

# SERIOUS TREATMENT SERIOUS DECISIONS

## H.A.E.R.T.: Healthier Acitretin Education and Remission Treatment

CAUSES BIRTH  
DEFECTS



DO NOT GET  
PREGNANT

**Acitretin Capsules**

**Alembic** 

## TABLE OF CONTENTS

## PAGES

Introduction-----	1
General Information -----	2-5
Avoiding Pregnancy -----	6-7
Additional Considerations -----	7
Birth Control Methods-----	8-10
Patient Self-Evaluation-----	11-12
Your Personal Record -----	13
Notes/Personal Contact Information-----	14
Important Phone Numbers -----	15
Patient Agreement/Informed Consent for Female Patients Form -----	16-17

### CAUSES BIRTH DEFECTS



### DO NOT GET PREGNANT

**CONTRAINDICATIONS AND WARNINGS:** Acitretin Capsules must not be used by females who are pregnant or who may become pregnant during therapy or at any time for at least 3 years after discontinuation of treatment. Acitretin capsules also must not be used by females of reproductive potential who may not use 2 effective forms of contraception (birth control) simultaneously for at least 1 month before, during and for at least 3 years after treatment. Two effective forms of contraception (birth control) are to be used simultaneously, even when 1 form is a hormonal contraceptive. Patients should not self-

medicate with St. John's Wort because of a possible interaction with hormonal contraceptives. Prescribers must obtain negative results for 2 pregnancy tests before initiating treatment with acitretin capsules. The first test is a screening test; the second is a confirmation test done during the first 5 days of the menstrual period immediately preceding therapy with acitretin capsules. For patients with amenorrhea, the second test should be done at least 11 days after the last act of unprotected sexual intercourse. If the second pregnancy test is negative, initiation of treatment with acitretin capsules should begin within 7 days of the specimen collection. Acitretin capsules should be limited to a monthly supply. Pregnancy testing throughout the treatment course should be monthly. Females must sign a Patient Agreement/Informed Consent for Female Patients form about the risks of birth defects. Acitretin is a metabolite of etretinate and major fetal abnormalities have been reported with both drugs. Acitretin can interact with ethanol to form etretinate. Therefore, females of reproductive potential must not ingest ethanol during treatment and for 2 months after cessation of treatment. Before prescribing, please see complete pregnancy warning in the accompanying complete prescribing information. Females who have undergone treatment with TEGISON® (etretinate) must continue to follow the contraception requirements for TEGISON.

Less frequent, but potentially serious, adverse events include hepatotoxicity, pancreatitis, and pseudotumor cerebri (please see WARNINGS in complete prescribing information), as well as hyperostosis, alterations in lipids, possible cardiovascular effects, ophthalmologic effects, capillary leak syndrome, and exfoliative dermatitis/erythroderma.

# INTRODUCTION

## ABOUT ACITRETIN CAPSULES

Acitretin capsules are a medicine used to treat severe forms of psoriasis 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. **Because acitretin capsules can have serious side effects**, you should talk with your prescriber about whether the possible benefits of acitretin capsules outweigh its possible risks.

In women of childbearing potential, acitretin capsules should be reserved for non-pregnant patients who are unresponsive to other therapies or whose clinical condition contraindicates the use of other treatments (see boxed CONTRAINDICATIONS AND WARNINGS - acitretin capsules can cause severe birth defects).

Most patients experience relapse of psoriasis after stopping therapy. Subsequent courses, when clinically indicated, have produced efficacy results similar to the initial course of therapy.

## ABOUT THE H.A.E.R.T. PROGRAM

This program applies to you because your doctor has prescribed acitretin capsules for you. This program is for women of childbearing potential.

Acitretin capsules can cause severe birth defects during treatment and for up to 3 years after a patient stops acitretin capsules. The H.A.E.R.T. program is intended to help you avoid getting pregnant during this time.

The Acitretin capsules H.A.E.R.T. Program contains several important components:

- This booklet
- Patient Agreement/Informed Consent for Female Patients form
- *A Medication Guide for Patients*

Read and complete all of these materials before taking acitretin capsules, and be sure to ask your doctor about any questions you have.

## YOUR SEXUAL PARTNER

It is strongly recommended that your sexual partner read this booklet in order to understand all of the facts about the risks of birth defects for women taking acitretin capsules. It is critical that you and your sexual partner know that you must not become pregnant during or within 3 years after you stop using acitretin capsules.

# GENERAL INFORMATION

## WHAT ARE ACITRETIN CAPSULES?

Acitretin capsules are a medicine used to treat severe forms of psoriasis in adults. Psoriasis is a skin disease that causes cells in the outer layer of the skin to grow faster than normal, creating a “traffic jam” of skin cells on the surface. The skin becomes red, irritated, inflamed, thicker, and sometimes has a silvery appearance.

Because acitretin capsules can have serious side effects, you should talk with your doctor to see if it is right for you.

Acitretin capsules might not work right away. It might take 2 or 3 months before your skin may begin to improve.

Psoriasis gets worse for some patients when they first start taking acitretin capsules.

Acitretin capsules have not been studied in children.

Please see the enclosed *Medication Guide for Patients* for additional information about acitretin capsules.

