

ISOTREX GEL

0.05% Isotretinoin USP

Consumer Medicine Information

Please read this leaflet carefully before you start to use Isotrex Gel. If there is anything which you do not understand, or if you would like more information or advice, ask your doctor or pharmacist. Please keep this leaflet; you might need to read it again.

Identification

Isotrex Gel contains the drug isotretinoin at a strength of 0.05%.

Isotrex Gel also contains hydroxypropylcellulose, butylated hydroxytoluene and ethanol.

Isotrex Gel is supplied in tubes containing 30g.

AUST R 47053

What is Isotrex Gel used for and how does it work

Isotrex Gel is used for the treatment of acne. The main actions of isotretinoin are to encourage normal development of the outer layer of the skin and to reduce the production of sebum (the natural oil in the skin).

Isotrex Gel will help to:

- Reduce the amount of sebum which the skin produces.
- Stop the blockage of the skin's pores, which can lead to a build-up of sebum in the skin.
- Loosen blackheads and white heads in the skin so that they will come out more easily.
- Stop new blackheads, whiteheads and spots from forming.

Before you use Isotrex Gel

Isotrex Gel might not be suitable for some patients. If the answer to any of the following questions is YES, please go back to your doctor. Do not start to use Isotrex Gel until you have checked with your doctor.

- Are you pregnant or trying to become pregnant?
- Are you breast-feeding?
- Have you, or any member of your close family had squamous cell or basal cell carcinoma?
- Are you allergic to any of the ingredients in Isotrex Gel?
A list of ingredients is given at the beginning of this leaflet.
- Are you using any other acne treatment which your doctor does not know about?

How to use Isotrex Gel

Isotrex Gel is normally used once a day just before going to bed at night, but your doctor might have suggested a different time or frequency which he or she thinks is more suitable for you.

Wash your skin carefully and dry it thoroughly before you apply Isotrex Gel. If possible wait 30 minutes after

washing and drying before using the gel.

Apply Isotrex Gel to all of the area of your skin which has acne, not just to individual spots. Apply the gel sparingly (if it does not rub into the skin easily you are using too much), using the tips of your fingers. Wash your hands after applying Isotrex Gel.

Other information about using Isotrex Gel

Make sure that you keep Isotrex Gel away from irritated areas of the skin, for example if you are sunburnt or have eczema.

You should also keep Isotrex Gel away from your eyes, lips and the angles of your nose.

Using more than the recommended amount of Isotrex Gel will not help the treatment of your acne.

Exposure to sunlight of areas treated with Isotrex Gel should be avoided or minimised. If you do have to expose skin which is being treated with Isotrex to the sun, use a maximum protection sunscreen (SPF 15+). Do not use sunbeds or sunlamps while you are treating your skin with Isotrex Gel.

It can take some time, about 6 to 8 weeks before the full effects of Isotrex Gel on acne are seen; this is due to the way acne forms and is

normal. Treatment should not be continued for longer than 3 months unless continuation is recommended by your doctor.

You can continue to use make-up and skin moisturisers while you are using Isotrex Gel, but try to avoid heavy, oily products.

Further information

Isotrex Gel can only be obtained from a pharmacy with a doctor's prescription. Remember that this medicine is for you; do not give it to other members of your family or to your friends.

Unwanted effects

Isotrex Gel can cause slight stinging and a feeling of warmth, particularly when the gel is first applied. You will probably also notice flaking and redness of your skin, especially during the first few weeks of treatment with Isotrex Gel. These effects are normal; if they bother you, you should stop using Isotrex Gel for a few days, and then use the gel every other day until your skin has built up tolerance.

If you suffer severe burning, peeling or itching, or if you suffer other effects not described in this leaflet, you should stop using Isotrex Gel and go back to your doctor.

Storage conditions

Isotrex Gel should be kept at temperatures below 25°C.

An expiry date is printed on the tube and carton. Do not use the gel after this date, or if there are any signs of deterioration.

In the case of overdose

Applying excessive amounts of Isotrex Gel to your skin will cause severe redness and irritation. Stop using Isotrex and use a moisturising cream until your skin returns to normal.

If Isotrex Gel is accidentally swallowed, contact your doctor, hospital casualty department or poisons centre.

Where to go for further information

If you have any questions about Isotrex Gel, or if you are unsure about any of the information in this leaflet, please see your doctor or pharmacist.

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

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