

Package leaflet: Information for the patient

IsotrexIN[®] Gel erythromycin 2% and isotretinoin 0.05%

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

1. What Isotrexin is and what it is used for

The name of this medicine is Isotrexin Gel (called Isotrexin in this leaflet), which is used to treat moderate acne. Isotrexin contains two different medicines called erythromycin and isotretinoin.

- Erythromycin is an antibiotic. It works by fighting bacteria that can cause acne (spots).
- Isotretinoin belongs to a family of medicines called retinoids, like vitamin A. It works by helping the skin so that blocked pores are less likely. This helps prevent spots.

Isotrexin helps to:

- make your skin less oily
- loosen blackheads and whiteheads so that they come out more easily
- stop new blackheads, whiteheads and spots from forming
- lower the number of bacteria which can cause acne
- lower the number of red, inflamed acne spots.

2. What you need to know before you use Isotrexin

Do not use Isotrexin if:

- you are allergic to erythromycin, isotretinoin or any of the other ingredients of Isotrexin (listed in Section 6)
- you are pregnant, if you think you could be pregnant, or if you are planning to become pregnant
- you are breast-feeding.

➔ Don't use Isotrexin if the above applies to you. If you are not sure, ask your doctor or pharmacist before using this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before using Isotrexin.

Before you use Isotrexin tell your doctor if:

- you have a history of inflammatory bowel disease or antibiotic-associated colitis (severe, prolonged or bloody diarrhoea following antibiotic use).

Antibiotics may cause a condition that result in severe diarrhoea and stomach cramps. This is unlikely to happen with antibiotics applied to the skin.

➔ If you develop stomach cramps or diarrhoea that does not improve or is severe, stop using Isotrexin and contact your doctor immediately.

Before you use Isotrexin your doctor needs to know if:

- you or any of your close family have had skin cancer
- you have had problems tolerating this or similar medicines in the past (you have found them too irritating for your skin)
- you have:
 - eczema
 - redness of the skin, broken blood vessels and tiny pimples usually in the centre of the face (*rosacea*)
 - redness and soreness around your mouth (*perioral dermatitis*)

Isotrexin may further irritate these conditions.

- you have skin reactions in the sunlight

➔ Check with your doctor if you think any of these may apply to you.

- Only use Isotrexin on your skin. Keep it away from areas such as your mouth, lips, and eyes.
- Don't use Isotrexin on any irritated areas of skin. For example if you have cuts or grazes, or sunburn.
- Don't use too much Isotrexin on sensitive areas of skin such as the neck.
- Don't use Isotrexin on skin that has had cosmetic treatment recently such as depilation, chemical hair treatment, chemical peel, dermabrasion or laser resurfacing.
- Take care not to use too much Isotrexin especially where it could run into your eyes or build up in the angles of your nose, skin folds, or other areas of the skin that do not require treatment.
- Avoid skin products that contain alcohol, spices or lime. These products may irritate your skin more if used with Isotrexin.

Sunlight

Using Isotrexin can make your skin more sensitive to sunlight. When you are using Isotrexin you need to:

- protect your skin from the sun. You can do this by using a sunscreen product which provides broad protection (protects against UVA and UVB rays) and wearing clothes to stop you getting sunburnt
- avoid using sun beds (sun lamps) or spending a long time in the sun

➔ If you do get sunburnt, stop using Isotrexin until your skin is better.

Very cold or windy weather may also irritate your skin while you are using Isotrexin.

Children

Isotrexin is for use by adults and adolescents with acne. It is not for use by children under 12 years.

Other medicines and Isotrexin

Tell your doctor or pharmacist if you are using, have recently used, or might use any other medicines.

If you have recently taken or used other medicines that contain erythromycin or clindamycin, there is an increased chance that Isotrexin will not work as well as it should.

➔ Tell your doctor or pharmacist if you have used or taken any other medicines that contain erythromycin or clindamycin recently.

Tell your doctor or pharmacist before using your medicine if:

- you are using benzoyl peroxide (another acne treatment). If used at the same time, it may make Isotrexin less effective. You may need to use these medicines at different times of the day (for example, one in the morning and the other at bedtime)
- you are using any other acne treatment. If used at the same time, it may make skin irritation worse. If your skin becomes very irritated, you may need to use a moisturiser, use Isotrexin less often or stop using it for a short period to allow your skin to recover and then re-start treatment. Stop treatment and see your doctor if skin irritation does not improve

➔ If you are not sure if the above applies to you, check with your doctor or pharmacist before using Isotrexin.

