

PRODUCT MONOGRAPH

Pr ACCUTANE™ ROCHE®

isotretinoin capsules USP, 10, 40mg

Nodular/Inflammatory and Conglobate Acne Therapy

Hoffmann-La Roche Limited
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Pr ACCUTANE™ ROCHE®
isotretinoin

This leaflet is part III of a three-part “Product Monograph” published when ACCUTANE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ACCUTANE. Contact your doctor or pharmacist if you have any questions about the drug.

Read this Consumer Information every time you get a prescription or a refill for ACCUTANE. There may be new information. This information does not take the place of talking with your doctor.

ABOUT THIS MEDICATION

What the medication is used for:

ACCUTANE is a medicine used to treat severe acne (nodular and or inflammatory acne) that cannot be cleared up by other acne treatments, including antibiotics.

What it does:

- The mechanism of action of ACCUTANE is not known. It is believed to act on the sebaceous glands (oil/wax producing glands) to reduce sebum excretion. This may indirectly reduce bacterial activity associated with acne and improve the condition.
- ACCUTANE contains the active ingredient isotretinoin. This is a vitamin A derivative, belonging to the retinoid class of medicines. Retinoids are normally used to treat skin problems.
- During the first few weeks of treatment, your acne may seem to get worse. Redness and itching of the affected skin are common initial effects. These should disappear as you continue to take ACCUTANE. Most often, the first signs of healing occur after two to three weeks of treatment. It may take one to two months before beneficial effects are seen. Most patients with severe acne notice a marked improvement after one or two courses of treatment with ACCUTANE.

When it should not be used:

- **Do not use if pregnant**
- **Do not get pregnant while taking ACCUTANE and stop taking immediately if you do get pregnant** (See SERIOUS WARNINGS AND PRECAUTIONS)
- **Do not breast feed** while taking ACCUTANE and for 1 month after stopping ACCUTANE. ACCUTANE may pass through your milk and harm the baby.
- **Do not take tetracyclines with ACCUTANE.** For some antibiotics, you may have to stop taking ACCUTANE until the antibiotic treatment is finished. Use of tetracyclines with ACCUTANE together can increase the chances of getting increased pressure in the brain. Certain antibiotics interfere with the effectiveness of birth control pills.

- **Do not take Vitamin A** supplements. Vitamin A in high doses has many of the same side effects as ACCUTANE. Taking both together may increase your chance of getting side effects.
- **Do not take ACCUTANE** if you have liver or kidney disease.
- **Do not take ACCUTANE** if you have high blood fat (lipid) levels.
- **Do not take ACCUTANE** if you are sensitive to retinoids, or hydrogenated soybean oil, parabens, partially hydrogenated soybean oil, soybean oil, or any other non-medicinal ingredient listed under: “What the non-medicinal ingredients are:”

What the medicinal ingredient is:

isotretinoin

What the non-medicinal ingredients are:

ACCUTANE 10 mg capsules:

beeswax, black iron oxide, gelatin, glycerol, hydrogenated hydrolysed starch, hydrogenated soybean oil, mannitol, partially hydrogenated soybean oil, propylene glycol, red iron oxide, shellac, sorbitol, soybean oil, titanium dioxide.

ACCUTANE 40 mg capsules:

beeswax, black iron oxide, gelatin, glycerol, hydrogenated soybean oil, methylparaben, partially hydrogenated soybean oil, propylene glycol, propylparaben, quinoline yellow WS, shellac, soybean oil, sunset yellow FCF, titanium dioxide.

What dosage forms it comes in:

ACCUTANE capsules 10 mg and 40 mg are available in blister packages of 30 capsules.

WARNINGS AND PRECAUTIONS

ACCUTANE can cause serious side effects. Before starting ACCUTANE, discuss with your doctor how bad your acne is, the possible benefits of ACCUTANE, and its possible side effects, to decide if ACCUTANE is right for you. Your doctor will ask you to read and sign a form indicating you understand some of the serious risks of ACCUTANE.

Possible serious side effects of taking ACCUTANE include birth defects and mental health problems.

Serious Warnings and Precautions

All patients must sign the informed consent form prior to initiating therapy.

