PACKAGE LEAFLET: INFORMATION FOR THE USER

Stiemycin®

2% w/v cutaneous solution Erythromycin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1. What Stiemycin is and what it is used for
- 2. What you need to know before you use Stiemycin
- 3. How to use Stiemycin
- 4. Possible side effects
- 5. How to store Stiemycin
- 6. Contents of the pack and other information

1. What Stiemycin is and what it is used for

Stiemycin contains a medicine called erythromycin. This is an antibiotic.

Stiemycin is used to treat acne (spots). It works by fighting the bacteria that can cause the acne spots. Stiemycin is for use by adults and adolescents with acne. It is not for use by children.

2. What you need to know before you use Stiemycin

Do not use Stiemycin if:

- you are allergic to erythromycin or any of the other ingredients of this medicine (listed in section 6). Do not use Stiemycin if the above applies to you. If you are not sure, talk to your doctor or pharmacist before you start using Stiemycin.

Warnings and precautions

Talk to your doctor before using Stiemycin if:

- you cannot tolerate or have previously had a skin reaction or allergy to erythromycin or any of the other ingredients of Stiemycin (listed in section 6)
- you have a history of inflammatory bowel disease or antibiotic-associated colitis (severe, prolonged or bloody diarrhoea following antibiotic use).

Only use Stiemycin on your skin. Take care not to get Stiemycin in your eyes, nostrils, mouth or on your lips. If you do, rinse well with water. Take care not to get Stiemycin on any irritated areas of skin, such as cuts, grazes, sunburn, or broken skin.

Other medicines and Stiemycin

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicine. This includes medicines bought without a prescription.

- Stiemycin can affect how other medicines work. Take care not to use Stiemcyin at the same time as clindamycin-containing acne medicines that are used on the skin.
- Tell your doctor if you are taking any other antibiotic medicine.

• Take care not to apply Stiemycin at the same time as other acne products that are used on the skin, unless your doctor or pharmacist has told you that you can.

Pregnancy, breast-feeding and fertility

- If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor for advice before taking this medicine.
- If you do become pregnant during treatment with Stiemycin tell your doctor.
- Don't use Stiemycin on your breast if you are breast-feeding.

Stiemycin contains propylene glycol

Stiemycin contains propylene glycol, which may cause skin irritation.

3. How to use Stiemycin

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

What you need to know before using Stiemycin

- Stiemycin should be applied only to your skin.
- Do not drink the solution.
- This product is flammable. Keep the product away from open fire and flames and all sources of ignition including smoking during and immediately after you've used it.
- When you use the bottle for the first time you will need to break the seal. To do this, remove the cap from the bottle and holding the bottle upright, press gently on the seal with a finger until you hear a 'pop'. The medicine is now ready to use.

How much to use

- Apply Stiemycin twice a day, in the morning and the evening.
- Using the product more frequently does not give better results.
- It can take at least six to eight weeks before you see the full benefit of Stiemycin.
- You should keep using the medicine according to your doctor's instructions up to a maximum of 6 months.

How to apply Stiemycin

- Completely remove any make-up.
- Wash the affected area with mild soap and warm water and gently dry.
- Remove the cap.
- Turn the bottle upside down and dab the pad onto the affected area.
- Use the pad to spread the solution gently over the whole area and not just to each individual spot.

After using Stiemycin

- Always replace the cap securely after use to stop the medicine from leaking or evaporating.
- Stiemycin contains ingredients to help the antibiotic reach the bottom of your hair follicles where the acne starts. These ingredients keep the skin wet for a few minutes after applying it.
- Allow your face to dry completely before using any make-up.
- You may notice a slight smell while it dries, this is normal.
- Wash your hands after use.

If you forget to use Stiemycin

- Don't apply a double dose to make up for forgotten doses.
- Apply the next dose at the usual time.

If you accidently swallow Stiemycin:

The ingredients of Stiemycin are not expected to be harmful if swallowed in the small amounts normally applied to the face. If you do accidentally get Stiemycin in your mouth, rinse at once with plenty of water. Seek medical advice if you swallow more than a small amount.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Stop using Stiemycin and see a doctor straight away if:

- you notice an allergic reaction (such as swelling of your face, eyes, lips or tongue, nettle rash or difficulty breathing).
- you develop severe or prolonged diarrhoea.

The following very common side effects have been reported (may affect more than 1 in 10 people):

- skin burning sensation
- skin irritation
- dry skin, especially at the start of treatment
- application site stinging
- redness of your skin, especially at the start of treatment.

Other side effects with frequencies that cannot be estimated from the available data include:

- allergic reaction
- diarrhoea, stomach pain, stomach discomfort
- itching, rash
- swelling on the face

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Stiemycin

Keep this medicine out of the sight and reach of children.

- Do not store above 25°C. Keep the container tightly closed when not in use.
- Contents are flammable. Keep away from all sources of fire, flame and heat.
- Do not leave in direct sunlight.
- Do not use medicine after the expiry date which is stated on the bottle and the carton after 'Exp'. The expiry date refers to the last day of that month.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Stiemycin contains

- The active substance is erythromycin 2% w/v
- The other ingredients are propylene glycol, ethanol absolute and polyoxyethylene-4-lauryl ether.

What Stiemycin looks like and contents of the pack

- The solution is supplied in an amber glass screw capped bottle.
- The bottle contains 50 ml of a clear, colourless liquid

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: GlaxoSmithKline UK Limited

Stockley Park West Uxbridge Middlesex UB11 1BT, UK

Manufacturer:

Stiefel Laboratories (Ireland) Ltd Finisklin Industrial Estate, Sligo, Ireland

or (only batch release site to be listed)

Famar Nederland B.V. Industrieweg 1,5531 AD Bladel, The Netherlands.

PL 19494/0055

Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name Stiemycin Reference number 19494/0055

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in June 2014.

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