SPOTEX- erythromycin gel
Pella Pharmaceuticals Co. Ltd

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Spotex

Composition

Each 1 g contains: Erythromycin base 40 mg.
Excipients: Ethanol 99.9%, Hydroxypropyl cellulose, Butylated hydroxytoluene.

Properties

Erythromycin which belongs to a class of chemicals called macrolide antibiotics; exerts its antibacterial action by binding to the 50S ribosomal subunit of susceptible bacteria and suppressing protein synthesis. Erythromycin is usually bacteriostatic but may be bactericidal in high concentrations or against highly susceptible organisms.

Indications

Spotex is indicated for the treatment of Acne Vulgaris, Acne appears as blackheads and whiteheads which people often refer to as pimples or spots. **Spotex** attacks the bacteria that are one of the main causes of acne. The name of these bacteria is Propionibacterium acnes

Contraindications

Spotex is contraindicated if you are allergic (hypersensitive) to Erythromycin or any of the other ingredients of **Spotex**.
An allergic reaction may include a rash or itching.

Precautions

If you use **Spotex** on your face don t get it in your eyes, nose/nostrils, mouth, or on your lips. If you do, wash the area with large amount of warm water. And do not use **Spotex** on areas where you have cuts or scrapes.
Excessive exposure to sunlight or ultraviolet rays (sun lamps) should be avoided during treatment with **Spotex** because the additional irradiation may lead to a more intense action.
If sunburn occurs, it is advisable to interrupt therapy until the severe erythema and peeling subside. Patients whose occupations require considerable exposure to the sun should exercise particular caution.

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine.

Lactation

Do not apply **Spotex** on your chest if you are breast feeding.
Ask your doctor or pharmacist for advice before taking any medicine.

Drug Interactions

Do not use **Spotex** with any other acne products that are used on the skin unless your doctor or pharmacist has told you that you can.
While you are using **Spotex**, do not use skin cleansers that remove dead skin (these are called exfoliants), medicated soaps or cosmetics containing alcohol. These could make your skin irritated or dry.
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Warnings

Topical gels and creams are intended for external use only and should be kept away from eyes, nose, mouth, and other mucous membranes because of its irritant effect. Do not apply to eyelids or to the skin at the corners of the eyes and mouth. Avoid the angles of the nose and nasolabial fold (if treatment in these areas; is necessary, apply very sparingly). Topical use may induce severe local erythema and peeling at the site of application. If the degree of local irritation warrants, patients should be directed to use the medication less frequently, discontinue use temporarily or discontinue use altogether.

Dosage and Administration

Use **Spotex** once in the morning and once in the evening, unless your doctor or pharmacist has told you otherwise.
Wash the affected areas with water or with a mild cleanser, and then thoroughly dry the affected areas and gently apply on a thin film of **Spotex** using the tips of your fingers. Don't forget to wash your hands afterwards.

The alcohol quickly evaporates and erythrornycin penetrates into your skin without leaving an unpleasant film, after you have used **Spotex**; screw the cap tightly on the tube.

How long you will have to use **Spotex** will depend on how quickly your acne improves. You may well use **Spotex** Gel for one month and then a lower strength product for one more month. Your doctor will decide which strength to prescribe for you.
It is recommended to use sunscreens over treated areas before sun exposure.

Overdosage

Do not put too much **Spotex** on your skin. You will not get rid of the acne any quicker.

If you put on too much, your skin may become irritated and red. Some peeling or discomfort could also occur. If any of these happen, use **Spotex** once a day in the evening until they have gone. Then apply **Spotex** twice a day as you did previously. If the effects continue or are causing you a lot of discomfort, stop using the product and ask your doctor or pharmacist for advice.
In the rare event that you accidentally swallow any of this product, seek medical advice.

Side Effects

Like all medicines **Spotex** can cause side effects, although not everybody gets them. These might include dryness, itching, redness, peeling or oiliness. You might feel a stinging or burning sensation when you put it on your skin. Usually the effects are not serious and happen at the start of treatment. More often than not, they go away as you continue to use the gel.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Storage

Store below 25 °C.

How supplied

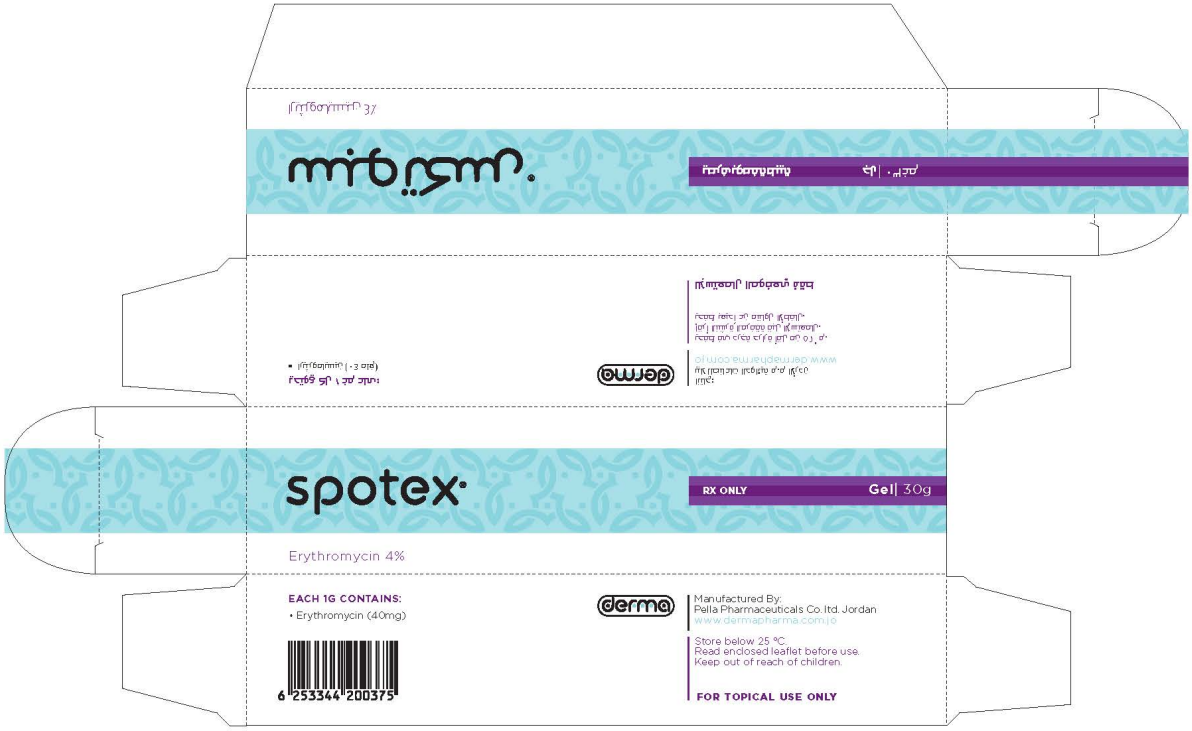
30 g packs.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Strictly follow the doctor's prescription, the method of use and the instruction of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicament out of reach of children

Primary Package

Secondary Package



SPOTEX

erythromycin gel

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:82160-126
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ERYTHROMYCIN (UNII: 63937KV33D) (ERYTHROMYCIN - UNII:63937KV33D)	ERYTHROMYCIN	1200 mg in 30 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82160-126-01	1 in 1 CARTON	09/10/2013	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/10/2013	

Labeler - Pella Pharmaceuticals Co. Ltd (562370925)

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