

ROACCUTANE Patient Information Leaflet

Why am I being prescribed Roaccutane?

Roaccutane (isotretinoin) is a drug prescribed for severe forms of acne and moderate acne resistant to adequate courses of standard therapy e.g. systemic antibiotics and topical therapy. It is being prescribed for you only. It is important not to share your medication with friends or family.

What dose do I take?

You will be advised on your dose. Usually you will start on a low dose for the first month to avoid a severe flare of acne and to get used to Roaccutane side effects. If tolerating this dose, you will be increased to the full dose after one month. The dose you are given will depend on your body weight. Roaccutane tablets come in 20 mg and 10 mg capsules. If you have any questions about the correct dose, please contact your prescribing Dermatologist.

When do I take Roaccutane?

Roaccutane is taken once a day with food or the dose can be split and tablets taken twice a day.

What are the possible side effects?

All patients experience dryness of the skin, lips and nostril. This may result in a skin rash if severe. Nasal dryness may cause nosebleeds. Dryness of the eyes may cause contact lens intolerance. Other undesirable side effects which are less common include muscle aches, headaches, visual disturbance, changes in hair texture, and mood changes including depression. Depression is a very important side effect and if you or any of your family notice that you develop a depressed mood or other symptoms such as difficulty sleeping, fatigue, poor appetite and lack of interest in usual activities, please contact your prescribing Dermatologist. Roaccutane has been rarely associated with inflammatory bowel disease. This may manifest as abdominal pain, diarrhoea, bleeding after toilet.

Blood tests before and during Roaccutane treatment:

As Roaccutane can on occasion affect the blood count, liver function and serum lipids (cholesterol and triglycerides), it is necessary to check these (baseline) before starting Roaccutane. Roaccutane is usually started at low dose ie 0.5mg/kg/day. Bloods should be repeated after one month at this dose. If the dose is increased after one month to 1mg/kg/day, bloods need to be repeated after a month at this full dose, two months following that (ie at four months) and every two months while on Roaccutane. It may be necessary to repeat the blood tests more frequently if any abnormality is detected.

The blood tests which will require monitoring each month are FBC, LFTs, fasting cholesterol and triglycerides (fasting from 8 p.m. until blood test next a.m., no coffee). Women require a monthly pregnancy test.

For Females:

As discussed with you during your consultation, you must not be pregnant or become pregnant while taking Roaccutane. You or your parent/guardian will have signed the Roaccutane acknowledgement form for female patients, accepting the risk and precautionary measures required to avoid pregnancy associated with taking Roaccutane. There is a high risk that an unborn baby could have severe birth defects. You or your parent/guardian will also have received a booklet on contraception for patients on Roaccutane.

Effective contraception, without interruption, is required for one month before starting treatment, throughout the duration of treatment and one month after the end of treatment. At least one and preferably two complimentary forms of contraception including a barrier method should be used.

Contact your prescribing Dermatologist immediately if you do become pregnant or think you may be pregnant during treatment or in the first month after treatment ends.

In addition to this leaflet, you will be given an information leaflet produced by Roche, the company that manufactures Roaccutane.

Pregnancy testing:

Medically supervised pregnancy tests must be performed on the day that Roaccutane is prescribed or in the three days prior to that date. Roaccutane is commenced after the patient has been using effective contraception for at least one month. It is prescribed during a menstrual period. For patients on the combined oral contraceptive pill this is during the week of the withdrawal bleed (the week off the Pill). Commencement of Roaccutane is recommended in the first three days of the menstrual cycle.

Pregnancy tests need to be repeated every month and can be performed on the day of your follow up appointment or in the three days prior to that date.

Five weeks after stopping treatment, women should undergo a final pregnancy test.

Women of child bearing potential may only receive a prescription for Roaccutane for one month. Dispensing of this prescription must be completed within seven days of the date on the prescription.

Patients need to be reviewed on a regular basis during treatment by their Dermatologist.

Other precautions:

- Roaccutane contains Arachis oil (peanut oil) and soya oil. Thus it is contra indicated in patients allergic to peanuts or soya.
- Roaccutane is a derivative of Vitamin A. Thus do not take vitamin supplements containing Vitamin A as this may increase the possibility of side effects.
- If you have been on antibiotics for your acne, do not take these in combination with Roaccutane.

- Patient should not donate blood during therapy and for 1 month following discontinuation of Roaccutane.

- Avoid exposure to intense sunlight. Wear a sunscreen with a SPF of at least 15.

- Avoid waxing as a method of hair removal during treatment with Roaccutane and for at least a period of 6 months following treatment as your skin may be more fragile and tear following this procedure.

- Avoid laser treatments for a period of 1 year following the end of treatment due to the risk of hypertrophic scarring and pigmentary change.

- Always inform your surgeon that you are on Roaccutane if surgery is anticipated.

- If you have any questions before, during or after Roaccutane therapy, please contact your Dermatologist.

Additional Precautions:

Patients should never give this medicine to another person and should return any unused capsules to their Pharmacist at the end of treatment. Roaccutane patients should not donate blood during therapy and for one month following discontinuation of Roaccutane.

Please read the package insert that comes with Roaccutane in addition to the brochures you have been provided with during your consultation. If you have any questions or concerns please do not hesitate to ask.

Dr Gillian E Gibson
Consultant Dermatologist
Tel: 021-4941566

Dr William J O Connor
Consultant Dermatologist
Tel: 021- 4941566