

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 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 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 the active substance erythromycin. This is an antibiotic.

Stiemycin is used to treat acne vulgaris (spots) in adults and adolescents. It is not for use by children under the age of 12 years.

It works by fighting the bacteria that can cause the acne spots.

You must talk to a doctor if you do not feel better or if you feel worse after 6-8 weeks.

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).

Warnings and precautions

Talk to your doctor or pharmacist before taking Stiemycin if:

- you are using any other acne treatments, creams or ointments, as possible irritation may occur.
- you are using other antibiotics or clindamycin as possible irritation may occur and the bacteria causing the acne may become used to (resistant to) the antibiotic in this medicine and therefore may not work as well.
- 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, mouth, lips or other mucus membranes. If you do, rinse well with water. Stiemycin will make your eyes sting and if you accidentally get some in your mouth, it will taste unpleasant.

Take care not to get Stiemycin on any irritated areas of skin, such as cuts, grazes, sunburn or broken skin.

Stiemycin contains propylene glycol, which may cause skin irritation.

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.

Other medicines and Stiemycin

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This includes medicines you get without a prescription, such as herbal medicines.

Stiemycin can affect how other medicines work. Take care not to use Stiemycin at the same time as clindamycin-containing acne medicines that are used on skin.

Pregnancy and breast-feeding

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

If you are breast-feeding, you should not apply Stiemycin to the breast area.

Stiemycin contains propylene glycol

Stiemycin contains propylene glycol, this 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.
- Due to the flammable nature of Stiemycin, you should avoid smoking or being near an open flame while you are applying it 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 6-8 weeks before you see the full effect of Stiemycin.
- You should notice a gradual improvement as the weeks go by.

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| Item Number: 31023865-02 | | List Colours: (include sample in fields provided: e.g. spot / spot-CMYK equivalent) | K | | |
| Manufacturing Site: GSK-ContractMfg-EUR-UK-Netherlands-Famar Bladel-Bladel | | | | | |
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Formulation
Tablet embossing
Storage conditions
Shelf Life

- Continuous daily use of Stiemycin for long periods is not recommended since the bacteria causing the acne can become used to (resistant to) the antibiotic in this medicine and therefore it may not work as well.

How to apply Stiemycin

1. Wash the affected area with soap and water. Gently pat your skin dry with a clean towel.
2. Remove the cap.
3. Turn the bottle upside down and dab the pad onto the affected area.
4. 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 use more Stiemycin than you should

This medicine contains ethanol. If you use more Stiemycin than you should systemic absorption should be considered.

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 accidentally 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 stop using Stiemycin

It is important to continue to use this medicine until the acne has gone. If you stop too soon your acne may return.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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.

Very common side effects (these 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

Rare side effects (these may affect up to 1 in 1,000 people):

- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine. Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the IMB via freepost, to the following address:

FREEPOST
Pharmacovigilance Section
Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

5. How to store Stiemycin

Keep this medicine out of the sight and reach of children. Do not use the 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 store above 25°C.

Replace the cap firmly after the use to prevent evaporation. Contents are flammable. Keep away from all sources of fire, flame and heat. Do not leave in direct sunlight.

Do not throw away any 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 20 mg/ml (2% w/v).
- The other ingredients are propylene glycol, ethanol absolute and polyoxyethylene 4 lauryl ether.

What Stiemycin looks like and the contents of the pack

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

Product Authorisation Holder and Manufacturer

Product Authorisation Holder:
GlaxoSmithKline (Ireland) Ltd. Stonemasons Way,
Rathfarnham Dublin 16, Ireland. Trading as Stiefel.
Manufacturer:
Famar Nederland B.V.
Industrieweg 1, 5531 AD Bladel, The Netherlands.

This leaflet was last revised in December 2013

Other sources of information

This package leaflet is available in formats that are suitable for the blind or partially sighted. Such formats are available on request.

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