

PACKAGE LEAFLET: INFORMATION FOR THE USER

Isotrex[®] Gel isotretinoin 0.05% w/w

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

1. What Isotrex Gel is and what it is used for

The name of your medicine is Isotrex Gel. Isotrex Gel contains an active ingredient called isotretinoin.

- Isotretinoin is similar to Vitamin A. It works by helping the skin so that blocked pores are less likely. This helps prevent spots.

Isotrex Gel is used to treat acne (spots) in young people who are going through or have gone through puberty, and in adults. It is not for use by children who have not started puberty. Isotrex helps to:

- loosen blackheads and whiteheads so that they come out more easily
- stop new blackheads, whiteheads and spots from forming
- lower the number of red, swollen acne spots.

2. What you need to know before you use Isotrex Gel

Do not use Isotrex Gel:

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

→ **Tell your doctor** if any of these apply to you. Don't use Isotrex.

Warnings and precautions

Talk to your doctor before using Isotrex Gel:

- if you or any of your close family have had skin cancer
- if you have had problems tolerating this or similar medicines in the past (you have found them too irritating for your skin)
- if 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**)

Isotrex may further irritate these conditions.

- if you have skin reactions in the sunlight

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

Take care not to use too much gel 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.

Only use Isotrex on your skin. Keep it away from areas such as your mouth, lips, and eyes.

Don't use Isotrex on any irritated areas of skin. For example if you have cuts or grazes, or sunburn.

Don't use too much Isotrex on sensitive areas of skin such as the neck.

Isotrex Gel can cause skin irritation when used with other medicines used to treat acne. If your skin becomes irritated, reduce the amount of times you use Isotrex Gel, or stop using it until the irritation goes away. Stop using Isotrex Gel all together if the irritation does not go away.

Sunlight

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

- protect your skin from the sun. You can do this by using sunscreen 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 Isotrex until your skin is better.

Other medicines and Isotrex

Tell your doctor or pharmacist if you are taking any other medicines, if you've taken any recently, or if you start taking new ones. This includes medicines obtained without a prescription.

In particular, tell your doctor or pharmacist:

- if you are using benzoyl peroxide (another acne treatment). If used at the same time, it may make Isotrex 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).
- if 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 Isotrex 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.

→ **Check with your doctor or pharmacist** if you think any of these may apply to you.

Pregnancy, breast-feeding and fertility

Don't use Isotrex Gel if you are pregnant.

- **Tell your doctor if you are pregnant** or planning to become pregnant
- **Use a reliable method of contraception** properly to prevent pregnancy, while you are using Isotrex Gel
- **If you do become pregnant during treatment** with Isotrex Gel, tell your doctor.

Don't breast-feed while you are using Isotrex Gel. Discuss with your doctor whether you choose to breast-feed or to use Isotrex Gel.

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

Isotrex Gel contains butylated hydroxytoluene (E321)

This can cause local skin reactions e.g. contact dermatitis, reddening or flaking of skin. It can also cause irritation to your eyes and mucous membranes such as the lining of your nose.

3. How to use Isotrex Gel

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

- Use Isotrex Gel once or twice each day. Your doctor will tell you how to use the medicine.
- It can take 6 to 8 weeks before you see the benefits of Isotrex Gel.
- You should keep using the medicine until your doctor tells you otherwise.
- This product is flammable. Keep the gel away from open fire and flames and all sources of ignition during and immediately after you've used it.

How to apply Isotrex Gel

1. **Wash your hands.**
2. Completely **remove any make-up.**
3. Wash **the area** with a mild soap and warm water, and dry gently.
4. Put a **thin layer of gel** on the affected skin, using your fingertips, and smooth in.
5. Apply to **all of the area of your skin which has acne**, not just each spot.
6. **Wash your hands** after using the gel.

If you use more Isotrex than you should

If you use too much Isotrex, or use it more frequently than you should, it may cause redness, peeling or irritation of your skin. If this happens, use the gel less often or stop using it for a few days and then start again. Using more gel than you should will not help your spots clear up more quickly.

If you accidentally swallow Isotrex

The ingredients of Isotrex should not be harmful if swallowed in small amounts.

- If you accidentally get Isotrex in your mouth, rinse at once with plenty of water
- Talk to a doctor if you swallow a lot of Isotrex.

If you forget to use Isotrex Gel

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

4. Possible side effects

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

Serious skin reactions: - severe burning, peeling, redness or itching of your skin.

→ Stop using Isotrex 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 (may affect more than 1 in 10 people):

These effects can occur on the area of skin where you use the gel. If they cause you a problem, try using Isotrex less often, or stop using it for a few days until the irritation goes away, then start again. Stop using Isotrex if the irritation does not go away:

- redness or peeling of your skin, especially during the first few weeks of use
- slight stinging or skin pain
- skin irritation or tenderness
- skin burning sensation
- dry skin
- itching

Other side effects

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

- darkening or lightening of skin
- sensitivity to sunlight

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.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Malta

ADR Reporting

The Medicines Authority

Post-Licensing Directorate

203 Level 3, Rue D'Argens

GŻR-1368 Gżira

Website: www.medicinesauthority.gov.mt

e-mail: postlicensing.medicinesauthority@gov.mt

5. How to store Isotrex Gel

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

- Store below 25°C.
- Keep the tube 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 Isotrex Gel 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.
- This product should be used within two months of first opening. After two months, discard any unused portion.

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 to protect the environment.

6. Contents of the pack and other information

What Isotrex Gel contains

- The active substance is isotretinoin 0.05% w/w (0.05 g per 100 g gel).
- The other ingredients are hydroxypropylcellulose, butylated hydroxytoluene (E321) and ethanol.

What Isotrex Gel looks like and contents of the pack

Isotrex Gel comes in tubes each containing 30 g of a greenish-yellow gel.

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 Business Park, Sligo, Ireland

Or

Glaxo Operations UK Ltd, Harmire Road,
Barnard Castle, Co. Durham, DL12 8DT, United Kingdom

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: Isotrex gel

Reference number: PL 19494/0063

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

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