

Patient Reminder Card

Doctor's name:

Telephone:

Notes:

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 the Roaccutane[®] Package 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.

Please report side effects to:

The Drug Surveillance Centre,
Roche Products (Ireland) Limited,
3004 Lake Drive, Citywest, Naas Road, Dublin 24

Telephone: (01) 4690700

Fax: (01) 4690793

Email: ireland.drug_surveillance_centre@roche.com

Or report to:

HPRA Pharmacovigilance, The Health Products
Regulatory Authority, Kevin O'Malley House,
Earlsfort Centre, Earlsfort Terrace, Dublin 2

Telephone: (01) 6764971

Fax: (01) 6762517

Email: medsafety@hpra.ie

Website: www.hpra.ie

Further Information

Please read the Roaccutane[®] Package Leaflet for further information on this medicine. If you have any questions about this medicine, please talk to your doctor or pharmacist.

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Roaccutane[®] ▼ (isotretinoin) Contraception and Pregnancy Prevention Patient Reminder Card

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See box on reverse for details on how to report.

Important reminder for men and women

- This medication has been prescribed to you only, **do not share it with anybody and return any unused capsules to the pharmacy.**
- **Do not donate blood during treatment and for 1 month after stopping** because an unborn baby could be harmed if a pregnant patient receives your blood.

Read the Package Leaflet carefully before you start treatment.

Important information to know*

Roaccutane® must not be taken during pregnancy.

Roaccutane® can seriously harm an unborn baby if taken during pregnancy.

If you become pregnant or think you might be pregnant during treatment, stop taking Roaccutane® immediately and contact your doctor.

If you think you might be pregnant within one month of stopping Roaccutane®, contact your doctor immediately, because some medicine may still be left in your body.

If you have any questions or concerns about taking Roaccutane®, talk to your doctor or pharmacist.

**This applies to all girls and women using Roaccutane® and who could become pregnant.*

What you must do*:

! Use at least one very reliable method of contraception (such as an intra-uterine device or an implant) or correctly use two effective methods that work in different ways (such as an oral contraceptive together with a condom) for one month before taking Roaccutane®, during treatment and for one month after stopping treatment.

! Do not become pregnant while taking Roaccutane®, or for one month after stopping treatment.

! Attend regular follow-up visits and have regular pregnancy testing:

- Before you start treatment, you will have to take a pregnancy test, which must be negative.
- To make sure you are not pregnant during treatment, you will have to take regular pregnancy tests, ideally every month.
- One month after stopping treatment, you will have to take a final pregnancy test.

**This applies to all girls and women using Roaccutane® and who could become pregnant.*