

MEDICATION GUIDE

Acitretin (a"sit re' tin) Capsules, USP

Read this Medication Guide carefully before you start taking acitretin, and read it each time you get more acitretin. There may be new information.

The first information in this Medication Guide is about birth defects and how to avoid pregnancy. **After this section there is important safety information about possible effects for any patient taking acitretin. All patients** should read this entire Medication Guide carefully. This information does not take the place of talking with your prescriber about your medical condition or treatment.

What is the most important information I should know about acitretin?

Acitretin can cause serious side effects, including:

- **Severe birth defects.** If you are a female who can get pregnant, you should use acitretin only if you are not pregnant now, can avoid becoming pregnant for at least 3 years, and other medicines do not work for your severe psoriasis or you cannot use other psoriasis medicines. Information about effects on unborn babies and about how to avoid pregnancy is found in the next section:

“What are the important warnings and instructions for females taking acitretin?”

CAUSES BIRTH DEFECTS



DO NOT GET PREGNANT

- **Liver problems,** including abnormal liver function tests and inflammation of your liver (hepatitis). Your prescriber should do blood tests to check how your liver is working before you start taking and during treatment with acitretin. Stop taking acitretin and call your prescriber right away if you have any of the following signs or symptoms of a serious liver problem:

- yellowing of your skin or the whites of your eyes
- nausea and vomiting
- loss of appetite
- dark urine

What are the important warnings and instructions for females taking acitretin?

- **Before you receive your first prescription for acitretin, 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.**

Important: If you are a female who can become pregnant:

- **You must not take acitretin if you are pregnant or might become pregnant during treatment or at any time for at least 3 years after you stop treatment because acitretin can cause severe birth defects.**
- **During treatment with acitretin and for 2 months after you stop treatment with acitretin, you must avoid drinks, foods, and all medicines that contain alcohol. This includes over-the-counter products that contain alcohol. Avoiding alcohol is very important, because alcohol changes acitretin**

into a drug that may take longer than 3 years to leave your body. The chance of birth defects may last longer than 3 years if you swallow any form of alcohol during treatment with acitretin and for 2 months after you stop taking acitretin.

- **You and your prescriber must be sure you are not pregnant before you start therapy with acitretin. You must have negative results from 2 pregnancy tests before you start treatment with acitretin.** A negative result shows you are not pregnant. Because it takes a few days after pregnancy begins for a test to show that you are pregnant, the first negative test may not ensure you are not pregnant. Do not start acitretin until you have negative results from 2 pregnancy tests.
 - The **first pregnancy test** (urine or blood) will be done at the time you and your prescriber decide if acitretin might be right for you.
 - The **second pregnancy test** will usually be done during the first 5 days of your menstrual period. You must start taking acitretin within 7 days of when the urine or blood for the second pregnancy test is collected.
- After you start taking acitretin, you must have a pregnancy test repeated each month that you are taking acitretin. This is to be sure that you are not pregnant during treatment because acitretin can cause birth defects. In addition, your prescription of acitretin will be limited to a monthly supply.
- For at least 3 years after stopping treatment with acitretin, you must have a pregnancy test repeated every 3 months to make sure that you are not pregnant.
- **Discuss effective birth control (contraception) with your prescriber. You must use 2 effective forms of birth control (contraception) at the same time during all of the following:**
 - for at least 1 month before beginning treatment with acitretin
 - during treatment with acitretin
 - for at least 3 years after stopping treatment with acitretin
- **If you are sexually active, you must use 2 effective forms of birth control (contraception) at the same time even if you think you cannot become pregnant, unless 1 of the following is true for you:**
 - You had your womb (uterus) removed during an operation (a hysterectomy).
 - Your prescriber said you have gone completely through menopause (the “change of life”).

