

# Pregnancy Prevention Program

MINT-ACITRETIN (acitretin) 10 mg and 25 mg Capsules

## ABOUT MINT-ACITRETIN

MINT-ACITRETIN (acitretin capsules) is an oral medication used to treat severe forms of psoriasis and severe keratinization disorders in adults. Psoriasis is a skin disease that causes cells in the outer layer of the skin to grow faster than normal and pile up on the skin's surface. In the most common type of psoriasis, the skin becomes inflamed and produces red, thickened areas, often with silvery scales. In some patients, psoriasis may worsen when they first start MINT-ACITRETIN treatment. Some may have more redness or itching. If this happens, tell your doctor. These side effects usually get better with time, but your doctor may need to change the dose of your medicine. Most patients experience return of their psoriasis after stopping treatment. If your psoriasis returns, your doctor may have you start your MINT-ACITRETIN treatment again.

**Because MINT-ACITRETIN can have serious side effects**, you should talk with your doctor about whether MINT-ACITRETIN is right for you. MINT-ACITRETIN must only be used in people who are not at risk of getting pregnant during MINT-ACITRETIN treatment and for **at least 3 years** after stopping MINT-ACITRETIN treatment. These patients must have tried other medications which did not work or they are unable to take other psoriasis medications. Your doctor will discuss other possible treatments as well as how to use MINT-ACITRETIN.

If you are female, in order to receive a prescription for MINT-ACITRETIN, your doctor will review the MINT-ACITRETIN Pregnancy Prevention Checklist and you will be asked to sign the MINT-ACITRETIN Pregnancy Prevention Consent Form before beginning treatment with MINT-ACITRETIN.

## WHAT SHOULD I AVOID WHILE TAKING MINT-ACITRETIN?

### MINT-ACITRETIN can cause severe birth defects

- Do not get pregnant during MINT-ACITRETIN treatment.
- Do not get pregnant for **at least 3 years** after stopping MINT-ACITRETIN treatment.
- Do not breastfeed during MINT-ACITRETIN treatment and for **at least 3 years** after stopping treatment.
- Do not drink alcohol (in drinks, food or medicines) during treatment and for 2 months after stopping MINT-ACITRETIN.



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- Do not donate blood during treatment and for **at least 3 years** after stopping MINT-ACITRETIN treatment
  - (females who are pregnant or may get pregnant must not receive blood from patients taking MINT-ACITRETIN).
- Do not share MINT-ACITRETIN with anyone, even if they have the same symptoms.

You must also read the MINT-ACITRETIN **Consumer Information Leaflet** for more information before you decide if MINT-ACITRETIN treatment is right for you.

## WARNINGS AND PRECAUTIONS

**In Females of  
Childbearing Potential:**



MINT-ACITRETIN (acitretin capsules) can cause severely deformed babies. You must not use MINT-ACITRETIN if you are pregnant, planning to become pregnant, or may become pregnant, during MINT-ACITRETIN treatment or at any time for **at least 3 years** after stopping MINT-ACITRETIN treatment.

MINT-ACITRETIN must not be used by **females of childbearing potential**. You must either abstain from sexual intercourse or use 2 effective and complementary forms of contraception (birth control), at the same time and without interruption, for at least 1 month before starting **MINT-ACITRETIN** treatment, during treatment, and for **at least 3 years** after stopping MINT-ACITRETIN treatment.

You must discuss effective birth control with your doctor before starting MINT-ACITRETIN treatment. You need to bear in mind that any method of birth control can fail. Low dose progesterone-only pills (mini pills) may not be an effective method to prevent pregnancy during MINT-ACITRETIN treatment and are not recommended. Patients must not use the herbal remedy St. John's Wort because it appears to interfere with hormonal contraceptives and there have been reports of pregnancies in females who have taken St. John's Wort with hormonal contraceptives.



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Before starting MINT-ACITRETIN treatment, 2 negative pregnancy tests (from a licensed laboratory) are needed. The second negative pregnancy test must not be older than 3 days when you start the first dose of MINT-ACITRETIN and,

You should wait to start MINT-ACITRETIN treatment, until the 2nd or 3rd day of your next menstrual period.

During MINT-ACITRETIN treatment you should visit your doctor each month and pregnancy tests should be arranged at 28-day intervals. A negative pregnancy test, not older than 3 days, is mandatory before the prescription is renewed at these visits.

After stopping MINT-ACITRETIN treatment, you must have pregnancy tests every 1-3 months for **at least 3 years** after your last dose.

