

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^{Pr}**MINT-ACITRETIN**

Acitretin capsules

Read this carefully before you start taking **MINT-ACITRETIN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **MINT-ACITRETIN**.

Serious Warnings and Precautions

You **must** sign the informed consent form before you start taking MINT-ACITRETIN.

Female patients:

Birth defects (deformed babies)

- **Do NOT** take MINT-ACITRETIN if you are pregnant or want to become pregnant. MINT-ACITRETIN can cause severely deformed babies.
- You must discuss **effective birth control** with your doctor before beginning treatment and you must use effective birth control without interruption as follows:
 - for at least one month before you start MINT-ACITRETIN.
 - while you are taking MINT-ACITRETIN; **and**
 - for at least 3 years after you stop taking MINT-ACITRETIN (discuss this with your doctor); and
- Bear in mind that any method of birth control can fail. It is recommended that you either abstain from sexual intercourse or use two effective methods of birth control at the same time (discuss this with your doctor).
- Low dose progesterone-only may not be an effective method to prevent pregnancy during treatment with MINT-ACITRETIN and is not recommended for use.
- **Do NOT take MINT-ACITRETIN until you are sure that you are not pregnant:**
 - You must have 2 negative pregnancy tests before you start MINT-ACITRETIN. The first test will be done at screening when MINT-ACITRETIN treatment is under consideration. A second (confirmatory) test must be done within 3 days before the first dose is taken. Both tests must show you are not pregnant.
 - You must wait until the second or third day of your next menstrual period before you start MINT-ACITRETIN.
- During treatment, you must have a pregnancy test at 28-day intervals in a licensed laboratory. The test must be no older than 3 days and show you are not pregnant before you can receive another prescription for MINT-ACITRETIN.

- After stopping treatment, you must have pregnancy tests every 1-3 months for at least 3 years after your last dose.
- Every time you start a new course of treatment with MINT-ACITRETIN, however long the intervening period may have been, you must use effective and uninterrupted birth control, during treatment and for **at least 3 years** after you stop taking MINT-ACITRETIN.
- **Contact your doctor immediately if you do become pregnant while taking MINT-ACITRETIN or after treatment has stopped.** You should discuss the serious risk of having a baby with severe birth deformities because you are taking or have taken MINT-ACITRETIN, as well as available options, with your doctor
- **Do NOT** breastfeed while taking MINT-ACITRETIN and until at least 3 years after the treatment has stopped.

All patients:

- **Do NOT** consume alcohol while taking MINT-ACITRETIN and for at least 2 months after the treatment has stopped.
- **Do NOT** donate blood while taking MINT-ACITRETIN and until at least 3 years after the treatment has stopped. If someone who is pregnant gets your donated blood, the baby may be exposed to MINT-ACITRETIN and be born with birth defects.

MINT-ACITRETIN can cause serious side effects, including:

- **Liver problems**
 - Cases of jaundice, toxic hepatitis (inflammation of the liver) and liver injury have been reported in patients taking MINT-ACITRETIN.
 - Before starting treatment and during treatment with MINT-ACITRETIN, your healthcare professional will do blood tests to check how your liver is working.
- **Pseudotumor cerebri (benign intracranial hypertension).** This is a condition where there is an increased pressure in the brain.
- **Mood changes (including irritability, aggression, depression, suicide and thoughts of suicide and self-harm)**
 - Before you take MINT-ACITRETIN, your healthcare professional will assess you for mood changes, including depression.
 - Tell your healthcare professional right away if you have any symptoms of new depression or worsening depression.

Psychotic disorder (hallucinations or delusions): This may cause you to experience hallucinations (seeing or hearing things) or delusions (have false beliefs).

What MINT-ACITRETIN is used for:

MINT-ACITRETIN is used in the treatment of:

- Severe psoriasis

- Other disorders of keratinization in adult patients who have not responded to standard treatments.

How MINT-ACITRETIN works:

MINT-ACITRETIN is a retinoid. It works by leading to a more normal pattern of growth for skin cells.

The ingredients in MINT-ACITRETIN are:

Medicinal ingredient: Acitretin

Non-medicinal ingredients: Black iron oxide, cellulose microcrystalline, disodium edetate, gelatin, maltodextrin, poloxamer 407, propylene glycol, red iron oxide, shellac glaze~45%, sodium ascorbate, titanium dioxide, and yellow iron oxide.