The following are considered effective forms of birth control:

Primary Forms:

- having your tubes tied (tubal ligation)
- partner's vasectomy
- IUD (Intrauterine device)
- birth control pills that contain both estrogen and progestin (combination oral contraceptives); not progestin-only “minipills”
- hormonal birth control products that are injected, implanted, or inserted in your body
- birth control patch

Secondary Forms (use with a Primary Form):

- diaphragms with spermicide
- condoms (with or without spermicide)
- cervical caps with spermicide
- vaginal sponges (contains spermicide)

At least 1 of your 2 methods of birth control must be a primary form.

- **If you have sex at any time without using 2 effective forms of birth control (contraception) at the same time, or if you get pregnant or miss your period, stop using acitretin and call your prescriber right away.**
- **Consider “Emergency Contraception” (EC) if you have sex with a male without correctly using 2 effective forms of birth control (contraception) at the same time.** EC is also called “emergency birth

control" which includes the "morning after" pill. Contact your prescriber **as soon as possible** if you have sex without using 2 effective forms of birth control (contraception) at the same time, because EC works best if it is used within 1 or 2 days after sex. EC is not a replacement for your usual 2 effective forms of birth control (contraception) because it is not as effective as regular birth control methods.

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 (1-866-245-6020) is also available for patients to receive automated birth control and emergency contraception information.

- **Stop taking acitretin right away and contact your prescriber if you get pregnant while taking acitretin or at any time for at least 3 years after treatment has stopped. You need to discuss the possible effects on the unborn baby with your prescriber.**
- **If you do become pregnant while taking acitretin or at any time for at least 3 years after stopping acitretin, you should report your pregnancy to Amneal Pharmaceuticals Medical Information Call Center at 1-877-835-5472 or directly to the Food and Drug Administration (FDA) MedWatch program at 1-800-FDA-1088.**

Your name will be kept in private (confidential). The information you share will help the FDA and the manufacturer evaluate the Pregnancy Prevention Program for acitretin.

- **Do not take acitretin if you are breastfeeding.** Acitretin can pass into your milk and may harm your baby. You will need to choose either to breastfeed or take acitretin, but not both.

What should males know before taking acitretin?

Small amounts of acitretin are found in the semen of males taking acitretin. Based upon available information, it appears that these small amounts of acitretin in semen pose little, if any, risk to an unborn child while a male patient is taking the drug or after it is discontinued. Discuss any concerns you have about this with your prescriber.

All patients should read the rest of this Medication Guide.

What is acitretin?

Acitretin is 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 can have serious side effects, you should talk with your prescriber about whether possible benefits of acitretin outweigh its possible risks. Acitretin may not work right away. You may have to wait 2 to 3 months before you get the full benefit of acitretin. Psoriasis gets worse for some patients when they first start treatment with acitretin.

Acitretin has not been studied in children.

Who should not take acitretin?

- **Do NOT take acitretin if you can get pregnant.** Do not take acitretin if you are pregnant or might get pregnant during treatment with acitretin or at any time for **at least 3 years** after you stop treatment with acitretin (see "**What are the important warnings and instructions for females taking acitretin?**").
- **Do NOT take acitretin if you are breastfeeding.** Acitretin can pass into your milk and may harm your baby. You will need to choose either to breastfeed or take acitretin, but not both.
- **Do NOT take acitretin if you have severe liver or kidney disease.**

- **Do NOT take acitretin if you have repeated high blood lipids (fat in the blood).**
- **Do NOT take acitretin if you take these medicines:**
 - methotrexate
 - tetracyclines

The use of these medicines with acitretin may cause serious side effects.

- **Do NOT take acitretin if you are allergic to acitretin**, the active ingredient in acitretin, to any of the other ingredients in acitretin (see the end of this Medication Guide for a list of all the ingredients in acitretin), or to any medicines that are like acitretin. Ask your prescriber or pharmacist if any medicines you are allergic to are like acitretin.