Do not breastfeed while taking MINT-ACITRETIN and for at least 3 years after the treatment has stopped.

Contact your doctor immediately if you do get pregnant while taking MINT-ACITRETIN or within 3 years after stopping treatment. You should discuss with your doctor the serious risk of having a baby with severe birth deformities and whether or not you wish to continue with the pregnancy.

Females of childbearing potential must not ingest alcohol (in drinks, food or medicines) during MINT-ACITRETIN treatment and for 2 months after stopping MINT-ACITRETIN. Before considering taking MINT-ACITRETIN, discuss this and other questions with your doctor and read the complete pregnancy warnings in this booklet and in the accompanying Consumer Information Leaflet about MINT-ACITRETIN.

**Females of childbearing potential must sign the Patient Information/Consent Form about the risks of severe birth defects.**

**Read and sign the informed consent form before taking MINT-ACITRETIN, and be sure to ask your doctor about any questions you have.**



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## YOUR SEXUAL PARTNER

It is strongly recommended that your sexual partner read this information in order to understand all of the facts about the risk of severe birth defects in babies when women of childbearing potential are pregnant, planning to become pregnant or may become pregnant during MINT-ACITRETIN treatment.

It is critical that both you and your sexual partner know that you must not become pregnant during, or within **at least 3 years**, after stopping MINT-ACITRETIN.

## BEFORE YOU TAKE MINT-ACITRETIN

**Warning: Before you decide to take MINT-ACITRETIN, you must have discussed the consequences of becoming pregnant during MINT-ACITRETIN treatment with your doctor and clearly understood them.**



**MINT-ACITRETIN can cause severely deformed babies.** It may also cause loss of the baby before birth (miscarriage), death of the baby, and early (premature) births. There is an extremely high risk that your unborn baby will be severely deformed if you take MINT-ACITRETIN while you are pregnant. **The risk exists even if MINT-ACITRETIN is taken for a short time and this risk extends for at least 3 years after stopping MINT-ACITRETIN.** Therefore, effective birth control measures, without interruption, are essential for 1 month before, while taking MINT-ACITRETIN and for **at least 3 years** after completion of MINT-ACITRETIN treatment. If you are a female of childbearing potential, your doctor should have discussed this risk of severe birth defects with you, and explained how to avoid becoming pregnant while taking MINT-ACITRETIN. Talk to your doctor if you have any questions about this.

**Some severe birth defects commonly associated with taking MINT-ACITRETIN are:**

- Low-set deformed or absent ears
- Wide-set eyes
- Depressed bridge of nose
- Enlarged head

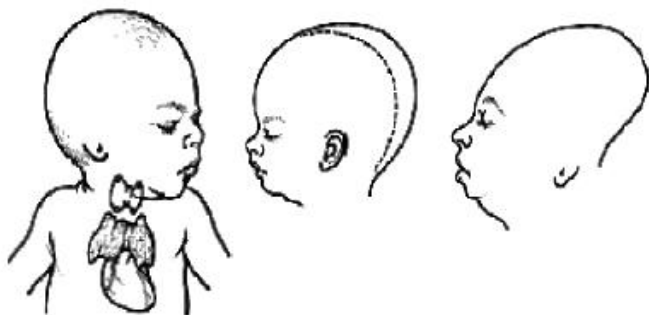


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- Small chin



**More severe birth defects are:**

- Mental retardation
- Internal defects affecting the brain, heart, lymph glands, and nervous system

## WHAT YOU NEED TO KNOW

The following pages discuss important information you need to understand before taking MINT-ACITRETIN. If you have any questions, please talk to your doctor. If you are a **woman of childbearing potential**, you must carefully read this **MINT-ACITRETIN Pregnancy Prevention Program** booklet.

**MINT-ACITRETIN can cause severe birth defects (deformed babies). It can also cause miscarriage, premature birth, or death of the baby.**

## Facts for Everyone Before Taking MINT-ACITRETIN

<p><b>Do not use MINT-ACITRETIN if you are pregnant, planning to become pregnant or may become pregnant.</b></p>	<p><b>MINT-ACITRETIN can cause severe birth defects (deformed babies). It can also cause miscarriage, premature birth, or death of the baby.</b></p>
<p>Do not get pregnant while taking MINT-ACITRETIN and for <b>at least 3 years</b> after</p>	<p>You <b>MUST</b> have 2 negative pregnancy tests before starting MINT-ACITRETIN (you must have a negative pregnancy test each month before</p>