**You may also ask your doctor to provide you with the complete prescribing information (package insert) for acitretin capsules.**

## WHAT SHOULD I AVOID WHILE TAKING ACITRETIN CAPSULES?

- Do not get pregnant during therapy and for 3 years after treatment discontinuation (acitretin capsules can cause birth defects).
- Do not breastfeed.
- Do not consume alcohol (women of reproductive potential only).
- Do not donate blood during therapy and for 3 years after treatment discontinuation. Other women who could get pregnant must not receive blood from patients being treated with acitretin capsules.
- Do not share acitretin capsules with anyone, even if they have the same symptoms.
- Avoid night driving if you develop any sudden vision problems.
- Avoid nonmedical ultraviolet (UV) light.

- Avoid dietary supplements containing vitamin A.
- Avoid progestin-only birth control pills (“minipills”).

## WHAT ARE THE POSSIBLE SIDE EFFECTS OF ACITRETIN CAPSULES?

**Acitretin capsules can cause birth defects.** Refer to the enclosed *Medication Guide for Patients* and see “What is the most important information I should know about acitretin capsules?” and “What are the important warnings and instructions for females taking acitretin capsules?”

Psoriasis gets worse for some patients when they first start treatment with acitretin capsules. Some patients have more redness or itching. If this happens, tell your prescriber. These symptoms usually get better as treatment continues, but your prescriber may need to change the amount of your medicine.

**Serious side effects.** These do not happen often, but they can lead to permanent harm, or rarely, to death. Stop taking acitretin capsules and call your prescriber right away if you get the following signs or symptoms:

- **Yellowing of your skin or the whites of your eyes, nausea and vomiting, loss of appetite, or dark urine.** These can be signs of serious liver damage.
- **Bad headaches, nausea, vomiting, blurred vision.** These symptoms can be signs of increased brain pressure that can lead to blindness or even death.
- **Vision Problems. Decreased vision in the dark (night blindness).** Since this can start suddenly, you should be very careful when driving at night. This problem usually goes away when treatment with acitretin capsules stops. Stop taking acitretin capsules and call your prescriber if you develop any vision problems or eye pain.

## GENERAL INFORMATION

- **Depression.** There have been some reports of patients developing mental problems including a depressed mood, aggressive feelings, or thoughts of ending their own life (suicide). These events, including suicidal behavior, have been reported in patients taking other drugs similar to acitretin capsules as well as patients taking acitretin capsules. Since other things may have contributed to these problems, it is not known if they are related to acitretin capsules.
- **Aches or pains in your bones, joints, muscles, or back, trouble moving, or loss of feeling in your hands or feet.** These can be signs of abnormal changes to your bones or muscles.
- **Frequent urination, great thirst or hunger.** Acitretin capsules can affect blood sugar control, even if you do not already have diabetes. These are some of the signs of high blood sugar.
- **Shortness of breath, dizziness, nausea, chest pain, weakness, trouble speaking, or swelling of a leg. These may be signs of a heart attack, blood clots, or stroke.** Acitretin capsules 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.
- **Blood vessel problems.** Acitretin capsules can cause fluid to leak out of your blood vessels into your body tissues. **Call your prescriber right away if you have any of the following symptoms:** sudden swelling in one part of your body or all over your body, weight gain, fever, lightheadedness or feeling faint, or muscle aches. If this happens your prescriber will tell you to stop taking acitretin capsules.
- **Serious allergic reactions.** See “Who should not take acitretin capsules?” in the Medication Guide. Serious allergic reactions can happen

during treatment with acitretin capsules. **Call your prescriber right away if you get any of the following symptoms of an allergic reaction:** hives, itching, swelling of your face, mouth, or tongue, or problems breathing. **If this happens, stop taking acitretin capsules and do not take it again.**

- **Serious skin problems.** Acitretin capsules can cause skin problems that can begin in a small area and then spread over large areas of your body. **Call your prescriber right away if your skin becomes red and swollen (inflamed), you have peeling of your skin, or your skin becomes itchy, and painful.** You should stop acitretin capsules if this happens.

**Common side effects.** If you develop any of these side effects or any unusual reaction, check with your prescriber to find out if you need to change the amount of acitretin capsules you take. These side effects usually get better if the dose of acitretin capsules is reduced or acitretin capsules are stopped.

- **Chapped lips, peeling fingertips, palms, and soles, itching, scaly skin all over, weak nails, sticky or fragile (weak) skin, runny or dry nose, or nosebleeds.** Your prescriber or pharmacist can recommend a lotion or cream to help treat drying or chapping.
- **Dry mouth**
- **Joint pain**
- **Tight muscles**
- **Hair loss.** Most patients have some hair loss, but this condition varies among patients. No one can tell if you will lose hair, how much hair you may lose, or if and when it may grow back. You may also lose your eyelashes.
- **Dry eyes.** Acitretin capsules may dry your eyes. Wearing **contact lenses** may be uncomfortable during and after treatment with acitretin capsules because of the dry feeling in your eyes. If this happens, remove your contact lenses and call

## GENERAL INFORMATION

your prescriber. Also read the section about vision problems under “Serious side effects”.

- **Rise in blood fats (lipids).** Acitretin capsules can cause your blood fats (lipids) to rise. 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 as directed by your prescriber.

These are not all the possible side effects of acitretin capsules. For more information, ask your prescriber or pharmacist.

### ACITRETIN CAPSULES CAN CAUSE SEVERE BIRTH DEFECTS.

If you are a woman who could possibly become pregnant, and you and your doctor think that acitretin capsules are right for you, there are very important things to understand before starting acitretin capsules.