All Females: Birth defects:

ACCUTANE can cause birth defects (deformed babies). It can also cause miscarriage, premature birth, or death of the baby. Therefore, adequate birth control measures are essential when taking ACCUTANE. See **“What are the important warnings for females taking ACCUTANE?”**

All Patients:

Mental health problems and suicide:

Some patients, while taking ACCUTANE or soon after stopping ACCUTANE, have become depressed or developed other serious mental health problems. Signs of these problems include feelings of sadness, irritability, unusual tiredness, trouble concentrating, and loss of appetite. Some patients taking ACCUTANE have had thoughts about putting an end to their own lives (suicidal thoughts), tried to end their own lives, and some people have ended their own lives. There were reports that some of these people did not appear depressed. There have been reports of patients on ACCUTANE becoming aggressive or violent.

No one knows if ACCUTANE caused these behaviours or if they would have happened even if the person did not take ACCUTANE.

For other possible serious side effects of ACCUTANE, see: “Serious Side Effects and What to do About Them” table.

There have been reports of serious skin reactions occurring with the use of ACCUTANE, such as erythema multiforme (EM), Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN) which can result in hospitalization, disability and/or death.

Stop using ACCUTANE and call your doctor immediately if you develop a serious skin reaction with symptoms such as blisters, peeling skin, severe red/purple rash, multiple lesions and sores, particularly in your mouth, nose, eyes and genitals, as well as facial and tongue swelling.

What are the important warnings for females taking ACCUTANE?

- **Do not take ACCUTANE if you are pregnant**
- **If you become pregnant, stop taking ACCUTANE and contact your doctor immediately**
- **ACCUTANE can cause deformed babies. There is an extremely high risk that your baby will be deformed if you are pregnant while taking ACCUTANE. This risk exists even if ACCUTANE is taken for a short time. If you are a female of childbearing potential, your physician should have discussed this risk with you, and**

explained how to avoid becoming pregnant while taking ACCUTANE.

- **You must avoid becoming pregnant while you are taking ACCUTANE and for at least one month after you stop taking ACCUTANE.**
 - **You must discuss effective birth control with your doctor before beginning ACCUTANE treatment, and you must use effective birth control:**
 - **For at least one month before you start ACCUTANE;**
 - **While you are taking ACCUTANE; and**
 - **For at least one month after you stop taking ACCUTANE;**
- Bearing in mind that any method of birth control can fail.**
- **It is recommended that you either abstain from sexual intercourse or use two reliable methods of birth control at the same time, even if you have a history of infertility or are not sexually active.**
 - **Do not take ACCUTANE until you are sure that you are not pregnant.**
 - **You must have two negative pregnancy tests, one of them must be done in a lab, before you start ACCUTANE and be assessed on a monthly basis while on the drug and one month after the termination of ACCUTANE. If your menstrual period is abnormal in length and intensity, first contact your doctor. (see the ACCUTANE PREGNANCY PREVENTION PLAN)**
 - **You must wait until the second or third day of your next normal menstrual period before you start ACCUTANE.**
 - **Stop taking ACCUTANE and contact your doctor immediately if you do become pregnant while taking ACCUTANE or during the first month after treatment has stopped, if you miss your period, or if you have sexual intercourse without using effective birth control. You should discuss with your doctor the serious risk of your baby having severe birth deformities because you are taking or have taken ACCUTANE. You should also discuss the desirability of continuing with your pregnancy.**
 - **Do not breast feed while taking ACCUTANE.**

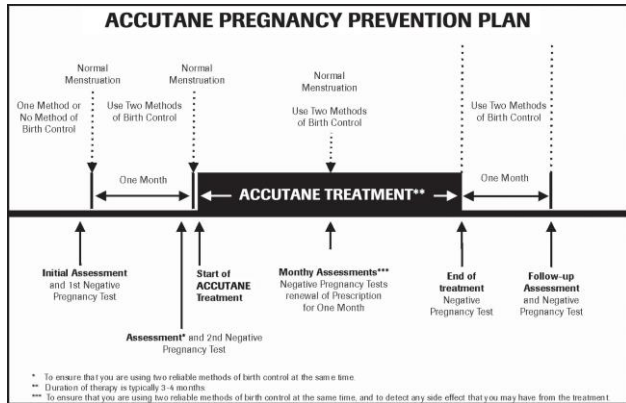
You should have been counseled using the manufacturer’s PREGNANCY PREVENTION PLAN® which includes:

- Comprehensive information about the risks of this drug
- A line drawing of a deformed baby
- A checklist of criteria you had to meet before receiving this drug
- Detailed information on birth control options
- A chart: “ACCUTANE PREGNANCY PREVENTION PLAN”
- An informed consent for you to review and sign. A copy of this form should be given to you by your doctor.