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<p>stopping MINT-ACITRETIN treatment.</p>	<p>receiving next month's prescription and every 1-3 months for <b>at least 3 years</b> after stopping MINT-ACITRETIN treatment).</p> <p>You must discuss <u>effective birth control</u> with your doctor before beginning treatment and you must use effective birth control without interruption as follows:</p> <p>You <b>MUST</b> either abstain from sexual intercourse or, You <b>MUST</b> use 2 effective and complementary forms of birth control starting 1 month before therapy, the whole time you are treated with MINT-ACITRETIN, and for <b>at least 3 years</b> after stopping MINT-ACITRETIN. When you stop taking MINT-ACITRETIN, you <b>MUST NOT</b> get pregnant for <b>at least 3 years</b>.</p> <p>Every time you start a new course of treatment with MINT-ACITRETIN, no matter how long the intervening period may have been, you must use effective and uninterrupted birth control during treatment and for <b>at least 3 years</b> after stopping MINT-ACITRETIN. If your period is abnormal in length or intensity, immediately contact your doctor.</p> <p>If you become pregnant, stop taking MINT-ACITRETIN and immediately contact your doctor.</p>
<p>Do not breastfeed while taking MINT-ACITRETIN and <b>for three years</b> after stopping MINT-ACITRETIN.</p>	<p>MINT-ACITRETIN may pass through your milk and harm your baby.</p>
<p>Do not drink alcohol while taking MINT-ACITRETIN, or for 2 months after you've stopped MINT-ACITRETIN treatment.</p>	<p>Alcohol can convert MINT-ACITRETIN to etretinate, a chemical that also causes birth defects and stays in the body longer.</p> <p>You are also at a greater risk of liver damage with the combination of MINT-ACITRETIN and alcohol.</p>
<p>Do not donate blood during MINT-ACITRETIN therapy and for <b>at least 3 years</b> after stopping MINT-ACITRETIN</p>	<p>If a pregnant woman gets your donated blood, her baby may be exposed to MINT-ACITRETIN and may be born with severe birth defects.</p>



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## SERIOUS SIDE EFFECTS.

**STOP TAKING MINT-ACITRETIN AND IMMEDIATELY CALL YOUR DOCTOR IF YOU GET THE FOLLOWING SERIOUS SIGNS:**

Bad headaches, abdominal pain, diarrhea, nausea, vomiting, blurred vision.	These symptoms can be signs of increased brain pressure that can lead to blindness or even death.
Decreased vision in the dark (night blindness), other visual problems.	Since this can start suddenly, you should be very careful when driving at night. This problem usually goes away when MINT-ACITRETIN therapy stops. If you develop night blindness, blurred vision, other vision problems or eye pain, <b>STOP DRIVING RIGHT AWAY</b> , stop taking MINT-ACITRETIN and contact your doctor or pharmacist.
Depression or worsening depression.	There have been reports of patients developing mental health problems including depressed mood, worsening depression, aggressive feelings, or thoughts of ending their own life (suicide) in patients taking MINT-ACITRETIN. If this happens to you, it is very important to stop taking MINT-ACITRETIN and immediately call your doctor and/or <b>IF YOU HAVE SUICIDAL THOUGHTS, IMMEDIATELY GO TO YOUR LOCAL EMERGENCY DEPARTMENT.</b>
Yellowing of your skin or the whites of your eyes, flu-like symptoms, nausea and vomiting, loss of appetite, or dark urine.	These can be signs of serious liver damage. Immediately contact your doctor.
Aches or pains in your bones, joints, muscles, or back; trouble moving; loss of feeling in your hands or feet.	These can be signs of abnormal changes to your bones or muscles. Immediately contact your doctor.



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<p>Severe reactions of the skin.</p>	<p>There have been reports of severe skin reactions, such as redness or rash. Immediately contact your doctor.</p>
<p>Shortness of breath, dizziness, nausea, chest pain, weakness, trouble speaking, or swelling of a leg, ankle or foot. These may be signs of a heart attack, blood clots, or stroke.</p>	<p>MINT-ACITRETIN can cause serious changes in blood fats (lipids). It is possible for these changes to cause blood vessel blockages that lead to heart attacks, strokes, or blood clots. <b>IF YOU THINK YOU ARE HAVING SYMPTOMS OF A HEART ATTACK, STROKE, OR BLOOD CLOT, IMMEDIATELY GO TO YOUR LOCAL EMERGENCY DEPARTMENT.</b></p>
<p>Frequent urination, extreme thirst, or hunger.</p>	<p>MINT-ACITRETIN can affect blood sugar control, even if you do not have diabetes. These are some of the signs of high blood sugar. Immediately contact your doctor.</p>



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## COMMON SIDE EFFECTS.

