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Reporting of side effects.

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report any side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ACEA GEL

Keep out of the reach and sight of children.

Do not store above 25°C.

Do not use Acea Gel after the expiry date which is stated on the tube and the carton. The expiry date refers to the last day of that month. Use within 8 weeks of opening.

Ask your pharmacist how to dispose of your medicine.

6. FURTHER INFORMATION

What Acea Gel contains:

The active ingredient is 0.75% w/w metronidazole.

The other ingredients are: glycerol, hydroxyethylcellulose, disodium edetate, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), ethyl parahydroxybenzoate (E214), sodium hydroxide, potassium dihydrogen phosphate and purified water.

What Acea Gel looks like and the contents of the pack:

Acea Gel is a clear, pale yellow gel contained in a metal tube with a plastic screw cap, containing either 5g, 25g or 40g.

Marketing Authorisation Holder and Manufacturer:

PL20685/0020

Marketing Authorisation Holder: Ferndale Pharmaceuticals Ltd, Unit 740 Thorp Arch Estate, Wetherby, West Yorkshire LS23 7FX, UK, Tel: (01937) 541122 e-mail: info@ferndalepharma.co.uk

Manufacturer:

Laleham Health and Beauty Ltd, Sycamore Park, Mill Lane, Alton, Hampshire, GU34 2PR, UK.

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acea gel

**Acea 0.75% w/w Gel
Metronidazole**

Read all of this leaflet carefully because it contains important information for you.

- Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any side effect becomes more serious, or if you notice any side effect not listed in this leaflet, please tell your doctor.

Information in this leaflet:

1. What Acea Gel is & what it is used for
2. Before you use Acea Gel
3. How to use Acea Gel
4. Possible side effects
5. How to store Acea Gel
6. Further information

1. WHAT ACEA GEL IS & WHAT IT IS USED FOR

Your medicine is called Acea 0.75% w/w Gel (referred to in this leaflet as Acea Gel). It is a water based gel containing 0.75% w/w of the active ingredient metronidazole.

Acea Gel is used for the **treatment of rosacea**, a skin condition usually affecting the facial cheeks and forehead in which the skin appears redder than normal.

Acea Gel belongs to a group of medicines called 'Antiprotozoal and Antibacterial Agents', which are used to control infection and inflammation in skin problems.

2. BEFORE YOU USE ACEA GEL

Do not use Acea Gel and talk to your doctor, if:

You are allergic (hypersensitive) to metronidazole, parahydroxybenzoates or any of the other listed ingredients (see section 6).

Using with other medicines:

Some medicines can interfere with your treatment, so please tell your doctor if you are taking or have recently taken any other medicines, including any obtained without a prescription.

You must talk to your doctor before using Acea Gel if:

- You are undergoing **haemodialysis**.
- You take **warfarin type oral anti-coagulants** (used to prevent blood clots).
- You are taking **phenobarbitone** (a sedative).

Using Acea Gel with alcohol:

You are advised **not to drink alcohol during treatment** with this medicine, because of the possibility of an unpleasant reaction, such as a headache, nausea, blurred vision, weakness, confusion or breathing difficulties.

Pregnancy and breast-feeding:

The safety of applying metronidazole to the skin during pregnancy and breast-feeding has not been adequately established, so you must talk to your doctor before use.

Important information about some of the ingredients:

The parahydroxybenzoates present in the gel may cause allergic reactions (possibly delayed).

3. HOW TO USE ACEA GEL

Always use Acea Gel exactly as instructed below. You should check with your doctor if you are not sure.

Dosage:

Adults and the elderly – Apply the gel twice daily, once in the morning and again in the evening, for 8 weeks. It is important to complete the course of treatment as it may take a few weeks

before you see any noticeable improvement in your condition. **Not recommend for use on children.**

Application:

1. Wash the face and forehead with a mild soap and dry.
2. Remove the tube from the carton and unscrew the cap.
3. Use the spike in the top of the cap to pierce the thin metal seal covering the tube nozzle.
4. Gently squeeze 1 cm (1/2 inch) of the gel onto clean fingers.
5. Apply the gel to the affected area of the skin, and rub gently to form a thin film.
6. Wash your hands and replace the cap.

This medicine is for external use only and if it is accidentally swallowed you should seek medical assistance.

If you forget to use Acea Gel, continue your treatment as before at the next planned morning or evening application.

If you accidentally apply too much Acea Gel, remove the excess with a tissue or soft cloth.

Avoid contact with the eyes. If accidental contact occurs, immediately wash out the gel carefully with water.

4. POSSIBLE SIDE EFFECTS

Like all medicines, as well as benefits, Acea Gel can cause side effects, although not everybody will experience them.

If any side effect becomes more serious, or if you notice any side effect not listed below, please tell your doctor. If necessary, remove the gel by washing the affected area with warm water.

- Use on unbroken skin may cause dryness and irritation.
- On rare occasions drowsiness, dizziness, headache, unsteadiness, skin rash, itching and darkening of the urine have been reported.
- If taken orally, metronidazole may lead to an unpleasant taste in the mouth, furred tongue, nausea, vomiting, stomach upset, hives (red, itchy raised areas of skin), swelling of the eyelids, face, lips, tongue and airways (causing difficulty in breathing) or a serious allergic reaction.

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