Before taking Acitretin, tell your prescriber about all your medical conditions, including if you have or have had:

- diabetes or high blood sugar
- liver problems
- kidney problems
- high cholesterol or high triglycerides (fat in the blood)
- heart disease
- depression
- alcoholism
- an allergic reaction to a medication

Your prescriber needs this information to decide if acitretin is right for you and to know what dose is best for you.

Tell your prescriber about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines can cause serious side effects if taken while you also take acitretin. Some medicines may affect how acitretin works, or acitretin may affect how your other medicines work.

Be especially sure to tell your prescriber if you are taking the following medicines:

- methotrexate
- tetracyclines
- glyburide
- phenytoin
- vitamin A supplements
- progestin-only oral contraceptives (“minipills”)
- TEGISON or TIGASON (etretinate). Tell your prescriber if you have ever taken this medicine in the past.
- St. John’s wort herbal supplement

Tell your prescriber if you are getting phototherapy treatment. Your doses of phototherapy may need to be changed to prevent a burn.

How should I take acitretin?

- Take acitretin with food.
- Be sure to take your medicine as prescribed by your prescriber. The dose of acitretin varies from patient to patient. The number of capsules you must take is chosen specially for you by your prescriber. This dose may change during treatment.
- If you miss a dose, do not double the next dose. Skip the missed dose and resume your normal schedule.
- If you take too much acitretin (overdose), call your local poison control center or emergency room.

You should have blood tests for liver function, cholesterol, and triglycerides before starting treatment and during treatment to check your body’s response to acitretin. Your prescriber may also do other tests.

Once you stop taking acitretin, your psoriasis may return. Do not treat this new psoriasis with leftover acitretin. It is important to see your prescriber again for treatment recommendations because your situation may have changed.

What should I avoid while taking acitretin?

- **Avoid pregnancy.** See “What is the most important information I should know about acitretin?,” and “What are the important warnings and instructions for females taking acitretin?”
- **Avoid breastfeeding.** See “What are the important warnings and instructions for females taking acitretin?”
- **Avoid alcohol.** Females who are able to become pregnant must avoid drinks, foods, medicines, and over-the-counter products that contain alcohol. The risk of birth defects may continue for longer than 3 years if you swallow any form of alcohol during treatment with acitretin and for 2 months after stopping acitretin (see “What are the important warnings and instructions for females taking acitretin?”).
- **Avoid giving blood. Do not donate blood** while you are taking acitretin and **for at least 3 years after stopping** treatment with acitretin. Acitretin in your blood can harm an unborn baby if your blood is given to a pregnant woman. Acitretin does not affect your ability to receive a blood transfusion.
- **Avoid progestin-only birth control pills (“minipills”).** This type of birth control pill may not work while you take acitretin. Ask your prescriber if you are not sure what type of pills you are using.
- **Avoid night driving if you develop any sudden vision problems.** Stop taking acitretin and call your prescriber if this occurs (see “What are the possible side effects of Acitretin?”).
- **Avoid non-medical ultraviolet (UV) light.** Acitretin can make your skin more sensitive to UV light. Do not use sunlamps, and avoid sunlight as much as possible. If you are taking light treatment (phototherapy), your prescriber may need to change your light dosages to avoid burns.
- **Avoid dietary supplements containing vitamin A.** Acitretin is related to vitamin A. Therefore, do not take supplements containing vitamin A, because they may add to the unwanted effects of acitretin. Check with your prescriber or pharmacist if you have any questions about vitamin supplements.
- **DO NOT SHARE acitretin with anyone else, even if they have the same symptoms.** Your medicine may harm them or their unborn child.

What are the possible side effects of acitretin?

Acitretin can cause serious side effects, including:

See “What is the most important information I should know about acitretin?” and “What are the important warnings and instructions for females taking acitretin?”