**IF YOU DEVELOP ANY OF THESE SIDE EFFECTS OR ANY UNUSUAL REACTION, CHECK WITH YOUR DOCTOR TO FIND OUT IF YOU NEED TO CHANGE THE DOSE OF MINT-ACITRETIN.**

**THESE SIDE EFFECTS USUALLY GET BETTER IF THE MINT-ACITRETIN DOSE IS REDUCED OR IS STOPPED.**

<p>Chapped lips; dry mouth; peeling fingertips, palms, and soles; itching; scaly skin all over; weak nails; sticky or fragile (weak) skin; runny or dry nose, or nosebleeds.</p>	<p>Your doctor or pharmacist can recommend a lotion or cream to help treat drying or chapping. If symptoms are severe, contact your doctor or pharmacist.</p>
<p>Skin problems such as cold sweat, excessive sweating, sensitivity to sunlight, inflamed, ulcerated, and oily or cracked skin.</p>	<p>Contact your doctor if these are bothersome.</p>
<p>Chills; joint pain; infections; infections around the skin of the fingernails; tight muscles; increased sensitivity to touch.</p>	<p>Contact your doctor if any of these symptoms are bothersome.</p>
<p>Hair loss/abnormal hair texture.</p>	<p>Most patients have some hair loss, but this condition varies among patients. Discuss this with your doctor.</p>
<p>Dry eyes. Inflammation along the edge of the eyelid or inflammation or infection in the lining of the eyelid (conjunctivitis).</p>	<p>MINT-ACITRETIN may dry your eyes. Wearing contact lenses may be uncomfortable when you start taking MINT-ACITRETIN. Your pharmacist can recommend some eye drops for dry eyes. Contact your doctor if inflammation is bothersome or you are concerned.</p>



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Ear problems such as pain, wax build up, buzzing	Contact your doctor if these are bothersome.
Bleeding or inflamed gums or lining of the mouth.	Contact your doctor if these are bothersome.
Rise in blood fats (lipids)	MINT-ACITRETIN can cause your blood fats (lipids) to rise and this will be monitored by blood tests. Most of the time this is not serious. But sometimes the increase can become a serious problem (see information under "Serious Side Effects"). You should have blood tests PERFORMED as directed by your doctor.

***These are not all the possible side effects of MINT-ACITRETIN. For any unexpected effects while taking MINT-ACITRETIN, contact your doctor or pharmacist.***



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## DO'S OF TAKING MINT-ACITRETIN

### DO:

Do discuss effective methods for birth control with your physician before beginning MINT-ACITRETIN treatment.	Do have a monthly pregnancy test while taking MINT-ACITRETIN and you must take a pregnancy test every 1-3 months for <b>at least 3 years</b> after stopping MINT-ACITRETIN.
Before starting MINT-ACITRETIN, have 2 pregnancy tests done in a licensed laboratory, proving that you are not pregnant. The 1st negative test will start the process, and the 2nd negative test will confirm the result. (Your doctor will tell you when and how to take the tests.)	Do abstain completely from sexual intercourse or use two reliable methods of birth control (see birth control methods below) together, even if you have a history of infertility or are not sexually active (unless you have had a hysterectomy) or are at least 1 year past menopause. Do discuss this with your doctor.
Use 2 forms of birth control at the same time, for at least 1 month before and during your MINT-ACITRETIN therapy and for <b>at least 3 years</b> after you stop MINT-ACITRETIN therapy. You and your doctor should choose 2 forms of birth control. At least one of the methods must be a primary method (see birth control methods below).	You cannot breastfeed a baby while taking MINT-ACITRETIN or for <b>at least 3 years</b> after stopping treatment.
Wait until the 2 <sup>nd</sup> or 3 <sup>rd</sup> day of your next normal menstrual period before you start taking MINT-ACITRETIN.	Ask your doctor if you are not sure what type of birth control pills you are using.



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## Stop taking MINT-ACITRETIN and immediately contact your doctor if:

- You become pregnant while taking MINT-ACITRETIN or during the 3 years after MINT-ACITRETIN treatment has stopped.
- You missed your period.
- If your period is abnormal in length (shorter or longer than usual) and intensity.

