

Pharmacist Guidance for Dispensing ACCUTANE™ ROCHE® (isotretinoin)

ACCUTANE (isotretinoin) belongs to the retinoid class of drugs that cause severe birth defects. Fetal exposure to ACCUTANE, even for short periods of time, presents a high risk of congenital malformations and miscarriage.

ACCUTANE is therefore strictly contraindicated during pregnancy and in women of childbearing potential, unless all conditions in the ACCUTANE Pregnancy Prevention Program are met.

1. It is strongly recommended that each ACCUTANE prescription be limited to a one-month supply in order to encourage patients to return for follow-up to monitor side-effects.

Prescriptions of ACCUTANE for **women of childbearing potential** should be limited to **30 days** of treatment. Continuation of treatment requires a new prescription. Dispensing should occur within **7 days** from the date of the prescription.

- i. Under the Pregnancy Prevention Program prescriptions presented more than **7 days** after the prescription date should be considered expired and the patient should be instructed to get a new prescription from their prescriber. For some female patients this may require a further negative pregnancy test.
- ii. Two reliable forms of contraception must be used simultaneously, even by female patients who normally do not employ contraception due to infertility or who claim absence of sexual activity or who have amenorrhea

2. **All patients** should be instructed:

- Never to give this medicine to another person, especially a female patient
- To return any unused capsules to their pharmacist at the end of treatment.
- Not to donate blood during therapy and for 1 month following discontinuation of ACCUTANE because of the potential risk to the fetus of a pregnant transfusion recipient.

3. For more information and additional Health Care Professional materials please visit www.acneandu.ca

To report an Adverse Event, please contact:

- Roche Medical Information Department (toll-free): 1-888-762-4388, or
- Medical Information mailbox: mississauga.canada_medinfo@roche.com

Please consult the product monograph at www.rochecanada.com/PMs/Accutane/Accutane_PM_E.pdf for important information relating to warnings and precautions, adverse reactions, drug interactions and dosing information which has not been discussed in this piece. The product monograph is also available by calling us at 1-888-762-4388.

This material was developed by Hoffmann-La Roche Limited as part of the Risk Minimization plan for ACCUTANE. This material is not intended for promotional use.

For more information, please call the birth control counselling line toll-free at 1-877-333-2263 or visit the ACCUTANE website at www.AcneandU.ca

If you require this information in an accessible format, please contact Roche at 1-800-561-1759.

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