Pregnancy and breast-feeding

Don't use Isotrexin if:

- you are pregnant or might become pregnant (you should stop using Isotrexin one menstrual cycle (period) before trying to get pregnant).
- you are breast-feeding. Discuss with your doctor whether you choose to breast-feed or to use Isotrexin.

Use a reliable method of contraception properly to prevent pregnancy while you are using Isotrexin.

➔ If you do become pregnant during treatment with Isotrexin, tell your doctor.

Ask your doctor or pharmacist for advice before using any medicine, if you are pregnant or breast-feeding.

Important information about some of the ingredients of Isotrexin

Isotrexin contains butylated hydroxytoluene (E321). This can cause local skin reactions (e.g. contact dermatitis). It can also cause irritation to your eyes and mucous membranes such as the lining of your nose.

3. How to use Isotrexin

Always use Isotrexin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Use Isotrexin once or twice each day. Your doctor will tell you how many times to use the medicine.
- It can take 6 to 8 weeks before you see the full effect of Isotrexin.
- You should keep using the medicine until your doctor tells you otherwise.

How to apply Isotrexin

1. Wash your hands.
2. Completely remove any make-up, wash the area with a mild soap and warm water, and dry gently.
3. Put a thin film of gel on the affected skin, using your fingertips.
4. Apply to all of the area of your skin which has acne, not just each spot.
 - Take care not to apply too much Isotrexin especially where the excess could run into the eyes, the angles of the nose or other areas of the skin that do not require treatment.
5. Wash your hands after using the gel.
6. After it has dried, you can use non-greasy make-up.

What else you need to know when applying Isotrexin

- Due to the flammable nature of Isotrexin, you should avoid smoking or being near an open flame while you're applying Isotrexin, and immediately after you've used it.

If you use more Isotrexin than you should

If you use more Isotrexin than you should, it may cause redness, peeling or irritation of your skin. If this happens, stop using the medicine for a few days. Using more Isotrexin than you should will not help your spots clear up more quickly.

If you accidentally swallow Isotrexin

The ingredients of Isotrexin should not be harmful if swallowed in small amounts. If you accidentally get Isotrexin in your mouth, rinse at once with plenty of water. Talk to a doctor if you swallow a lot of Isotrexin.

If you forget to use Isotrexin

- Do not apply a double dose to make up for the forgotten doses.
- Apply the next dose at the usual time.

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

4. Possible side effects

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

Stop using Isotrexin and see a doctor straight away if:

- you have an allergic reaction: difficulty breathing or swallowing caused by sudden swelling of the throat, face, lips or mouth. A sudden swelling of hands, feet and ankles, or an itchy rash (*hives*)
 - you have severe burning, peeling or itching of your skin
 - you develop severe or prolonged diarrhoea
- ➔ Stop using Isotrexin and see a doctor straight away, if you notice any of the side effects above you may need urgent medical treatment.

Very common side effects

These may affect **more than 1 in 10** people:

- skin pain
- rash
- dry skin
- itchy skin
- skin burning sensation

- redness of the skin
- skin irritation
- skin peeling or scaling

Common side effects

These may affect **up to 1 in 10** people:

- itchy skin rash (*dermatitis, eczema*)

These effects are normal. If they cause you a problem, try using Isotrexin less often, or stop using it for a few days and then start again.

Other side effects

These side effects have occurred in a very small number of people but their exact frequency is unknown:

- allergic reaction
- swelling of the face
- itchy, bumpy rash (*hives*)
- abdominal pain
- diarrhoea
- increased sensitivity of the skin to sunlight
- discolouration of the skin

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 via 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 Isotrexin

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

- Isotrexin should be stored below 25°C.
- Do not use Isotrexin after the expiry date which is stated on the tube and carton (after "Exp:"). The expiry date refers to the last day of that month.

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 Isotrexin contains

- The active substances are erythromycin 2.0% (2 g per 100 g gel) and isotretinoin 0.05% (0.05 g per 100 g gel).
- The other ingredients are hydroxypropylcellulose, butylated hydroxytoluene and ethanol.

What Isotrexin looks like and contents of the pack

Isotrexin comes in tubes each containing 30 g of a pale yellow gel.

Marketing Authorisation Holder and Manufacturer

GlaxoSmithKline UK Limited

Stockley Park West
Uxbridge
Middlesex UB11 1BT
UK

Manufacturer:
Stiefel Laboratories (Ireland) Ltd
Finisklin Business Park
Sligo
Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Germany, Italy, Portugal: Isotrexin gel
France: Antibiotrex
Spain: Isotrex Eritromicina gel
United Kingdom: IsotrexIN gel

This leaflet was last revised in December 2013

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 **Isotrexin Gel**

Reference number PL 19494/0068

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

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