### Safety information about MINT-ACITRETIN and pregnancy

#### HELPFUL HINTS:

#### ACITRETIN SCHEDULE FOR PREGNANCY PREVENTION & SAFE PREGNANCY PLANNING

	1 MONTH BEFORE TREATMENT	BEFORE TREATMENT	DURING ACITRETIN TREATMENT	2 MONTHS AFTER TREATMENT	3 YEARS AFTER TREATMENT
2 FORMS OF BIRTH CONTROL					
2 NEGATIVE PREGNANCY TESTS					
ONGOING PREGNANCY TEST	Each month before receiving prescription and every 3 months for 3 years after stopping treatment				
NO ALCOHOL					
NO BLOOD DONATION					
SIGN INFORMED CONSENT FORM					

Important safety information about MINT-ACITRETIN and the **MINT-ACITRETIN Pregnancy Prevention Program** is available from:

- Online: [www.Mint-Acitretin.com](http://www.Mint-Acitretin.com)  
or
- To speak to someone or to report an Adverse Reaction, please contact the Mint Pharmaceuticals Telephone Hotline at (toll-free) 1-877-398-9696



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## USING BIRTH CONTROL

MINT-ACITRETIN is a very powerful drug, and women must be very careful not to become pregnant. If it is possible for you to become pregnant, and you and your doctor agree on using MINT-ACITRETIN, you must use one of the primary birth control methods combined with one of the secondary birth control methods. The methods chosen need to be discussed with your family doctor and/or gynecologist as the chosen methods must be individualized for each woman.

- **There are many birth control methods to choose from.**
- **Discuss all available birth control methods with your doctor to decide on what 2 methods are most appropriate for you.**

## PRIMARY BIRTH CONTROL METHODS

- Birth control pills (but not “mini-pills”)
- Birth control patch
- Intrauterine device (IUD)
- Injected, implanted or inserted hormonal birth control products
- Having your tubes tied
- Partner’s vasectomy

## SECONDARY BIRTH CONTROL METHODS

- Diaphragm with spermicide
- Cervical cap with spermicide
- Latex condom with or without spermicide

Before you receive your MINT-ACITRETIN prescription, you should have discussed and signed a Patient Information/Consent Form with your doctor. This is to help make sure you understand the risk of birth defects and how to avoid getting pregnant. If you did not talk to your doctor about this or did not sign the consent form, immediately contact your doctor.

**TOLL-FREE NUMBER** for safety information about **MINT-ACITRETIN** and the **MINT-ACITRETIN Pregnancy Prevention Program: 1-877-398-9696**

This toll-free, automated line is available to all patients on MINT-ACITRETIN.

- You can obtain safety information about MINT-ACITRETIN and the **MINT-ACITRETIN Pregnancy Prevention Program.**



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- You can also share this information and phone number with members of your family and your partner.

If you need more information about birth control options, the following sites are available.

- Action Canada for Sexual Health & Rights bilingual hotline 1-888-642-2725
- Birth control counselling hotline 1-877-398-9696

If you need more information about drugs and birth defects, the following sites are available on the internet:

- Action Canada for Sexual Health & Rights [www.actioncanadashr.org](http://www.actioncanadashr.org)



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## COMMONLY ASKED QUESTIONS

### What you should know about emergency contraception

If one of your two birth control methods fail while taking MINT-ACITRETIN or within 3 years after you stop, contact your doctor or pharmacist regarding options for emergency contraception as soon as possible.

Call your doctor, or the Action Canada for Sexual Health & Rights bilingual hotline, 1-888-642-2725, for information about getting emergency contraception in your area, or call the Mint Pharmaceuticals toll-free MINT-ACITRETIN medical information hotline at 1-877-398-9696.

### IMPORTANT INFORMATION FOR MALE PATIENTS

For male patients treated with MINT-ACITRETIN, available data, based on the level of maternal exposure from semen and seminal fluid indicate a minimal, if any, risk to an unborn child. Male patients should be reminded that they must not share their medication with anyone particularly not females.

### How long do I need to use birth control?

- You need to start using 2 forms of birth control (1 primary and 1 secondary method) at least 1 month before you begin taking MINT-ACITRETIN
- You need to use 2 forms of birth control during your entire treatment with MINT-ACITRETIN and,
- You need to continue to use 2 forms of birth control for **at least 3 years** after you stop taking MINT-ACITRETIN.

If you think you have had unprotected sex or you feel that your contraception has failed while taking MINT-ACITRETIN:

- Immediately call your doctor to discuss your options.



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