Please note that the manufacturer of ACCUTANE provides confidential contraception counseling (from a health care

professional). For more information, please contact Hoffmann-La Roche Limited.

If you were not counseled using the PREGNANCY PREVENTION PLAN[®], please contact your doctor for more information.



All patients should read the rest of this Consumer Information.

Do not take ACCUTANE unless you completely understand its possible risks and are willing to follow all of the instructions in this Consumer Information.

What should you tell your doctor before starting ACCUTANE?

- Tell your doctor if you or someone in your family has ever had any mental illness, including depression, suicidal behaviour, or psychosis. Psychosis means a loss of contact with reality, such as hearing voices or seeing things that are not there. Also, you should tell your doctor if you are taking medicines for any of these problems.
- Tell your doctor if you or any member of your family have liver disease, kidney disease, heart disease or high cholesterol or, diabetes or asthma.
- Tell your doctor if you plan vigorous physical activity during treatment with ACCUTANE.
- Tell your doctor if you have any food or drug allergies.
- Tell your doctor if you are taking any vitamin preparations or health food supplements that contain Vitamin A.
- Tell your doctor the brand of contraceptives you are taking. There are certain types of contraceptives that should not be taken while on ACCUTANE.
- Tell your doctor if you are taking an antibiotic (particularly tetracyclines).

What should you avoid while taking ACCUTANE?

- **Do not give blood** while you take ACCUTANE and for 1 month after stopping ACCUTANE. If someone who is pregnant gets your donated blood, her baby may be exposed to ACCUTANE and may be born with birth defects.
- **Do not have cosmetic procedures to smooth your skin, such as waxing, dermabrasion, or laser procedures,**

while you are using ACCUTANE and for at least 6 months after you stop. ACCUTANE can increase your chance of scarring or inflammation of the skin from these procedures. Check with your doctor for advice about when you can have cosmetic procedures.

- **Avoid the use of artificial ultraviolet lights** such as the ones used in tanning machines and **protect yourself from excessive sunlight.** ACCUTANE may make your skin more sensitive to ultraviolet light. When necessary, sunscreen with a high protection factor of at least SPF 15 should be used
- **Avoid the use of exfoliative anti-acne agents**
- **Do not share ACCUTANE with other people.** It can cause birth defects and other serious health problems.
- **Do not take Vitamin A**
- **Do not take antibiotics unless you have discussed with your doctor. See “When it should not be used”**

INTERACTIONS WITH THIS MEDICATION

- **Do not use low dose birth control pills.** They may not work while you take ACCUTANE.
- The following medications may interact with ACCUTANE or ACCUTANE may interfere with the actions of: low-dose contraceptives, antibiotics, corticosteroids, phenytoin, and natural health products such as herbs (i.e., St. John’s Wort)

PROPER USE OF THIS MEDICATION

If you are of child bearing age, your doctor will limit your ACCUTANE prescription to 30 days, so that continued treatment will require a new prescription.

Usual dose:

- Read your prescription label carefully and be sure to take the exact amount of medicine prescribed by your doctor. Your doctor may change your prescribed dose from time to time, therefore, it is important that you check the label each time you fill your ACCUTANE prescription. If you have any questions, call your doctor.
- Take ACCUTANE with food or just after a meal.
- Be sure to return to your doctor as scheduled. It is important for your doctor to see you regularly, every month, when you are taking ACCUTANE. Blood tests and other tests allow your doctor to check your response to ACCUTANE. Discuss your progress and any concerns with your doctor.

Overdose:

In case of an overdose or suspected overdose, contact your doctor, hospital emergency department or the regional poison control centre, even if there are no symptoms.

Missed Dose:

If you forget to take a dose of ACCUTANE it may be taken later the same day, but, do not take more ACCUTANE in one day than your doctor has prescribed.

Do not double dose.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Effect	Symptom	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Signs of inflammation of the liver, pancreas or intestine (bowel)	<ul style="list-style-type: none"> severe stomach pain, diarrhea, rectal bleeding; yellowing of the skin or eyes and/or dark urine. 			✓
Signs of Bone and Muscle Changes	<ul style="list-style-type: none"> aches or pains in bones or joints, back pain, or difficulty in moving, muscle pain, especially after vigorous exercise muscle weakness with or without pain can be a sign of serious muscle damage <p>Tell a healthcare provider you are taking ACCUTANE if you break a bone.</p>			✓
Signs of hyper-sensitivity (allergic) reactions	<ul style="list-style-type: none"> hives, swollen face or mouth, trouble breathing, fever, rash, red patches, bruises <p>In some patients a rash can be serious these include;</p> <ul style="list-style-type: none"> conjunctivitis (red or inflamed eyes, like “pink eye”), a rash with fever, blisters on legs, arms or face and/or sores in your mouth, throat, nose, eyes, or if your skin begins to peel. 			✓
Signs of increased pressure in the brain	<ul style="list-style-type: none"> bad headaches, blurred vision, dizziness, nausea, vomiting, seizures (convulsions) and stroke. 			✓
Signs of hearing and vision differences	<ul style="list-style-type: none"> changes in your hearing or ringing in your ears changes in your vision especially at night, decreased night 			✓

