MEDICATION GUIDE FOR PATIENTS

ACITRETIN CAPSULES, USP
(a" si tre' tin)
10 mg and 25 mg

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

The first information in this 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 capsules.** 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 capsules?

Acitretin capsules can cause serious side effects, including:

1. **SEVERE BIRTH DEFECTS.** IF YOU ARE A FEMALE WHO CAN GET PREGNANT, YOU SHOULD USE ACITRETIN CAPSULES 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 CAPSULES?"



2. **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 capsules. Stop taking acitretin capsules 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 capsules?

- **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.**

NOTE: If you are a female who can become pregnant.

- **You must not take acitretin capsules if you are pregnant or might become pregnant during treatment or at any time <u>for at least 3 years</u> after you stop treatment because acitretin capsules can cause severe birth defects.**
- **During treatment with acitretin capsules and for 2 months after you stop treatment with acitretin capsules, 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 capsules and for 2 months after you stop taking acitretin capsules.
- **You and your prescriber must be sure you are not pregnant before you start therapy with acitretin capsules. You must have negative results from two pregnancy tests before you start treatment with acitretin capsules.** 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 capsules until you have negative results from two pregnancy tests.
    - The **first pregnancy test** (urine or blood) will be done at the time you and your prescriber decide if acitretin capsules 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 capsules within 7 days of when the urine or blood for the second pregnancy test is collected.
- After you start taking acitretin capsules, you must have a pregnancy test repeated each month that you are taking acitretin capsules. This is to be sure that you are not pregnant during treatment because acitretin capsules can cause birth defects. In addition, your prescription of acitretin capsules will be limited to a monthly supply.
- For at least 3 years after stopping treatment with acitretin capsules, 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 two effective forms of birth control (contraception) at the same time during all of the following:**
    - for at least one month before beginning treatment with acitretin capsules
    - during treatment with acitretin capsules
    - for at least 3 years after stopping treatment with acitretin capsules
- **If you are sexually active, you must use two effective forms of birth control (contraception) at the same time even if you think you cannot become pregnant, unless one 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").
- **You can get a free birth control counseling session and pregnancy testing from a prescriber or family planning expert. Your prescriber can give you an acitretin capsules Contraception Counseling Referral Form for this free session.**

The following are considered effective forms of birth control:

<u>Primary Forms:</u>

- 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

<u>Secondary Forms (use with a Primary Form):</u>

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

At least one of your two methods of birth control must be a primary form.

- **If you have sex at any time without using two effective forms of birth control (contraception) at the same time, or if you get pregnant or miss your period, stop using acitretin capsules and call your prescriber right away.**
- **Consider "Emergency Contraception" (EC) if you have sex with a male without correctly using two effective forms of birth control (contraception) at the same time.** EC is also called "emergency birth control" or the "morning after" pill. Contact your prescriber **as soon as possible** if you have sex without using two 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 two effective forms of birth control (contraception) because it is not as effective as regular birth control methods.
  You can get EC from private doctors or nurse practitioners, women's health centers, or hospital emergency rooms. You can get the name and phone number of EC providers nearest you by calling the free Emergency Contraception Hotline at 1-888-668-2528 (1-888-NOT-2-LATE).
- **Stop taking acitretin capsules right away and contact your prescriber if you get pregnant while taking acitretin capsules 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 capsules or at any time for at least 3 years after stopping acitretin capsules, you should report your pregnancy to Mylan Pharmaceuticals Inc. at 1-877-446-3679 (1-877-4-INFO-RX) 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 capsules.
- **Do not take acitretin capsules if you are breast feeding**. Acitretin can pass into your milk and may harm your baby. You will need to choose either to breast feed or take acitretin capsules, but not both.

What should males know before taking acitretin capsules?

Small amounts of acitretin are found in the semen of males taking acitretin capsules. 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 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 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 possible benefits of acitretin capsules outweigh its possible risks.

