



SIGMAPHARM'S ACITRETIN CAPSULES, USP

CONTRACEPTION COUNSELING REFERRAL PROGRAM



Expert Counseling With No Added Expenses

Before you can start taking acitretin, you have to be sure that you are not pregnant and that you understand how to avoid pregnancy. That's why Sigmapharm Laboratories, LLC will pay for you to go to a contraception counselor. This specialist will provide you with expert counseling about birth

control (contraception and avoiding pregnancy). This counseling is very important, even if you already feel you know about birth control, and even if you are not having sex or do not plan to have sex.

6 SIMPLE INSTRUCTIONS

1

Make an appointment to see a contraception counselor and give him/her the attached forms. The counselor should call your prescriber if there are any questions about why you are there or about how the program works.

2

Notify your prescriber after you have had contraception counseling.

3

Ask the contraception counselor to mail a copy of the form to your prescriber. **You will not get your first prescription for acitretin until your prescriber has received this signed form, and you must have negative results from 2 pregnancy tests.** Your first test 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 right before you plan to start acitretin. If the second pregnancy test is negative, initiation of treatment with acitretin should begin within 7 days of the specimen collection. Acitretin should be limited to a monthly supply.

4

You must use **2 effective forms of birth control** (contraception) at the same time for at least 1 month before beginning treatment with acitretin, during treatment with acitretin, and for at least 3 years after you stop taking acitretin.

5

You are not required to pay any charges for the counseling by the contraception counselor. If you are asked to pay, have your contraception counselor send your signed Authorization for Use or Disclosure of Health Information form to the address below. The counselor should follow the instructions on the attached forms. The fee will be paid by Sigmapharm Laboratories, LLC.

6

Finally, if your contraception counselor performs a pregnancy test, the laboratory bill should be sent to the following address:

Sigmapharm Laboratories, LLC.
Attn: P.P.E.T. program
PO BOX 162
Morrisville, NC 27560



SIGMAPHARM'S ACITRETIN CAPSULES, USP

CONTRACEPTION COUNSELING REFERRAL FORM



Notes to Contraception Counselor

This patient, _____, is being considered for treatment with acitretin. She has been referred to you for contraception counseling before she receives a prescription for acitretin.

Acitretin is a potent teratogen; therefore, it is essential to rule out pregnancy before her treatment begins and for you to fully inform the patient about effective contraception. The typical course of therapy with acitretin may last several months, depending upon the patient's response to the medication. The patient must choose **2 effective forms of contraception** to be used simultaneously for at least 1 month prior to initiation of therapy with acitretin, during therapy with acitretin, and for at least 3 years after discontinuing therapy with acitretin. According to the package insert for acitretin, the following are considered effective forms of contraception:

Primary: Tubal ligation, partner's vasectomy, intrauterine devices, injectable/implantable/insertable hormonal birth control products, and birth control patch. Birth control pills that contain both estrogen and progestin (combination oral contraceptives) are considered an effective form of birth control; however, progestin-only ("minipills") birth control pills should be avoided.

Secondary: Condoms (with or without spermicide), diaphragms and cervical caps (which must be used with a spermicide), and vaginal sponges (contain spermicide).

The patient must choose at least 1 primary form of contraception.

Please explain the patient's options for contraception, the risk of possible contraceptive failure, and the requirements for achieving maximal effectiveness with her chosen methods. Please inform me if the patient does not choose 2 effective forms of contraception. The patient should also be counseled about emergency contraception.

Therapy cannot begin until pregnancy has been ruled out by negative results from 2 pregnancy tests with a sensitivity of at least 25 mIU per mL. The first test should be done at the time the patient decides to pursue therapy. The second test should be done during the first 5 days of the menstrual period immediately preceding the beginning of therapy with acitretin; or, if the patient has amenorrhea, the pregnancy test should be done at least 11 days after the last act of unprotected sexual intercourse (without using 2 effective forms of contraception simultaneously). If the second pregnancy test is negative, initiation of treatment with acitretin should begin within 7 days of the specimen collection. Acitretin should be limited to a monthly supply.

Prescriber's name: _____ (Please affix label, or type or print clearly.)

Address: _____

Telephone: _____

Prescriber's signature: _____ Date: _____

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Information to Be Returned to Prescriber

I have provided the following for your patient _____ (Name)

Comprehensive contraception counseling

Information about emergency contraception

The patient had a negative pregnancy test on _____ (Date)

The patient has chosen 2 methods of contraception.

Yes No

Primary method: _____

Secondary method: _____

Name: _____ (Please affix label, or type or print clearly.)

Address: _____

Telephone: _____

Contraception counselor's signature: _____ Date: _____



Reimbursement

NOTE: Reimbursement is offered only for contraception counseling and pregnancy testing, if performed. Other services that may be provided during this visit are not eligible for reimbursement.

The prescriber who actually prescribes acitretin is not eligible for reimbursement by Sigmapharm.

REIMBURSEMENT INSTRUCTIONS

To receive reimbursement, you must call a toll-free number for reimbursement. After you have provided all the requested information, a check will be sent to you by mail.

Steps: Dial 1-855-273-0150

- You will be asked to provide the following information:
 - Your name and address
 - Your office phone number
 - Name of graduate school from which you graduated
 - Year of graduation
 - The name and address of the referring prescriber
 - The patient's name
 - Whether you have provided contraception counseling and information on emergency contraception
 - Your normal and customary charge for providing these services
- A check will then be processed and mailed to you within 30 days.
- To check on the status of a previous request, you will need to provide only your name, address, and phone number. A representative will contact you to update your request status.

REIMBURSEMENT FOR PREGNANCY TEST

If you have performed pregnancy testing in the office or sent the patient directly to the laboratory, please instruct the laboratory to send the bill to the following address:

Sigmapharm Laboratories, LLC
Attn: P.P.E.T. Program
PO BOX 162
Morrisville, NC 27560

Important: Your name and address must be included on the invoice from the laboratory. The laboratory will be reimbursed directly.

NOTE TO CONSULTANTS: BY PARTICIPATING IN THIS PROGRAM, YOU AGREE TO PROVIDE SIGMAPHARM WITH ACCESS TO ADDITIONAL INFORMATION SHOULD IT BECOME NECESSARY TO CONFIRM THE APPROPRIATENESS OF THIS REQUEST FOR REIMBURSEMENT. SIGMAPHARM RESERVES THE RIGHT TO PLACE LIMITATIONS ON REIMBURSEMENTS OR DENY REIMBURSEMENTS IN CERTAIN SITUATIONS.



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Prescriber's name: _____ (Please affix label, or type or print clearly.)

Address: _____

Telephone: _____

Prescriber's signature: _____ Date: _____

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The patient has chosen 2 methods of contraception.

Yes No

Primary method: _____

Secondary method: _____

Name: _____ (Please affix label, or type or print clearly.)

Address: _____

Telephone: _____

Contraception counselor's signature: _____ Date: _____



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CAUSES BIRTH DEFECTS



DO NOT GET PREGNANT

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Address: _____

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The patient has chosen 2 methods of contraception.

Yes No

Primary method: _____

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Name: _____ (Please affix label, or type or print clearly.)

Address: _____

Telephone: _____

Contraception counselor's signature: _____ Date: _____

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