

Informed Consent For MINT-ACITRETIN Patients

TO BE SIGNED BY THE PATIENT



Do not sign this form or take MINT-ACITRETIN if there is anything that you do not understand about the information your doctor has given you about using MINT-ACITRETIN.

Part I: For all patients (male and female)

My doctor has provided me with verbal and written information about MINT-ACITRETIN and I understand the following:

- MINT-ACITRETIN is a medicine used to treat severe psoriasis and other skin disorders. My doctor has informed me about my choices in treating psoriasis and severe keratinisation disorders.
- MINT-ACITRETIN may cause serious side effects.
- Side effects include severe birth defects in unborn babies of females who have taken MINT-ACITRETIN
 - in the month before pregnancy,
 - during pregnancy and,
 - in females who become pregnant during the 3 years after stopping MINT-ACITRETIN treatment. (Females of childbearing potential must also complete Part II of this form).
- I must return all unused MINT-ACITRETIN to my doctor or pharmacist at the end of my treatment.
- I must not share MINT-ACITRETIN with any other person.
- I must not donate blood during treatment with MINT-ACITRETIN and for 3 years after stopping treatment with MINT-ACITRETIN.
- I must not consume alcohol (in drinks, food, or medicines) while taking MINT-ACITRETIN and for at least 2 months after the treatment has stopped.

Patient, Parent/Guardian Signature: _____

Address: _____ Telephone # _____

Physician name: _____ Date: _____

Part II: Only for female patients of childbearing potential

My doctor has provided me with verbal and written information, including a Patient Self-Evaluation about MINT-ACITRETIN, and I understand the following:

- I must not breastfeed a baby while taking MINT-ACITRETIN and for at least 3 years after I stop taking MINT-ACITRETIN.
- I must not get pregnant while taking MINT-ACITRETIN and I must wait at least 3 years after I stop taking MINT-ACITRETIN if I am planning to get pregnant.
- To be sure I am not pregnant, I must have two (negative) pregnancy tests, from a licensed laboratory. The second test must not be older than 3 days before I start MINT-ACITRETIN and I must wait until the 2nd or 3rd day of my next menstrual period before I start taking MINT-ACITRETIN.
- I must return to see my doctor as scheduled and for monthly (28-day intervals) pregnancy tests and to get a new prescription.
- I must either abstain from sexual intercourse or use **two effective and complementary birth control methods** (see list below) for at least:
 - 1 month before starting MINT-ACITRETIN,
 - during MINT-ACITRETIN treatment,
 - and for at least 3 years after stopping MINT-ACITRETIN treatment.
 - I must do this even if I think I cannot become pregnant, I do not have regular menstrual periods, or if I am currently sexually inactive.
 - I understand that two “effective and complementary birth control methods” means using one “primary” and one “secondary” method at the same time (Table 1).
- Birth control methods may fail. No birth control method is completely reliable and my doctor has explained this to me.
- Low dose progesterone-only mini pills may not be an effective method to prevent pregnancy during treatment with MINT-ACITRETIN and are not recommended for use.
- The effectiveness of hormonal birth control methods may be reduced when you take certain drugs or certain herbal remedies such as St John’s Wort. I have talked to my doctor about the other prescription drugs and/or over-the-counter medicines I am taking.
- I will stop taking MINT-ACITRETIN immediately and contact my doctor if:
 - I get pregnant during treatment or during the 3 years after stopping MINT-ACITRETIN treatment, or if
 - I miss my menstrual period, or
 - I stop using birth control, or
 - I have unprotected sex at any time.
- After stopping MINT-ACITRETIN treatment, I must have pregnancy tests every 1-3 months **for at least 3 years** after my last MINT-ACITRETIN dose.
- Every time I start a new course of treatment with MINT-ACITRETIN, however long the intervening period may have been, I must use effective and uninterrupted birth control during treatment **and for at least 3 years** after stopping MINT-ACITRETIN.
- If I become pregnant I will discuss with my doctor the serious risk of having a baby with severe birth deformities because I am taking or have taken MINT-ACITRETIN, and whether or not I wish to continue with the pregnancy.

Table 1: Primary and Secondary Birth Control Methods

Primary methods	Secondary methods
Birth control pills, tubal ligation, partner’s vasectomy, topical/insertable/injectable hormonal birth control products and intrauterine devices (IUDs).	Diaphragms, latex condoms and cervical caps. Each must be used with a spermicidal cream or jelly.

Patient, Parent/Guardian Signature: _____

Address: _____ Telephone # _____

Physician name: _____ Date: _____

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

- **Online:** www.Mint-Acitreten.com or
- **To speak to someone or to report an Adverse Reaction, please contact the Mint Pharmaceuticals MEDICAL SAFETY INFORMATION LINE at (toll-free) 1-877-398-9696**