

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Isotrexin 20 mg/g + 0.5 mg/g Gel Erythromycin + Isotretinoin

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 your medicine is Isotrexin Gel (called Isotrexin in this leaflet). Isotrexin contains two active ingredients; erythromycin (an antibiotic) that works by fighting the bacteria that cause acne, and isotretinoin (which belongs to a family of medicines called retinoids, like vitamin A), which works by helping the skin so that blocked pores are less likely. This helps prevent spots.

Isotrexin is used to treat mild to moderate acne (spots). It helps to:

- fight the bacteria that can cause acne
- treat existing blackheads, whiteheads, and spots
- stop new blackheads, whiteheads, and spots from forming
- lower the number of red, inflamed acne spots
- make your skin less oily

Isotrexin is for use by adults and adolescents with acne. **It is not for use by children under 12 years**, as the safety and effectiveness are not known in this age group.

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 this medicine Isotrexin (listed in Section 6).
- you are pregnant
- you are planning a pregnancy

Warnings and precautions

Talk to your doctor or pharmacist before using Isotrexin if

- you are using any other acne products

- you have had problems tolerating this or similar medicines in the past (you have found them too irritating for your skin)
- you or any of your close family have had skin cancer
- you have skin reactions in sunlight
- you have any other medical conditions.

Only use the gel on your skin. Take care to avoid areas such as your eyes, mouth, lips or inside your nose. **Don't use Isotrexin on any irritated areas of skin**, for example:

- cuts, scrapes, sunburn or broken skin
- skin that has had cosmetic treatment such as depilation, chemical hair treatment, chemical peel, dermabrasion or laser resurfacing recently.

If you accidentally get Isotrexin on irritated skin or in the eyes, mouth, lips or inside your nose **rinse the affected area immediately with plenty of water.**

Don't use too much Isotrexin on sensitive skin such as:

- the neck
- areas of skin with eczema
- areas of redness with broken blood vessels and tiny pimples, usually on the central area of the face (rosacea)
- areas of redness and soreness around the mouth (perioral dermatitis)

Don't allow Isotrexin to accumulate in folds of your skin, including those between the nose and lips.

Most patients will experience some skin redness and peeling during the first few weeks of treatment. **If your skin becomes 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.

Avoid skin products that contain alcohol, spices or lime. These products may irritate your skin more if used with Isotrexin.

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

→ **Stop treatment and see your doctor** if skin irritation is severe (severe redness, dryness, itching, stinging or burning) or does not improve.

Isotrexin can make your **skin more sensitive to the harmful effects of the sun**. Avoid using sunbeds/lamps and spending a long time in the sun while using Isotrexin. **Use a sunscreen** product which provides broad protection (protects against UVA and UVB rays) and wear protective clothing to prevent sunburn.

Antibiotics may cause a condition that results in severe diarrhoea and stomach cramps. Although 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.**

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.

Other medicines and Isotrexin

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

Isotrexin can cause skin irritation if used with other medicines on the skin. This includes:

- medicines that contain **benzoyl peroxide** (also used to treat acne).
 - **Tell your doctor or pharmacist** if you are using any other medicines for acne. You may need to use the two products at different times of the day (e.g. one in the morning and the other at bedtime).
 - **Stop treatment and see your doctor** if skin irritation becomes severe (severe redness, dryness, itching, stinging or burning).

Isotrexin can affect how other medicines work, this includes:

- medicines that contain **clindamycin** (another antibiotic).

Isotrexin should not be used at the same time as medicines that contain clindamycin.

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

Pregnancy and breast-feeding

DO NOT use Isotrexin if you are pregnant or thinking of becoming pregnant. Your doctor can give you more information.

If you are breast-feeding, you must check with your doctor before you use Isotrexin. You will need to discuss with your doctor whether you choose to breast-feed or to use Isotrexin.

Isotrexin contains butylated hydroxytoluene (E321). This can cause local skin reactions. 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 this medicine exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

- Isotrexin should be applied **only to your skin**.
- Use Isotrexin once or twice each day over the whole of the affected area. It can take up to 8 weeks before you see the effect of Isotrexin.
- You should keep using the medicine until your doctor tells you otherwise.

How to apply Isotrexin

1. Completely **remove any make-up**.
2. **Wash your hands**.
3. **Rinse the entire affected area** of skin with warm water and a mild cleanser and gently pat dry.
4. Apply a **thin layer** of gel on the entire affected area of skin, not just each spot, using your fingertips and smooth in.
5. **Take care not to apply too much Isotrexin** especially where it could run into the eyes, the angles of the nose, any skin folds, or other areas of the skin that do not require treatment.
6. Replace the cap on the tube after use.
7. **Wash your hands** after using the gel.

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 get a lot of dryness or skin peeling, you can use a moisturiser, use Isotrexin less frequently or stop treatment for a short period to allow your skin to adjust to the treatment. However, this medicine may not work properly if it is not applied every day.

If you use more Isotrexin than you should

Take care not to apply too much. Applying too much Isotrexin or applying it more frequently will not help your spots clear up more quickly, and may cause skin irritation. If this does happen, use the gel less often, or stop using Isotrexin for a few days and then start again.

If you forget to use Isotrexin

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

If you accidentally swallow Isotrexin

The ingredients of Isotrexin are not expected to be harmful if swallowed in the small amounts normally applied to the face. If you do accidentally get Isotrexin in your mouth, it may cause irritation so rinse at once with plenty of water. **If you do accidentally swallow a large amount of Isotrexin, seek medical advice.** It may cause sickness and diarrhoea.

4. Possible side effects

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

Stop using Isotrexin and see a doctor straight away if you:

- have an **allergic reaction** (such as 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).
- have severe **burning, peeling or itching** of your skin.
- have developed **severe or prolonged diarrhoea**.

Very common side effects

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

- skin pain
- rash
- skin irritation
- redness of the skin
- skin dryness
- skin peeling or scaling
- skin burning sensation
- itchy skin

Common side effects

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

- application site reaction such as dermatitis, eczema and dry skin

Rare side effects

These may affect **up to 1 in 1,000** people:

- allergic reaction
- itchy, bumpy rash (*hives*)
- abdominal pain/discomfort

- diarrhoea
- increased sensitivity of the skin to sunlight
- discolouration of the skin
- swelling of the face

➔ **Tell your doctor or pharmacist** if any of the side effects listed becomes **severe or troublesome**, or if you notice any side effects not listed in this leaflet.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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.

Contents are flammable. Keep Isotrexin away from all sources of fire, flame and heat. Do not leave Isotrexin in direct sunlight.

Replace cap firmly after use to prevent evaporation

Do not store above 25°C. Keep the container tightly closed when not in use.

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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Isotrexin contains

The active substances are erythromycin and isotretinoin. Each gram of gel contains 20 milligrams of erythromycin and 0.5 milligrams of isotretinoin.

The other ingredients are hydroxypropylcellulose, butylated hydroxytoluene (E321) (see section 2) and ethanol.

What Isotrexin looks like and the contents of the pack

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

Marketing Authorisation Holder and Manufacturer

Product Authorisation Holder:

GlaxoSmithKline (Ireland) Ltd., 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland. Trading as Stiefel.

Manufacturer:

Stiefel Laboratories (Ireland) Ltd., Finisklin Business Park, Sligo, Ireland.

This leaflet was last revised in July 2018

Trade marks are owned by or licensed to the GSK group of companies
© 2018 GSK group of companies or its licensor.