#### 1 You MUST NOT get pregnant while taking acitretin capsules.

- You MUST have 2 negative pregnancy tests before starting acitretin capsules. You MUST start treatment with acitretin capsules within 7 days of the specimen collection. You MUST have a pregnancy test each month before receiving the next month's prescription and every 3 months for 3 years after discontinuation.
- You MUST use 2 forms of birth control starting 1 month before treatment, the whole time you are treated with acitretin capsules, and for 3 years after you stop taking acitretin capsules.

#### 2 If you stop taking acitretin capsules, you MUST NOT get pregnant for at least 3 years. Keeping track of this time interval is

extremely important.

- 3 You MUST NOT consume alcohol of any kind while taking acitretin capsules, or for 2 months after you've stopped acitretin capsules.
- 4 You MUST NOT donate blood during therapy and for 3 years after treatment discontinuation.
- 5 You MUST sign the Patient Agreement/Informed Consent for Female Patients Form.

**IF YOU CANNOT AGREE TO THESE REQUIREMENTS, ACITRETIN CAPSULES ARE NOT FOR YOU.**

# GENERAL INFORMATION

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

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

# AVOIDING PREGNANCY

CAUSES BIRTH DEFECTS



DO NOT GET PREGNANT

## IMPORTANT INFORMATION FOR FEMALE PATIENTS

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 acitretin capsules,

you must:

- Before starting acitretin capsules, take 2 pregnancy tests proving that you're not pregnant. The first negative test will start the process, and the second negative test will confirm the results. (Your doctor will tell you when and how to take the tests.) Initiation of treatment with acitretin capsules should begin within 7 days of the specimen collection and should be limited to a monthly supply.
- Use 2 forms of birth control at the same time, for at least 1 month before and during your treatment with acitretin capsules and for at least 3 years after you stop treatment with acitretin capsules. You and your doctor should choose 2 forms of birth control. At least one of the methods must be a primary method.

**PRIMARY:** (you must choose at least 1 from this list)

- Birth control pills (but not progestin-only "minipills")
- Birth control patch
- Intrauterine device (IUD)
- Injected, implanted, or inserted hormonal birth control products
- Having your tubes tied
- Partner's vasectomy

**SECONDARY:** (you may choose 1 from this list to use with primary method)

- Diaphragm with spermicide
- Cervical cap with spermicide
- Condom with or without spermicide
- Vaginal sponge (contains spermicide)

Before you receive your first prescription for acitretin capsules, you should have discussed and signed a Patient Agreement/Informed Consent for Female Patients form with your prescriber. 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 prescriber about this and sign the form, contact your prescriber.

## WHOM CAN I CONTACT FOR BIRTH CONTROL INFORMATION?

**TOLL-FREE NUMBER: 1-800-724-4242**

A 24-hour, toll-free, automated birth control counseling line has been set up for you to use.

Remember, calling this number is completely confidential - you will never have to give your name, and you cannot be identified.

A 24-hour, toll-free, automated line is available to all patients on acitretin capsules. 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 on the Internet:

- Association of Reproductive Health Professionals: [www.arhp.org](http://www.arhp.org)
- Planned Parenthood: [www.plannedparenthood.org](http://www.plannedparenthood.org)

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

- Organization of Teratology Information Services: [www.mothersbaby.org](http://www.mothersbaby.org)
- Centers for Disease Control and Prevention: [www.cdc.gov](http://www.cdc.gov)

## COMMONLY ASKED QUESTIONS

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

- You need to start using 2 forms of birth control at least 1 month before you begin taking acitretin capsules.
- You need to use 2 forms of birth control during your entire treatment with acitretin capsules.
- You need to continue to use 2 forms of birth control for 3 years after you stop taking acitretin capsules.

If you think you have had unprotected sex or you feel that your contraception has failed while taking acitretin capsules:

- Contact your prescriber, women's health centers, pharmacies, or hospital emergency rooms for information on how to get emergency contraception. A 24-hour, toll-free number (1-800-724-4242) is also available for patients to receive automated birth control and emergency contraception information.



# AVOIDING PREGNANCY

## What is “emergency contraception”?

Emergency contraception is an option that can be used if you have had unprotected sex or your birth control method failed while taking acitretin capsules (or within 3 years after you stop). “Unprotected” means using fewer than 2 types of birth control, or 1 of the forms you were using failed. Emergency contraception, which includes the “morning-after pill”, needs to be used as directed after having unprotected sex.

If you think you've become pregnant while taking acitretin capsules or within 3 years of stopping:

- Stop taking acitretin capsules.

- Call your doctor to tell him/her you might be pregnant.
- Call Alembic Pharmaceuticals at **1-866-210-9797**.
- Or call FDA MedWatch at **1-800-332-1088 (1-800-FDA-1088)**.

## IMPORTANT INFORMATION FOR MALE PATIENTS

Very small amounts of acitretin are found in semen of males taking the medication (1/200,000 of a single 25 mg capsule). Based upon available information, it appears that these small amounts of acitretin in semen pose little, if any, risk to an unborn child. Discuss any concerns you may have about this with your doctor.

# ADDITIONAL CONSIDERATIONS

## What about alcohol?

Alcohol can increase the length of time acitretin is stored in a woman's body, causing the risk of birth defects to last longer than 3 years. It is essential that women of reproductive potential do not drink alcohol during treatment with acitretin capsules, or for 2 months after they stop treatment.

Alcohol is in more places than you think. Even small amounts found in cold medicine, or alcohol used in cooking, can make the possibility of birth defects last MUCH longer. Be very careful not to allow any kind of alcohol into your body.