Acitretin capsules may not work right away. You may have to wait 2 to 3 months before you get the full benefit of acitretin capsules. Psoriasis gets worse for some patients when they first start treatment with acitretin capsules.

Acitretin capsules have not been studied in children.

Who should not take acitretin capsules?

- **Do NOT take acitretin capsules if you can get pregnant.** Do not take acitretin capsules if you are pregnant or might get pregnant during treatment with acitretin capsules or at any time for **at least 3 years** after you stop treatment with acitretin capsules (see "What are the important warnings and instructions for females taking acitretin capsules?").
- **Do NOT take acitretin capsules if you are breast feeding.** Acitretin can pass into your milk and may harm your baby. You will need to choose either to breast feed or take acitretin capsules, but not both.
- **Do NOT take acitretin capsules if you have severe liver or kidney disease.**
- **Do NOT take acitretin capsules if you have repeated high blood lipids (fat in the blood).**
- **Do NOT take acitretin capsules if you take these medicines:**
  - methotrexate
  - tetracyclines

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

Tell your prescriber if you have or ever 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 capsules are 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 capsules. Some medicines may affect how acitretin capsules work, or acitretin capsules 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.

<u>How should I take acitretin capsules?</u>

- Take acitretin capsules with food.
- Be sure to take your medicine as prescribed by your prescriber. The dose of acitretin capsules 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 capsules (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 capsules. Your prescriber may also do other tests.

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

What should I avoid while taking acitretin capsules?

- **Avoid pregnancy.** 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?".
- **Avoid breast feeding.** See "What are the important warnings and instructions for females taking acitretin capsules?"
- **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 capsules and for 2 months after stopping acitretin capsules (see "What are the important warnings and instructions for females taking acitretin capsules?").
- **Avoid giving blood. Do not donate blood** while you are taking acitretin capsules and **for at least 3 years after stopping** treatment with acitretin capsules. Acitretin in your blood can harm an unborn baby if your blood is given to a pregnant woman. Acitretin capsules 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 capsules. 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 capsules and call your prescriber if this occurs (see "Serious side effects.").
- **Avoid non-medical ultraviolet (UV) light.** Acitretin capsules 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 capsules. Check with your prescriber or pharmacist if you have any questions about vitamin supplements.
- **DO NOT SHARE acitretin capsules 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 capsules?

Acitretin capsules can cause serious side effects. **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?"**

Stop taking acitretin capsules 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 capsules stops. Stop taking acitretin capsules 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 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; 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?" 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 your prescriber. Also read the section about vision 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.

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.

These are not all the possible side effects of acitretin capsules. 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 capsules?

- Keep acitretin capsules away from sunlight, high temperature, and humidity.
- **Keep acitretin capsules and all medicines out of the reach of children.**

What are the ingredients in acitretin capsules, USP?

Active ingredient: acitretin, USP

Inactive ingredients: edetate disodium, gelatin, maltodextrin, microcrystalline cellulose, poloxamer 407, red iron oxide, sodium ascorbate and titanium dioxide. The 25 mg capsules also contain black iron oxide and yellow iron oxide.

The black imprinting ink for the 10 mg capsules contains black iron oxide, potassium hydroxide, propylene glycol, shellac and strong ammonia solution.

The white imprinting ink for the 25 mg capsules contains povidone, propylene glycol, shellac, sodium hydroxide and titanium dioxide.

General information about the safe and effective use of acitretin capsules

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use acitretin capsules for a condition for which it was not prescribed. Do not give acitretin capsules to other people, even if they have the same symptoms that you have.

This Medication Guide summarizes the most important information about acitretin capsules. If you would like more information, talk with your prescriber. You can ask your pharmacist or prescriber for information about acitretin capsules that is written for health professionals. For more information, call Mylan Pharmaceuticals Inc. at 1-877-446-3679 (1-877-4-INFO-RX).

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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Mylan Pharmaceuticals Inc.
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USV Limited
H-17/H-18, OIDC,
Mahatma Gandhi Udyog Nagar,
Dabhel, Daman, 396 210, India

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