

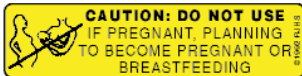
DRUG NAME: Accutane (isotretinoin), Capsules: 10mg, 20mg, and 40mg.

MANUFACTURER: ROCHE

INDICATIONS FOR USE: For the treatment of severe recalcitrant nodular acne unresponsive to conventional therapy including systemic antibiotics.

In order to assist you with your patient counseling we recommend the use of the following Patient Advisory Label(s) when you dispense *Accutane*:

A-46



Research: Pregnant women or those who may become pregnant must not use this medication. There is an extremely high risk that a deformed infant will result if pregnancy occurs while taking this drug in any amount even for short periods. Potentially, all exposed fetuses can be affected. It is not known if this drug is excreted into the breast milk.

A-11



Research: Photosensitization (photoallergy or phototoxicity) may occur; caution patients to take protective measure (i.e. sunscreens, protective clothing) against exposure to ultraviolet light or sunlight.

A-10



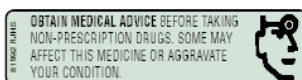
Research: In some people, this medication irritates the stomach and may cause some pain or discomfort. To avoid this, it is recommend that this medication be taken with some food.

A-13



Research: This labels is considered the “universal” counseling label that reminds the patient to following the instructions as outlined by his/her physician.

A-14



Research: Non-Prescription Items that contain alcohol and vitamin supplements that contain vitamin A may affect the action of this medicine or may aggravate a side effect (i.e. vision).

Please Note: The Patient Advisor® is intended to provide the healthcare professional with easily accessible, practical drug counseling information to use when verbally communicating about a particular drug with a patient. The information printed here is designed to assist, not replace, professional judgement. Professional judgement must always be used when considering what type of information is to be supplied to the patient. The author, manufacturer or distributor make no claims regarding proper use of this information.

References available upon request.

To obtain Labels or other Patient Counseling Information:



R•J Health Systems, Inc.

P.O. Box 290616 • Wethersfield, CT 06129-0616 • Phone: 860-563-1223 Fax: 860-563-1650 • or on the Web: www.rjhealthsystems.com

ACCUTANE (isotretinoin)

Be sure to read all this information and contact your doctor or pharmacist if you have any questions that are not answered here.

THIS MEDICATION IS USED: To treat severe cystic acne.

PROPER USE OF THIS MEDICATION:

- Take this medication exactly as your doctor has instructed.
- This medication should be taken with a full glass of water (4 ounces) or with food (crackers, bread or a full meal) to reduce the chance of stomach upset.

IMPORTANT INFORMATION TO REMEMBER:

- If your mouth becomes dry, you could suck on hard sour candy (sugarless), ice chips or chew gum.
- You must take this medication regularly as ordered by your doctor. It may take 1 to 2 months for you to see the full effects of this medication.
- This medication may cause your skin to be more sensitive to the effects of the sun or sunlamps. If you must go out in the sun, wear protective clothing, use sunglasses, and use a suitable sunscreen.
- **DO NOT** stop your medication abruptly or change the amount taken without first talking with your doctor or pharmacist.
- Talk with your doctor or pharmacist before taking a Non-Prescription drug that contains alcohol or vitamin A. Some may affect this medicine or aggravate a potential side effect.
- If you become pregnant or think you are pregnant, call your doctor immediately.
- While on this medication, you should practice contraception 1 month before, during and 1 month after you stop this medication.
- **KEEP** in a cool, dry place. **DO NOT** keep in your bathroom medicine cabinet or a cabinet above the stove. Heat or moisture may cause the medication to break down.
- **KEEP** all medicines out of the reach of children.

POSSIBLE SIDE EFFECTS:

Dry lips and mouth, indigestion, headache, diarrhea, nosebleeds, crusty skin, thinning of the hair, skin sensitivity to sunlight and sun lamps.

MISSED DOSE INSTRUCTIONS:

If you miss a dose, take it as soon as possible. **BUT** if it is almost time for the next dose, **DO NOT** take the missed dose or **DO NOT DOUBLE** the next dose. Instead, continue with your regular dosing schedule.