If you have any questions about alcohol and acitretin capsules, ask your doctor.

## What about breastfeeding?

Do not take acitretin capsules if you're breastfeeding. Acitretin capsules can pass into your milk and may harm your baby.

## What about donating blood?

No person (male or female) should donate blood while taking acitretin capsules, or for at least 3 years after stopping therapy. The acitretin in your blood, if given to a pregnant woman, could harm her baby. Acitretin capsules do not affect your ability to receive a blood transfusion.

# BIRTH CONTROL METHODS

The following descriptions have been supplied to give you an overview of how each birth control method works in your body. For more information, please ask your doctor, refer to the information included with the individual product, or use the resources listed in the **WHOM CAN I CONTACT FOR BIRTH CONTROL INFORMATION?** section on Page 06.

## WHAT ABOUT MINIPILLS?

Do not use "minipills," which may not work while you take acitretin capsules. Ask your prescriber if you are not sure what type of pills you are using.

## PRIMARY METHODS

You must choose at least 1 from the following methods.

### BIRTH CONTROL PILLS<sup>1</sup>

"The Pill" contains hormones that prevent you from becoming pregnant. These hormones prevent your ovaries from releasing eggs and may also keep sperm from joining with an egg. The Pill is safe and effective for most women, and is taken once daily.

The Pill needs to be prescribed by a doctor.

Two kinds are available for most women: one has a combination of hormones, and the other has only one hormone ("minipills").

Do not use "minipills," which may not work while you take acitretin capsules. Ask your prescriber if you are not sure what type of pills you are using.

**Effectiveness:** Fewer than 1 in 100 women will become pregnant each year with perfect use. With typical use, 9 in 100 women will become pregnant each year.

### BIRTH CONTROL PATCH<sup>1</sup>

The patch, available by prescription, sends hormones into your body through your skin. These hormones help prevent your ovaries from releasing eggs and may also keep sperm from joining with an egg. A new patch is placed on the skin once a week for three weeks in a row, followed by a patch-free week.

**Effectiveness:** Fewer than 1 in 100 women will become pregnant each year with perfect use. With typical use, 9 in 100 women will become pregnant each year.

### INTRAUTERINE DEVICE<sup>1</sup>

The intrauterine device (IUD) is placed inside your uterus by a doctor and usually either contains copper or releases hormones. Both kinds of IUDs prevent fertilization, by affecting movement of sperm so they can't join with an egg.

**Effectiveness:** Fewer than 1 in 100 women will become pregnant each year if an IUD is used.

### INJECTED, IMPLANTED, OR INSERTED HORMONAL BIRTH CONTROL<sup>1</sup>

There are several different kinds of hormonal birth control that can prevent pregnancy.

**Injected or implanted hormones:** This form is given to you by your healthcare provider at specific time intervals. These hormone shots or implants prevent your ovaries from releasing eggs and may also keep sperm from joining with an egg.

**Injected hormone effectiveness:** Fewer than 1 in 100 women will get pregnant each year with perfect use. With typical use, 6 in 100 women will get pregnant each year.

**Implanted hormone effectiveness:** Fewer than 1 in 100 women will get pregnant each year. It lasts up to 3 years.

**Inserted hormones:** This form is usually called the "vaginal ring," and you insert it into your vagina. It must be prescribed by your doctor. After being properly inserted, it releases a continuous low dose of hormones into your body. These hormones prevent your ovaries from releasing eggs and may also keep sperm from joining with an egg. The ring remains in the vagina for 3 weeks, and then is removed for 1 week.

**Effectiveness:** Fewer than 1 in 100 women will become pregnant each year with perfect use. With typical use, 9 in 100 women will become pregnant each year.

## BIRTH CONTROL METHODS

### **TUBAL LIGATION<sup>1</sup> (“HAVING YOUR TUBES TIED”) OR YOUR PARTNER’S VASECTOMY<sup>1</sup>**

Sterilization of women and men requires operations and are meant to be permanent.

“Having your tubes tied” (or tubal ligation) is intended to block a woman’s fallopian tubes, where sperm would join with an egg. There are different types of sterilization incision methods and a non-incision method (Essure). The non-incision method, Essure, takes about 3 months before it is effective. An x-ray should be performed by your doctor to confirm if the fallopian tubes are fully blocked.

A vasectomy is an operation that permanently disconnects a man’s semen duct, which carries sperm. Vasectomies do not work immediately, and it often takes up to 3 months before all the live sperm are gone. A semen analysis should be performed to confirm if there are no more live sperm.

**Tubal ligation effectiveness:** Approximately 5 in 1,000 women will become pregnant after having a tubal ligation performed with traditional incision methods. Fewer than 3 in 1,000 women will become pregnant after having tubal ligation performed with Essure.

**Vasectomy effectiveness:** 1 in 1,000 men will become fertile again after a vasectomy has been performed.

### **CONTINUOUS ABSTINENCE<sup>1</sup>**

Continuous abstinence is not having sex play with a partner at all.

**Effectiveness:** When used continuously, abstinence is 100% effective in preventing pregnancy.

### **MEDICALLY CONFIRMED MENOPAUSE<sup>2</sup>**

**Menopause is the time at “midlife” when woman has her last period.** It happens when the ovaries stop releasing eggs — usually a gradual process.

Sometimes it happens all at once. It is confirmed when a woman has missed her period for 12 consecutive months (which can not be attributed to other causes). Menopause also results in lower levels of estrogen and other hormones.