MINT-ACITRETIN comes in the following dosage form:

Capsules: 10 mg and 25 mg

Do not use MINT-ACITRETIN if you:

- are pregnant, or plan to become pregnant
- become pregnant while taking MINT-ACITRETIN. You must stop taking MINT-ACITRETIN immediately. See “**Serious warnings and precautions**” box.
- are breastfeeding.
- are allergic to acitretin, or any of the other ingredients in MINT-ACITRETIN,
- are allergic to other retinoids, or Vitamin A, or its metabolites,
- consume alcohol (in drinks, food or medicines),
- have severe liver problems.
- have severe kidney problems.
- have consistent high blood lipid levels
- take tetracyclines, medicines used to treat bacterial infections.
- take methotrexate, medicine used to treat cancer and other conditions caused by overactive immune system.
- have high vitamin A levels (hypervitaminosis A).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MINT-ACITRETIN. Talk about any health conditions or problems you may have, including if you:

- have high cholesterol or triglycerides.
- have high blood sugar or have a family history of diabetes. You may need to check your blood sugar levels more frequently at the beginning of treatment.
- have liver problems
- have kidney problems
- have or have had depression or have a family history of depression.
- have eye problems or wear contact lenses. MINT-ACITRETIN may cause dry eyes, light sensitivity, or other eyes problems.

Other warnings you should know about:

- **MINT-ACITRETIN Pregnancy Prevention Program**

You should have been counselled using the manufacturer's MINT-ACITRETIN Pregnancy Prevention Program which includes:

- Comprehensive information about the risks of this drug
- A line drawing of a deformed baby
- A checklist of the criteria you had to meet before receiving this drug
- Detailed information on birth control options
- A chart outlining the MINT-ACITRETIN Pregnancy Prevention Program
- An informed consent form for you to review and sign (for males and females)

If you were not counselled using the MINT-ACITRETIN Pregnancy Prevention Program, please contact the marketing agent for Canada, Mint Pharmaceuticals Inc. Medical Safety Information Line at (toll-free) **1-877-398-9696**.

- **Skin**

- Avoid prolonged exposure to sunlight or sun lamps while taking MINT-ACITRETIN. Use protective clothing or hat or sunscreen with SPF 30 or more. MINT-ACITRETIN may make your skin more sensitive to UV light.
- Avoid cosmetic procedures that smooth your skin (such as waxing, dermabrasion or laser procedures), while taking MINT-ACITRETIN and for a period of time after stopping. MINT-ACITRETIN may cause scarring or inflammation of the skin from these procedures. Check with your healthcare professional for advice about when you can have cosmetic procedures.
- Avoid the use of anti-acne agents that exfoliate your skin since it can irritate your skin.
- You should use a skin moisturizing ointment or cream and a lip balm while taking MINT-ACITRETIN. This is because MINT-ACITRETIN can make your skin and lips dry.

- **Check-ups and testing**

- You will have regular visits with your healthcare professional during your treatment with MINT-ACITRETIN. They will:
 - Do blood tests to check blood lipid levels (cholesterol, triglycerides), sugar levels and liver health.
 - Assess you for mood changes.
 - Examine you for signs of bone abnormalities and vision problems.
- In female patients, your healthcare professional will ask you to have pregnancy tests before treatment with MINT-ACITRETIN and regularly during and after treatment. During treatment, a pregnancy test is needed every 28 days. After stopping treatment, pregnancy tests must be done every 1-3 months for 3 years after your last dose.

- **Driving and using machinery**

- MINT-ACITRETIN may change your vision and ability to drive at night. Be cautious when driving any vehicles or doing tasks that require special attention, especially at night.

- **Children (younger than 18 years of age)**

- You should not take MINT-ACITRETIN if you are younger than 18 years of age.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions:

Serious drug interactions with MINT-ACITRETIN include:

- Vitamin A or retinoids.
- Methotrexate. Taking MINT-ACITRETIN with methotrexate may increase your risk of hepatitis.
- Tetracyclines. Taking MINT-ACITRETIN with tetracyclines may increase your risk of increased pressure in the skull (intracranial pressure).
- Alcohol. It converts MINT-ACITRETIN to etretinate, a chemical that also causes birth defects and stays in the body longer.

The following may also interact with MINT-ACITRETIN:

- Phenytoin, medicine used to treat seizures
- Glyburide, or a sulfonylurea, medicines used to treat diabetes
- St John's Wort
- Low dose birth control pills. Low dose birth control pills that contain progesterone only (mini pills) may not work while you are taking MINT-ACITRETIN.

How to take MINT-ACITRETIN :

- Always take MINT-ACITRETIN exactly as your healthcare professional tells you.
- Take by mouth once daily with food or after a meal.

Usual dose:

Your dose will depend on your medical condition and the recommendations of your healthcare professional. Your healthcare professional may change or stop your dose depending on how well MINT-ACITRETIN is working for you.

For Severe psoriasis: starting dose of 25 mg once daily; maintenance daily dose from 25 mg to 50 mg; maximum daily dose of 75 mg.