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Serious side effects you must immediately tell your doctor about:

ACCUTANE may cause serious side effects. Stop taking ACCUTANE and call your doctor right away if you or a family member notices that you have any of the following signs and symptoms, listed in the table below:

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Effect	Symptom	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Signs of mental health problems such as depression or psychosis (a severe mental disturbance)	<ul style="list-style-type: none"> changes in your mood such as becoming depressed, feeling sad, or having crying spell losing interest in your usual activities changes in your normal sleep patterns becoming more irritable or aggressive than usual (for example, temper outbursts, thoughts of violence) losing your appetite, becoming unusually tired having trouble concentrating withdrawing from family and friends having thoughts about taking your own life (suicidal thoughts) <p>Your doctor may recommend a consultation with a specialist if you become depressed or experience these changes in mood.</p>			✓

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Effect	Symptom	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
	vision may occur suddenly in some patients (take caution when driving at night), persistent feelings of dry eyes			
Signs of heart problems	<ul style="list-style-type: none"> chest pain, palpitations, vascular thrombotic disease, stroke, leg swelling, seizures (convulsions), slurred speech, problems moving or any other serious unusual problems. 			✓
Signs of problems with blood sugar levels	<ul style="list-style-type: none"> fainting, become very thirsty, urinating a lot, feeling weak. 			✓

ACCUTANE may affect blood fat, cholesterol, or sugar levels. Therefore it is important for you to see your doctor at regularly scheduled visits.

What are the other possible side effects of ACCUTANE?

It is important to watch for the symptoms listed in the table above as these may be signs of serious side effects.

The side effects listed below are generally temporary and disappear when ACCUTANE treatment is stopped; however, you must tell your doctor if any of your side effects do not clear up in a few weeks after you stop taking ACCUTANE. **You must also check with your doctor, if these effects become bothersome, to see if any change in your medication is needed.**

- **Some of the most common side effects are:** dryness of the skin, lips, mouth, and lining of the nose. It is recommended that you use a skin-moisturizing ointment or cream and a lip balm from the start of treatment of ACCUTANE.
- Some other side effects that may occur include: facial or body rash, flaking of the skin, itching, peeling of the palms and soles, increased sensitivity to the sun, sunburn, inflammation of the lips, mild nose bleed, bleeding and inflammation of the gums, easily injured skin and increased fatigue. You may experience some redness, dryness, or irritation of the eyes.
- If you wear contact lenses, you may find them uncomfortable during treatment because ACCUTANE may

cause dry eyes. This may continue after treatment has stopped. Dry eyes can be helped by applying a lubricating eye ointment or tear replacement therapy.

- In some patients variable amounts of hair loss have occurred. In rare cases, this hair loss persisted after treatment was completed.

These are not all of the possible side effects associated with ACCUTANE. Your doctor or pharmacist can give you more detailed information that is written for health care professionals.

HOW TO STORE IT

- **Keep out of reach from children.**
- ACCUTANE should be stored at 15-30°C. Store in the original package. Protect from exposure to moisture, heat and light.
- ACCUTANE does not need to be refrigerated.

SPECIAL HANDLING INSTRUCTIONS

It is recommended that ACCUTANE not be disposed of in household waste or waste water. Please return any unused ACCUTANE to the pharmacist or use an established "collection system" if available in your location.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at**
www.healthcanada.gc.ca/medeffect
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This Consumer Information is only a summary of some important information about ACCUTANE. Medicines are sometimes prescribed for purposes other than those listed in a Consumer Information. If you have any concerns or questions about ACCUTANE, ask your doctor. Do not use ACCUTANE for a condition for which it was not prescribed.

This document plus the full product monograph, prepared for health professionals can be found at:
<http://www.rochecanada.com>, or by contacting Hoffmann-La Roche Limited at: 1-888-762-4388

This leaflet was prepared by Hoffmann-La Roche Limited

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