**Induced menopause** occurs if the ovaries are removed or damaged during surgery, chemotherapy, or radiation therapy. In this case, menopause begins immediately.

**Women reach menopause at different times.** The timing is not related to age at last pregnancy, age of menarche (first period), the birth control pill, breastfeeding, class, fertility patterns, height, having been pregnant, or race.

The average age for menopause is 51. If menopause is reached naturally or surgically before the age of 40, it is called early or premature menopause.

Estrogen levels drop very abruptly after induced menopause — when *both* ovaries are removed surgically or damaged by radiation or chemotherapy.

Women in **perimenopause** (the period of gradual changes that lead into menopause) have reduced fertility, but they are not infertile. Although menstruation may be sporadic, pregnancy *can* happen. That’s why women need to consider birth control during perimenopause.

Only your doctor can confirm that you have reached menopause and do not need to pursue contraceptive options.

### **HYSTERECTOMY<sup>3</sup>**

Hysterectomy is the removal of the uterus. It is major surgery and is not usually used for sterilization. It is used to correct significant medical conditions. Hysterectomy ends menstruation as well as the possibility of pregnancy.

# BIRTH CONTROL METHODS

## SECONDARY METHODS

You may choose 1 from these options to use with a primary method. Spermicide must be used with the diaphragm and cervical cap. Spermicide is available in a variety of forms and contains a chemical that prevents sperm from joining with an egg. Spermicide may cause irritation. Changing forms or brands may help. Spermicide is not required with condoms or vaginal sponge.

### DIAPHRAGM<sup>1</sup>

The diaphragm is a shallow latex cup that you insert into your vagina. You must have a custom fitting from a healthcare professional to obtain a diaphragm. The diaphragm must be used with spermicide, and must stay in place for 6 hours after sex. If you have sex again or if you have sex more than 6 hours after you put in the diaphragm, more spermicide needs to be inserted deep into your vagina.

The diaphragm should not be left in place longer than 24 hours.

**Effectiveness:** 6 in 100 women will become pregnant each year with perfect use. With typical use, 12 in 100 women will become pregnant each year.

### CERVICAL CAP<sup>1</sup>

The cervical cap is very similar to the diaphragm, except that it is smaller and covers only the cervix. You must have a custom fitting from a healthcare professional to obtain a cervical cap.

The cervical cap must be used with spermicide. With each sexual act, check that the cervical cap is still covering the cervix and insert more spermicide deep into your vagina. The cervical cap must stay in place for 6 hours after sex and should not be left in longer than 48 hours.

**Effectiveness for women who have never been pregnant or given birth vaginally:** 14 in 100 women who use the cervical cap will become pregnant each year.

**Effectiveness for women who have given birth vaginally:** 29 in 100 women who use the cervical cap will become pregnant each year.

### CONDOM<sup>1</sup>

Male condoms are made of latex or plastic and are worn on the penis during intercourse. Condoms prevent pregnancy by preventing sperm from entering the vagina. Condoms are non-prescription and available at drugstores, health centers, or grocery stores.

**Effectiveness:** 2 in 100 women whose partners use condoms will become pregnant each year with perfect use. With typical use, 18 in 100 women whose partners use condoms will become pregnant each year.

### VAGINAL SPONGE<sup>1</sup>

The vaginal sponge is made of plastic foam and contains spermicide. The vaginal sponge should be inserted before intercourse deep into the vagina so that it covers the cervix. The vaginal sponge continuously releases a spermicide and blocks sperm from entering the uterus. The vaginal sponge can be inserted up to 24 hours before intercourse and must stay in place for 6 hours after sex. It should not be left in place longer than 30 hours.

**Effectiveness for women who have never given birth:** 9 in 100 women will become pregnant each year with perfect use. With typical use, 12 in 100 women will become pregnant each year.

**Effectiveness for women who have previously given birth:** 20 in 100 will become pregnant each year with perfect use. With typical use, 24 in 100 will become pregnant each year.

# PATIENT SELF-EVALUATION

Now that you have read the H.A.E.R.T. brochure and talked with your doctor about acitretin capsules and its risks, please use this self-evaluation exercise to test your understanding of some of the most important points.

Please choose the best answer for each of the following 7 questions.

**1. Treatment with acitretin capsules requires prevention of pregnancy because:**

- a. Severe psoriasis may get worse after pregnancy
- b. Acitretin capsules can cause birth defects
- c. Psoriasis is more likely in children of psoriasis patients
- d. None of the above

**2. Before starting treatment with acitretin capsules, it is important to be certain I am not pregnant.**

To be certain, I must:

- a. Test my urine at home with 2 pregnancy test kits
- b. Have my doctor order 2 pregnancy tests, 2 weeks apart
- c. Have my doctor do a screening test for pregnancy when we decide to treat me with acitretin, and then test for pregnancy again during the first 5 days of my period (or at least 11 days after the last time I had sex without birth control) to confirm I am not pregnant
- d. Not have sex for one month

**3. I must start using 2 effective forms of birth control:**

- a. At least 1 month before starting acitretin capsules
- b. At the time I take the first dose of acitretin capsules

- c. After my period ends
- d. Now

**4. I must continue using 2 effective forms of birth control:**

- a. As long as I continue to take acitretin capsules
- b. For 1 year after I stop taking acitretin capsules
- c. For 3 years after I stop taking acitretin capsules
- d. Until menopause

**5. True or False? (circle one)      T      F**

It is important to avoid alcohol while taking acitretin capsules and for 2 months after stopping acitretin capsules because alcohol can change acitretin into another substance that may also cause birth defects, and that lasts in the body for even longer than acitretin.