For Other disorders of keratinization: 10 mg once daily; maximum daily dose of 50 mg

Overdose:

If you think you, or a person you are caring for, have taken too much MINT-ACITRETIN, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs

or symptoms.

Missed dose:

- If you miss a dose of MINT-ACITRETIN, take it as soon as you remember on the same day. However, if it is almost time for your next dose, skip the missed dose and take the next dose at your regular time.
- Do NOT take a double dose to make up for a missed dose.

Possible side effects from using MINT-ACITRETIN:

These are not all the possible side effects you may have when taking MINT-ACITRETIN. If you experience any side effects not listed here, tell your healthcare professional.

- Back pain, bone pain or muscle pain
- Brittle nails
- Bleeding or inflammation of the gums, or inflammation of the mucous lining of the mouth
- Chills, increased sensitivity to touch.
- Dry eyes, particularly if you wear contact lenses
- Dry mouth, chapped lips, runny or dry nose
- Decreased or increased appetite
- Ear problems such as pain, wax build-up, or buzzing in the ear
- Eye problems such as light sensitivity, pain, impaired vision
- Hair loss or abnormal hair texture. Whether all your hair will return to normal after treatment cannot be predicted.
- Infections, including skin around the fingernail
- Inflammation along the edge of the eyelid (blepharitis), inflammation or infection of the membrane lining the eyelids (conjunctivitis)
- Nose bleeds
- Skin problems such as cold sweat, excessive sweating, sensitivity to sunlight, inflamed, ulcerated, and oily or cracked skin.
- Tiredness, pain, thirst
- Trouble sleeping

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Abdominal pain: Stomach pain			√
Diarrhea			√
Headache			√
Nausea			√

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Vomiting			√
Skin Atrophy: Fragile skin	√		
Alopecia: Hair loss	√		
Chelitis: Inflamed lips	√		
Pruritis: Itching	√		
Skin exfoliation: Peeling of Fingertips, Peeling skin all over the body	√		
Rash erythematous: Redness or Rash		√	
Sticky Skin: Skin is sticky	√		
Hearing problems: impaired hearing, ringing in the ears		√	
UNCOMMON			
Blurred vision: Cloudy vision or difficulty focusing eyes			√
Dry eye: Persistent feeling of dry eyes		√	
Jaundice: Yellowing of the skin or eyes and/or flu-like symptoms and/or dark urine			√
Heart Problems: Shortness of breath, Weakness, Nausea, Dizziness, Chest Pain, and Trouble Speaking. These can be signs of heart attack or stroke.			√
Peripheral oedema: Swelling of a leg, ankle, foot or arm. These can be signs of blood clot			√
VERY RARE			
Visual impairment: Decreased night vision		√	
Arthralgia: Aches or Pain in Joints or Difficulty Moving. Bone changes have been detected by X-ray examination in patients taking acitretin. The extent of any harm from these changes is not presently known		√	
Serious Skin Reactions such as erythema multiforme (EM), Stevens-Johnson Syndrome (SJS)			√

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
and toxic epidermal necrolysis (TEN): Severe red / purple rash, fever or not feeling well, red or inflamed eyes, facial and tongue swelling, blisters, peeling skin, multiple lesions and sores, especially in your mouth, nose, eyes and genitals.			
UNKNOWN FREQUENCY			
Allergic reactions: Rash, hives, itching, swelling of the face, lips, tongue or throat, difficulty breathing or swallowing			√
Capillary leak syndrome: Sudden swelling in one part or all over your body, weight gain, fever, light-headedness, feeling faint or muscle aches			√
Exfoliative dermatitis: Red, swollen, itchy, painful or peeling skin. It can begin in a small area and then spread over large areas of your body.			√
Madarosis: Eyelash and sometimes eyebrow loss		√	
Rectal haemorrhage: Rectal bleeding			√
Suicidal thoughts: Thoughts of suicide or self-harm			√
Worsened emotional or behavioral problems: Worsening depression, Changes in Mood (such as becoming depressed, feeling sad or having crying spells), Aggressive behaviour (such as, temper outbursts, thoughts of violence), psychotic disorder (hallucinations or delusions)			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at 15°C to 30°C. Protect MINT-ACITRETIN capsules from sunlight, heat and humidity. Store in original package. MINT-ACITRETIN does not need to be refrigerated. MINT-ACITRETIN should not be used after the expiry date (EXP) shown on the package. Keep MINT-ACITRETIN and all medications out of the reach and sight of children.

If you want more information about MINT-ACITRETIN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.mintpharma.com; or by calling 1-877-398-9696.

This leaflet was prepared by Mint Pharmaceuticals Inc.

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