Stop taking acitretin and call your prescriber right away if you get the following signs or symptoms of possible serious side effects:

- **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 stops. Stop taking acitretin and call your prescriber if you develop any vision problems or eye pain.
- **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 as well as patients taking acitretin. Since other things may have contributed to these problems, it is not known if they are related to acitretin.
- **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 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 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 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, light-headedness or feeling faint, or muscle aches. If this happens, your prescriber will tell you to stop taking acitretin.
- **Serious allergic reactions.** See “Who should not take acitretin?” Serious allergic reactions can happen during treatment with acitretin. **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 and do not take it again.**
- **Serious skin problems.** Acitretin 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 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 you take. These side effects usually get better if the dose of acitretin is reduced or acitretin is 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 may dry your eyes. Wearing **contact lenses** may be uncomfortable during and after treatment with acitretin because of the dry feeling in your eyes. If this happens, remove your contact lenses and call your prescriber. Also read the section about vision problems under “Serious side effects.”
- **Rise in blood fats (lipids).** Acitretin 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.

Psoriasis gets worse for some patients when they first start treatment with acitretin. 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.

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

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store acitretin?

- Store Acitretin between 68°F to 77°F (20°C to 25°C)
- Keep acitretin away from sunlight, high temperature, and humidity.

Keep acitretin and all medicines out of the reach of children.

General information about the safe and effective use of acitretin

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use acitretin for a condition for which it was not prescribed. Do not give acitretin to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about Acitretin that is written for health professionals.

What are the ingredients in acitretin?

Active ingredient: acitretin.

Inactive ingredients: microcrystalline cellulose, maltodextrin, sodium ascorbate, gelatin, black imprinting ink (the solid components are shellac glaze, propylene glycol and iron oxide black). Gelatin capsule shells contain gelatin, red ferric oxide (10 mg, 22.5 mg and 25 mg only), yellow ferric oxide (17.5 mg and 25 mg only), sodium lauryl sulfate, and titanium dioxide (10 mg, 17.5 mg and 25 mg only).

This Medication Guide summarizes the most important information about acitretin. If you would like more information, talk with your prescriber. You can ask your pharmacist or prescriber for information about acitretin that is written for health professionals.

For more information about acitretin call 1-877-835-5472 or go to www.acitretinEPPA.com.
This Medication Guide has been approved by the U.S. Food and Drug Administration.

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Manufactured by:

Micro-Sphere SA

Via Cantonale

CH-6996 Ponte Cremenaga

Lugano

Switzerland

Distributed by:

Amneal Pharmaceuticals LLC

Bridgewater, NJ 08807

Patient Agreement/Informed Consent For Female Patients

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

CAUSES BIRTH
DEFECTS



DO NOT GET
PREGNANT

*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 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 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.

INITIAL: _____

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

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, and for 2 months after I stop taking acitretin.

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, for the entire time of therapy with acitretin, and for at least 3 years after stopping acitretin.

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 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. I understand that if the second pregnancy test is negative, I must start taking acitretin within 7 days of the specimen collection. I will then have pregnancy tests on a monthly basis during therapy with acitretin as instructed by my prescriber. In addition, for at least 3 years after I stop taking acitretin, I will have a pregnancy test every 3 months.

INITIAL: _____

10. I understand that I should not start taking acitretin 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 and every 3 months for at least 3 years after stopping acitretin 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 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.

INITIAL: _____

14. If I do become pregnant while on acitretin or at any time within 3 years of stopping acitretin, I understand that I should report my pregnancy to Amneal Pharmaceuticals Medical Information Call Center and its affiliates at 1-877-835-5472 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 Education and Pregnancy Prevention for Acitretin (EPPA™) Program Booklet. My prescriber has answered all my questions about acitretin. I understand that it is my responsibility to follow my doctor's instructions, and not to get pregnant during treatment with acitretin or for at least 3 years after I stop taking acitretin.

I now authorize my prescriber, _____, to begin my treatment with acitretin.

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 and have answered those questions to the best of my ability.

Prescriber signature: _____

Date: _____

Rev. 01-2024-03