**6. True or False? (circle one)      T      F**

A female patient with severe psoriasis has used birth control pills for 7 years after her last child was born and they have worked just fine. She still needs to add a second method of birth control before starting treatment with acitretin capsules.

**7. True or False? (circle one)      T      F**

Avoiding pregnancy during and after treatment with acitretin capsules is equally the responsibility of my doctor, my partner, and me.

## ANSWERS

**1. b**

While a and c are both true, the reason pregnancy prevention is required is because acitretin capsules can cause birth defects which can be severe. Acitretin stays in the body for a long time, so you should not get pregnant for at least 3 years after stopping treatment. If you think you may want to become pregnant in the near future, you should NOT take acitretin capsules.

**2. c**

When we talk about “2 negative pregnancy tests,” we

mean a screening test and then a confirmation test during your period. Both tests must be negative BEFORE starting acitretin capsules. It is important to be sure you are not pregnant because acitretin could harm your developing baby.

**3. a**

It is important to be sure you have made the right choice of birth control for you and are comfortable using the 2 forms of birth control. If cooperation from your partner is involved, as with condoms, you need to be certain you both understand and accept the requirement to use condoms every time you have sex.

# PATIENT SELF-EVALUATION

Starting 1 month before acitretin capsules also help ensure you are not pregnant. If you and your doctor have decided acitretin capsules are right for you, now is a good time to start using 2 forms of birth control, but you must use them for at least 1 month before starting acitretin capsules.

## 4. c

Because acitretin remains in your body for a long time after you stop taking the drug, the risk of birth defects continues, and you must not get pregnant for at least 3 years after stopping acitretin capsules.

## 5. TRUE

Even a small amount of alcohol can affect how the body handles acitretin.

## 6. TRUE

Every method of birth control can fail, including birth control pills. Because the risk of birth defects with exposure to acitretin is so serious, 2 reliable methods are recommended.

## 7. FALSE

Only you can truly prevent pregnancy. While your doctor

will give you information, refer you to counseling, and encourage you to make the right decision, and your partner's cooperation and support with birth control methods is essential, the success of pregnancy prevention during and after treatment is your responsibility.

## SCORING

7 correct? Well done!

If you got any question wrong, please review the brochure again and make sure you understand. Thank you!

Please be sure to discuss any questions or concerns you may have with your doctor before starting treatment with acitretin capsules. Other treatment options should be used if you are not willing or able to take seriously the responsibility for pregnancy prevention and actively follow all recommendations.

# YOUR PERSONAL RECORD

**NAME** \_\_\_\_\_

You **MUST** have 2 negative pregnancy tests performed by your doctor that show you are **NOT** pregnant before starting therapy with acitretin capsules.

The first test will be at the time that you and your doctor decide that acitretin capsules might be right for you.

**1. TEST DATE** \_\_\_\_\_ **TEST RESULT** \_\_\_\_\_

The second test will usually be done during the first 5 days of your menstrual period. If the second pregnancy test is negative, initiation of treatment with acitretin capsules should begin within 7 days of the specimen collection. Acitretin capsules should be limited to a monthly supply.

**2. START OF MENSTRUAL PERIOD** \_\_\_\_\_

**TEST DATE** \_\_\_\_\_ **TEST RESULT** \_\_\_\_\_

## DATE THERAPY WITH ACITRETIN CAPSULES BEGAN

<i><b>FOLLOW-UP APPOINTMENTS</b></i>	
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time

## DATE THERAPY WITH ACITRETIN CAPSULES STOPPED

<i><b>FOLLOW-UP APPOINTMENTS</b></i>	
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time
Date	Time

# NOTES / PERSONAL CONTACT INFORMATION

---

---

---

---

---

---

---

---

---

---

---

---

---

---

---

PHYSICIAN NAME: \_\_\_\_\_

PHYSICIAN PHONE: \_\_\_\_\_

PHARMACY NAME: \_\_\_\_\_

PHARMACY PHONE: \_\_\_\_\_

OTHER: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

OTHER: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_



# IMPORTANT PHONE NUMBERS

## BIRTH CONTROL COUNSELING

1-800-724-4242

## IF YOU BECOME PREGNANT

1-866-210-9797 (Alembic Pharmaceuticals)

Or

1-800-332-1088 (1-800-FDA-1088)

CAUSES BIRTH  
DEFECTS



DO NOT GET  
PREGNANT

### REFERENCES:

1. Planned Parenthood: Birth Control. Available at: <https://www.plannedparenthood.org/learn/birth-control>. Accessed June 27, 2022.
2. The North American Menopause Society: Menopause & Me. Available at: <http://www.menopause.org/for-women>. Accessed June 27, 2022.
3. MedlinePlus: Hysterectomy. Available at: <http://www.nlm.nih.gov/medlineplus/hysterectomy.html>. Accessed June 27, 2022.

# PATIENT AGREEMENT/INFORMED CONSENT FOR FEMALE PATIENTS

CAUSES BIRTH DEFECTS



DO NOT GET PREGNANT

## To be completed by the patient\* and signed by her prescriber

\*Must also be initialed by the parent or guardian of a minor patient (under age 18)

Read each item below and initial in the space provided to show that you understand each item.

