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FOR PATIENTS



IMPORTANT INFORMATION
CONCERNING YOUR TREATMENT WITH

Roaccutane
(isotretinoin)

FOR SEVERE CYSTIC ACNE

WARNING:

This product causes birth defects.

Refer "Essential Information for Female Patients".

**ESSENTIAL INFORMATION
FOR FEMALE PATIENTS**

ROACCUTANE is an effective treatment for cystic acne. However, the drug causes birth defects. To avoid this risk and the distress it could cause you, IT IS ESSENTIAL THAT YOU READ AND UNDERSTAND THE FOLLOWING:

1. The possibility that you may be pregnant **MUST** be ruled out by you and your doctor immediately before you start taking ROACCUTANE.
2. You must avoid becoming pregnant by using strict birth control measures for one month before treatment, during the whole period of treatment and for at least four weeks after treatment has ceased.
3. Wait until the second or third day of your next normal menstrual period before beginning ROACCUTANE therapy.
4. Should you become pregnant during the period of treatment (or in the first four weeks following the end of treatment) immediately **STOP** taking ROACCUTANE and advise your doctor.
5. Do **NOT** breast feed while taking ROACCUTANE.
6. If you have any doubts about these instructions or about the effects of ROACCUTANE, please discuss these with your doctor.

This information is also available from Roche in the following languages: Arabic, Croatian, Greek, Italian, Spanish, Turkish and Vietnamese.

PLEASE READ CAREFULLY

How to take and treat Roaccutane capsules:

ROACCUTANE should be taken **with** meals.

It is most important that you take your ROACCUTANE capsules **exactly** as directed — take the full course as instructed by your doctor. However, if you miss a dose, do **NOT** double the next dose.

Do not give ROACCUTANE to other members of your family or friends: Keep them out of reach of children. Do not expose the capsules to sunlight or excessive heat — store them in a cool place.

What to expect and what to do about it:

You may notice some worsening of your skin condition during the first two to four weeks of therapy. Do not be discouraged as this is a sign that the treatment is working and you should begin to notice a gradual improvement over two to four months. Most patients notice their skin condition continues to improve even after completing the treatment.

In the first few weeks, perhaps before you see any healing, you may have some side effects. These side effects are usually mild and dose-related.

- The most common side effect is dryness of the lips, lining of the nose or eyes. Apply a moisturizer or petroleum jelly to keep skin soft but do NOT apply to acne lesions. Mild nosebleeds can also occur and petroleum jelly can be used to moisten the lining of the nostrils. These side effects disappear completely in a few days to a few weeks after the dose of ROACCUTANE is lowered or stopped.
- Some other reactions that have occurred include bleeding and inflammation of the gums, itching, rash, skin fragility and peeling of the palms and soles. In a small number of patients thinning of the hair has occurred (and, in rare cases, has persisted).
- You may experience some increased sensitivity to sunburn during and for some weeks after the treatment. Use a non-oily sunscreen preparation when out of doors.
- If you wear contact lenses, you may experience decreased tolerance to your lenses during and after therapy.
- Although rare, severe headaches, blurred vision, gastrointestinal upsets and rectal bleeding have occurred. Consult your doctor immediately if you experience any of these problems.
- You should also consult your doctor if you experience joint pain or stiffness, or if your acne begins to show a tendency to form 'crusts'.

Please note that ROACCUTANE cannot improve scars or pitting that were present before treatment started, but it will prevent such skin damage in the future.

Can I take other medications with ROACCUTANE?

You can take other drugs with ROACCUTANE but **check first** with your doctor. Do NOT take vitamin preparations that contain Vitamin A (check with a chemist if you are unsure). Avoid the use of topical creams or ointments for acne during therapy unless otherwise advised by your doctor.

Blood tests:

Your doctor will carry out blood tests to check your body's response to ROACCUTANE. Raised cholesterol and triglyceride levels occur in a small minority of patients and may result in the need to follow a low cholesterol diet for the period of treatment. Your doctor will advise you if this is necessary.

Tell your doctor:

If you are allergic to any foods or medication or are sensitive to parabens (a preservative), let your doctor know.

If you are a diabetic or there is a history of diabetes in your family, advise your doctor since blood sugar testing may be important.

Advise your doctor if you are planning to undergo vigorous physical activity during treatment.

Consult your doctor if you have any questions about the treatment.

Roaccutane = Trade Mark

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