

ISOTREX® GEL

Isotretinoin 0.05% w/w

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you use Isotrex Gel.

This leaflet answers some common questions about Isotrex. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you using Isotrex Gel against the risks this medicine could have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What is Isotrex Gel used for?

Isotrex Gel is used to treat acne (spots).

Isotrex belongs to a group of medicines called retinoids.

Isotrex Gel works by:

- Making your skin less oily
- Loosening blackheads and whiteheads so that they come out more easily
- Stopping new blackheads, whiteheads and spots from forming
- Lowering the number of red, inflamed acne spots.

Your doctor may have prescribed Isotrex Gel for another reason.

Isotrex Gel is not addictive.

Before you use Isotrex Gel

Do not use if:

You must not use Isotrex Gel if:

- you have ever had an allergic reaction to isotretinoin or any of the ingredients listed toward the end of this leaflet. (See "Ingredients")
- **if you or any of your close family have had skin cancer**
- **if you are pregnant or trying to become pregnant**
- **if you are breast-feeding**
- **the expiry date (EXP) printed on the pack has passed.**
- **the packaging is torn or shows signs of tampering**

Tell your doctor if:

You must tell your doctor if:

- **you are allergic to foods, dyes, preservatives or any other medicines.**
- **you are using any other medicines for acne.**

You may need to use the two products at different times of the day (eg. one in the morning and the other at bedtime).

- **you are taking any other medicines, including medicines you buy without a prescription.** Isotrex Gel can affect how other medicines work, or cause skin irritation with other medicines. This includes:
 - medicines containing benzoyl peroxide (also used to treat acne).
- **you are breastfeeding, pregnant or trying to become pregnant.**
- **you cannot tolerate or have skin reactions in sunlight to isotretinoin or any of the other ingredients of Isotrex Gel**
- **you suffer from eczema, redness of the skin, broken blood vessels and tiny pimples usually on the central area of the face (rosacea) or redness and soreness around the mouth (perioral dermatitis). Isotrex Gel may further irritate these conditions.**

How do I use Isotrex Gel?

How much to use

Use Isotrex Gel as directed by your doctor or pharmacist.

- Use Isotrex Gel once daily at night time over the whole of the affected area. Your doctor will tell you how many times to use the medicine.
- You should keep using the medicine until your doctor tells you otherwise.

How to apply it

- **Due to the flammable nature of Isotrex Gel, you should avoid smoking or being near an open flame while you're applying Isotrex Gel, and immediately after you've used it.**
- **Wash your hands.**
- **Completely remove any make-up.**
- **Wash the affected area with a mild soap and warm water, and gently dry.**
- **Put a thin film of gel on the affected skin using your fingertips, and smooth in.**
- **Apply to all the area of your skin which has acne, not just each spot.**
- **Take care not to apply too much gel especially where it could run into your eyes, the angles of your nose, any skin folds, or other areas of the skin that do not require treatment. Applying too much gel or applying it more frequently will not help your spots clear up more quickly, and may cause redness, peeling and discomfort. If this does happen, use the gel less often, or stop using it for a few days and then start again once the irritation subsides.**
- **Wash your hands after using the gel.**

How long to use it for

- It can take 6 to 8 weeks before you can see the full benefit of Isotrex Gel.

Do not stop using Isotrex Gel or change the dose without first checking with your doctor.

Use in children and elderly patients

Isotrex Gel is for use by adults and adolescents with acne.

It is not for use by children.

If you forget to use Isotrex Gel

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

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (In Australia call 13 11 26. In New Zealand call 0800 POISON or 0800 764 766) for advice, if you think you or anyone else may have used too much Isotrex Gel, even if there are no signs of discomfort or poisoning.

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

If you are not sure what to do, contact your doctor or pharmacist.

While you are using Isotrex Gel

Things you must do

Tell your doctor if, for any reason, you have not used your medicine exactly as directed.

Tell your doctor if you are pregnant or planning to become pregnant.

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

If you do become pregnant during treatment with Isotrex Gel, tell your doctor.

Breast-feeding is not recommended during treatment with Isotrex Gel. Discuss with your doctor whether you choose to breast-feed or to use Isotrex Gel.

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

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Isotrex Gel to treat any other complaints unless your doctor says so.

Do not use the gel on any irritated areas of the skin, such as cuts, grazes, sunburn, or broken skin.

Do not use too much Isotrex Gel on sensitive skin such as the neck, or allow it to accumulate in folds of your skin, including those between the nose and lips.

Isotrex Gel can cause increased sensitivity to sunlight. Avoid using sunlamps and spending a long time in the sun while using Isotrex Gel. Use a sunscreen product and protective clothing to prevent sunburn.

Things to be careful of

Be careful driving or operating machinery until you know how Isotrex Gel affects you.

What are the side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to using Isotrex Gel, even if the problem is not listed below.

Like other medicines, Isotrex Gel can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side-effects are:

- redness of your skin
- skin flaking
- skin pain
- itching
- skin irritation
- skin tenderness
- burning feeling on the skin, especially when first applied
- application site stinging
- dry skin

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

Other rare effects include:

- darkening of fair skin
- lightening of darker skin
- sensitivity to sunlight

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

Tell your doctor immediately if you notice any of the following:

- **Wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be a symptom of an allergic reaction.**
- **Severe burning, peeling or itching of your skin.**

Stop using Isotrex Gel.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

How do I store Isotrex Gel?

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Isotrex Gel should be stored below 25°C.

Keep the container tightly closed when not in use. Contents are flammable. Keep Isotrex Gel away from all sources of fire, flame and heat. Do not leave Isotrex Gel in direct sunlight.

Do not leave in a car, on a window sill or in a bathroom.

Return any unused or expired medicine to your pharmacist.

Product description

What Isotrex Gel looks like

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

Ingredients

Isotrex Gel contains the active ingredient isotretinoin.

Isotrex Gel also contains

- hydroxypropylcellulose,

- butylated hydroxytoluene and
- ethanol.

Sponsor

Isotrex Gel is supplied in Australia by:

GlaxoSmithKline Australia Pty Ltd
Level 4
436 Johnston Street
Abbotsford
Victoria 3067
Australia

Isotrex Gel is supplied in New Zealand by:

GlaxoSmithKline NZ Limited
AMP Centre
Cnr Albert & Customs Streets
Private Bag 106600
Downtown
Auckland 1143
New Zealand

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

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This information provided applies only to:
Isotrex®.

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