**Do not sign this consent and do not take acitretin capsules if there is anything that you do not understand.**

(Patient's name) \_\_\_\_\_

1. I understand that there is a very high risk that my unborn baby could have severe birth defects if I am pregnant or become pregnant while taking acitretin capsules in any amount even for short periods of time. Birth defects have also happened in babies of women who became pregnant after stopping treatment with acitretin capsules.

INITIAL: \_\_\_\_\_

2. I understand that I must not become pregnant while taking acitretin capsules and for at least 3 years after the end of my treatment with acitretin capsules.

INITIAL: \_\_\_\_\_

3. I know that I must avoid all alcohol, including drinks, food, medicines, and over-the-counter products that contain alcohol. I understand that the risk of birth defects may last longer than 3 years if I swallow any form of alcohol during therapy with acitretin capsules, and for 2 months after I stop taking acitretin capsules.

INITIAL: \_\_\_\_\_

4. I understand that I must not have sexual intercourse, or I must use 2 separate, effective forms of birth control **at the same time**. The only exceptions are if I have had surgery to remove the womb (a hysterectomy) or my prescriber has told me I have gone completely through menopause.

INITIAL: \_\_\_\_\_

5. I understand that I have to use 2 effective forms of birth control (contraception) at the same time for at least 1 month before starting acitretin capsules, for the entire time of therapy with acitretin capsules, and for at least 3 years after stopping acitretin capsules.

INITIAL: \_\_\_\_\_

6. I understand that any form of birth control can fail. Therefore, I must use 2 different methods at the same time, every time I have sexual intercourse.

INITIAL: \_\_\_\_\_

7. I understand that the following are considered effective forms of birth control: Primary: Tubal ligation (having my tubes tied), partner's vasectomy, birth control pills (not progestin- only "minipills"), injectable/implantable/ insertable/topical (patch) hormonal birth control products, and IUDs (intrauterine devices). Secondary: Condoms (with or without spermicide, which is a special cream or jelly that kills sperm), diaphragms and cervical caps (which must be used with a spermicide), and vaginal sponges (contains spermicide). I understand that at least 1 of my 2 methods of birth control must be a primary method.

INITIAL: \_\_\_\_\_

8. I will talk with my prescriber about any medicines or dietary supplements I plan to take while taking acitretin capsules because certain birth control methods may not work if I am taking certain medicines or herbal products (for example, St. John's wort).

INITIAL: \_\_\_\_\_

9. Unless I have had a hysterectomy or my prescriber says I have gone completely through menopause, I understand that I must have 2 negative pregnancy test results before I can get a prescription to start acitretin capsules. I understand that if the second pregnancy test is negative, I must start taking my acitretin capsules within 7 days of the specimen collection. I will then have pregnancy tests on a monthly basis during therapy with acitretin capsules as instructed by my prescriber. In addition, for at least 3 years after I stop taking acitretin capsules, I will have a pregnancy test every 3 months.

INITIAL: \_\_\_\_\_

10. I understand that I should not start taking acitretin capsules until I am *sure* that I am not pregnant and have negative results from 2 pregnancy tests.

INITIAL: \_\_\_\_\_

11. I have received information on emergency contraception (birth control), including information on its availability over-the-counter.

INITIAL: \_\_\_\_\_

12. I understand that on a monthly basis during therapy with acitretin capsules and every 3 months for at least 3 years after stopping acitretin capsules that I should receive counseling from my prescriber about contraception (birth control) and behaviors associated with an increased risk of pregnancy.

INITIAL: \_\_\_\_\_

13. I understand that I must stop taking acitretin capsules right away and call my prescriber if I get pregnant, miss my menstrual period, stop using birth control, or have sexual intercourse without using my 2 birth control methods during and at least 3 years after stopping acitretin capsules.

INITIAL: \_\_\_\_\_

14. If I do become pregnant while on acitretin capsules or at any time within 3 years of stopping acitretin capsules, I understand that I should report my pregnancy to Alembic at 1-866-210-9797 or to the Food and Drug Administration (FDA) MedWatch program at 1-800-FDA-1088. The information I share will be kept confidential (private) unless disclosure is legally required. This will help the company and the FDA evaluate the pregnancy prevention program to prevent birth defects.

INITIAL: \_\_\_\_\_

**I have received a copy of the H.A.E.R.T. brochure. My prescriber has answered all my questions about acitretin capsules. I understand that it is my responsibility to follow my doctor's instructions, and not to get pregnant during treatment with acitretin capsules or for at least 3 years after I stop taking acitretin capsules.**

I now authorize my prescriber, \_\_\_\_\_, to begin my treatment with acitretin capsules. \_\_\_\_\_

Patient signature: \_\_\_\_\_ Date: \_\_\_\_\_

Parent/guardian signature (if under age 18): \_\_\_\_\_ Date: \_\_\_\_\_

Please print: Patient name and address: \_\_\_\_\_

\_\_\_\_\_ Telephone: \_\_\_\_\_

I have fully explained to the patient, \_\_\_\_\_, the nature and purpose of the treatment described above and the risks to females of childbearing potential. I have asked the patient if she has any questions regarding her treatment with acitretin capsules and have answered those questions to the best of my ability.

Prescriber signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Alembic Pharmaceuticals, Inc.**

550 Hills Drive, Suite 104B  
Bedminster, NJ 07921, USA



# PATIENT AGREEMENT/INFORMED CONSENT FOR FEMALE PATIENTS

CAUSES BIRTH DEFECTS



DO NOT GET PREGNANT

## To be completed by the patient\* and signed by her prescriber

\*Must also be initialed by the parent or guardian of a minor patient (under age 18)

Read each item below and initial in the space provided to show that you understand each item.

