

Reason for Update: QRD + HPRA details change  
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Text Date: 19/05/2015  
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### **Package leaflet: Information for the user**

#### **ISOTREX<sup>®</sup> 0.5 mg/g GEL** 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 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 the active substance isotretinoin. This belongs to a group of medicines called retinoids.

Isotrex Gel is used to treat mild to moderate inflammatory and non-inflammatory acne vulgaris in adults and adolescents over 12 years of age. It is not for use by children.

It 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 red, inflamed 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 in this medicine (listed in section 6).

##### **Warnings and precautions**

Talk to your doctor or pharmacist before using Isotrex Gel:

- if you cannot tolerate or have skin reactions in sunlight to isotretinoin or any of the other ingredients of Isotrex Gel (listed in section 6).
- If you or any of your close family have had skin cancer.
- If you suffer from eczema, redness of the skin, broken blood vessels and tiny pimples on the face (rosacea), or redness and soreness around the mouth (perioral dermatitis).

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Only use Isotrex Gel on your skin.

Avoid contact with areas such as your mouth, eyes, mucous membranes and any irritated areas of skin such as cuts, grazes, sunburn, broken or eczematous skin.

Take care when applying Isotrex Gel to the neck and other sensitive areas of skin.

Take care not to let the medicine accumulate in folds of your skin including those between your nose and lips.

### **Sunlight**

Isotrex Gel may cause increased sensitivity to sunlight. Avoid using sunlamps and spending a long time in the sun while using Isotrex Gel. When exposure to strong sunlight cannot be avoided, use a sunscreen product and wear protective clothing.

### **Children**

Do not use this medicine on children under 12 years of age because the safety and efficacy have not been established.

### **Other medicines and Isotrex Gel**

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.

Some acne treatments can affect how Isotrex Gel works, or cause skin irritation when used together. These include:

- other acne treatments that are applied to the skin
- other acne treatments that are applied to the skin which contain benzyl peroxide.

You may need to use the two products at different time of the day, one in the morning and the other in the evening.

If irritation persists stop using Isotrex Gel.

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

### **Pregnancy and breast-feeding**

It is not recommended to use Isotrex Gel 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.

### **Isotrex Gel contains butylated hydroxytoluene (E321)**

Isotrex Gel contains butylated hydroxytoluene (E321). This may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

## **3. How to use Isotrex Gel**

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

- Use Isotrex Gel once or twice each day. Your doctor will tell you how many times to use the medicine.

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- It can take 6 to 8 weeks before you see the full effect of Isotrex Gel.
- Keep using this medicine until your doctor tells you otherwise.
- Due to the flammable nature of Isotrex Gel, you should avoid smoking or being near an open flame while you are applying the gel and immediately after you've used it.

### **How to apply Isotrex Gel**

1. Wash your hands.
2. Completely remove any make-up and wash the affected area.
3. Put a thin film of gel on the affected skin, using your fingertips and smooth in.
4. Apply to all of the area of your skin which has acne, not just each spot.
5. Take care not to apply too much gel.
6. Wash your hands after using the gel.
7. After it has dried, you can use non-greasy make-up.

### **If you forget to use Isotrex Gel**

- Do not apply a double dose to make up for forgotten doses as excessive application will not improve efficacy, but may increase the risk of skin irritation.
- Apply the next dose at the usual time.

### **If you accidentally swallow Isotrex Gel**

The ingredients of Isotrex Gel are not expected to be harmful if swallowed in the small amounts normally applied to the face. If you do accidentally get Isotrex Gel in your mouth, rinse at once with water. Seek medical advice if you swallow a large amount.

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

## **4. Possible side effects**

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

### **Serious skin reactions: Signs include:**

- Severe burning, peeling or itching of your skin.

Contact your doctor immediately if you get any of these symptoms. Stop using Isotrex gel.

### **Very common:** may affect more than 1 in 10 people

- redness of your skin
- skin flaking
- skin pain
- itching
- skin irritation
- skin tenderness
- skin burning sensation
- application site stinging
- dry skin

These effects are normal. If they cause a problem, try using Isotrex Gel less often, or stop using it for a few days and then resume once the reaction subsides. If irritation persists, treatment should be discontinued.

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

- darkening of fair skin
- lightening of darker 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 via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Isotrex Gel**

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

Do not use this medicine 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.

Store below 25°C. Replace the cap securely after use. Contents are flammable. Keep away from all sources of fire, flame and heat. Do not leave Isotrex Gel in direct sunlight.

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 protect the environment.

## **6. Contents of the pack and other information**

### **What Isotrex Gel contains**

- The active substance is isotretinoin. Each gram of gel contains 0.5 mg of isotretinoin.
- The other ingredients are hydroxypropylcellulose, butylated hydroxytoluene (E321) and ethanol.

### **What Isotrex Gel looks like and the contents of the pack**

Isotrex Gel is a soft, greenish-yellow gel. Isotrex Gel is available in aluminium tubes fitted with a polyethylene screw-cap, packed into a carton each containing 30 g gel.

### **Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder:

GlaxoSmithKline (Ireland) Ltd, Stonemasons Way, Rathfarnham, Dublin 16, Ireland. Trading as Stiefel.

Manufacturer:

Glaxo Operations UK Ltd (trading as Glaxo Wellcome Operations), Harmire Road, Barnard Castle, Co. Durham DL12 8DT, United Kingdom.

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

**This leaflet was last revised in June 2015.**

**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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