessive use) that contribute to an increased systemic exposure.
E-Sol gel is contraindicated (see Section Contraindications) in pregnancy, or in women planning a pregnancy.
If the product is used during pregnancy, or if the patient becomes pregnant while taking this drug, treatment should be discontinued.

■ **Side Effects**

Skin and Subcutaneous Tissue Disorders :

There may be rare cases of skin irritation in the form of erythema, burning, drying or peeling of the skin may be observed. In very rare cases the above symptoms may also be an expression of a hypersensitivity reaction (allergic contact eczema).There may be an apparent deterioration in acne with an increase in inflammatory symptoms at the commencement of treatment; this is a sign that the medicine is beginning to act and is usually transitory. If the above occurs, treatment should not be interrupted but the frequency of application reduced.
Rarely, a temporary hypopigmentation or hyperpigmentation has been reported in individuals treated with tretinoin. Temporary depigmentation in non-caucasians is possible.

Skin and Subcutaneous Tissue Disorders Frequency not known :

Severe cutaneous adverse reactions (SCARs) including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS) & acute generalised exanthematous pustulosis (AGEP).

■ **Overdose and Treatment**

E-Sol gel is for topical use only. Over dosage will not occur since the amount of erythromycin and tretinoin applied is too small to induce systemic toxicity. If the product is accidentally taken orally, unless the amount is small, gastric lavage should be performed as soon as possible.

■ **Storage condition :** Store in a light-resistant tight container below 30°C.

■ **Shelf-life :** 3 years

■ **Dosage forms and packaging available :** E-Sol gel 10g/tube/box

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