**Do not sign this consent and do not take acitretin capsules if there is anything that you do not understand.**

(Patient's name) \_\_\_\_\_

1. I understand that there is a very high risk that my unborn baby could have severe birth defects if I am pregnant or become pregnant while taking acitretin capsules in any amount even for short periods of time. Birth defects have also happened in babies of women who became pregnant after stopping treatment with acitretin capsules.

INITIAL: \_\_\_\_\_

2. I understand that I must not become pregnant while taking acitretin capsules and for at least 3 years after the end of my treatment with acitretin capsules.

INITIAL: \_\_\_\_\_

3. I know that I must avoid all alcohol, including drinks, food, medicines, and over-the-counter products that contain alcohol. I understand that the risk of birth defects may last longer than 3 years if I swallow any form of alcohol during therapy with acitretin capsules, and for 2 months after I stop taking acitretin capsules.

INITIAL: \_\_\_\_\_

4. I understand that I must not have sexual intercourse, or I must use 2 separate, effective forms of birth control **at the same time**. The only exceptions are if I have had surgery to remove the womb (a hysterectomy) or my prescriber has told me I have gone completely through menopause.

INITIAL: \_\_\_\_\_

5. I understand that I have to use 2 effective forms of birth control (contraception) at the same time for at least 1 month before starting acitretin capsules, for the entire time of therapy with acitretin capsules, and for at least 3 years after stopping acitretin capsules.

INITIAL: \_\_\_\_\_

6. I understand that any form of birth control can fail. Therefore, I must use 2 different methods at the same time, every time I have sexual intercourse.

INITIAL: \_\_\_\_\_

7. I understand that the following are considered effective forms of birth control: Primary: Tubal ligation (having my tubes tied), partner's vasectomy, birth control pills (not progestin- only "minipills"), injectable/implantable/ insertable/topical (patch) hormonal birth control products, and IUDs (intrauterine devices). Secondary: Condoms (with or without spermicide, which is a special cream or jelly that kills sperm), diaphragms and cervical caps (which must be used with a spermicide), and vaginal sponges (contains spermicide). I understand that at least 1 of my 2 methods of birth control must be a primary method.

INITIAL: \_\_\_\_\_

**I have received a copy of the H.A.E.R.T. brochure. My prescriber has answered all my questions about acitretin capsules. I understand that it is my responsibility to follow my doctor's instructions, and not to get pregnant during treatment with acitretin capsules or for at least 3 years after I stop taking acitretin capsules.**

I now authorize my prescriber, \_\_\_\_\_, to begin my treatment with acitretin capsules. \_\_\_\_\_

Patient signature: \_\_\_\_\_ Date: \_\_\_\_\_

Parent/guardian signature (if under age 18): \_\_\_\_\_ Date: \_\_\_\_\_

Please print: Patient name and address: \_\_\_\_\_

Telephone: \_\_\_\_\_

I have fully explained to the patient, \_\_\_\_\_, the nature and purpose of the treatment described above and the risks to females of childbearing potential. I have asked the patient if she has any questions regarding her treatment with acitretin capsules and have answered those questions to the best of my ability.

Prescriber signature: \_\_\_\_\_ Date: \_\_\_\_\_

8. I will talk with my prescriber about any medicines or dietary supplements I plan to take while taking acitretin capsules because certain birth control methods may not work if I am taking certain medicines or herbal products (for example, St. John's wort).  
INITIAL: \_\_\_\_\_

9. Unless I have had a hysterectomy or my prescriber says I have gone completely through menopause, I understand that I must have 2 negative pregnancy test results before I can get a prescription to start acitretin capsules. I understand that if the second pregnancy test is negative, I must start taking my acitretin capsules within 7 days of the specimen collection. I will then have pregnancy tests on a monthly basis during therapy with acitretin capsules as instructed by my prescriber. In addition, for at least 3 years after I stop taking acitretin capsules, I will have a pregnancy test every 3 months.  
INITIAL: \_\_\_\_\_

10. I understand that I should not start taking acitretin capsules until I am *sure* that I am not pregnant and have negative results from 2 pregnancy tests.

INITIAL: \_\_\_\_\_

11. I have received information on emergency contraception (birth control), including information on its availability over-the-counter.

INITIAL: \_\_\_\_\_

12. I understand that on a monthly basis during therapy with acitretin capsules and every 3 months for at least 3 years after stopping acitretin capsules that I should receive counseling from my prescriber about contraception (birth control) and behaviors associated with an increased risk of pregnancy.

INITIAL: \_\_\_\_\_

13. I understand that I must stop taking acitretin capsules right away and call my prescriber if I get pregnant, miss my menstrual period, stop using birth control, or have sexual intercourse without using my 2 birth control methods during and at least 3 years after stopping acitretin capsules.

INITIAL: \_\_\_\_\_

14. If I do become pregnant while on acitretin capsules or at any time within 3 years of stopping acitretin capsules, I understand that I should report my pregnancy to Alembic at 1-866-210-9797 or to the Food and Drug Administration (FDA) MedWatch program at 1-800-FDA-1088. The information I share will be kept confidential (private) unless disclosure is legally required. This will help the company and the FDA evaluate the pregnancy prevention program to prevent birth defects.

INITIAL: \_\_\_\_\_

**Alembic Pharmaceuticals, Inc.**

550 Hills Drive, Suite 104B  
Bedminster, NJ 07921, USA

**Prescriber Copy**

