



What is the ACITRETIN P.P.E.T. Patient Survey?

The Acitretin P.P.E.T Survey is a short, easy-to-answer questionnaire about your use of acitretin, pregnancy prevention and your understanding of the risks associated with using acitretin. The questions are very similar to the topics that you have already discussed with your doctor or nurse.

The survey is voluntary, but all women who have the potential to become pregnant while taking acitretin and for three years after they stop taking acitretin are being asked to participate.

**CAUSES
BIRTH DEFECTS**



**DO NOT
GET PREGNANT**

HELPFUL INFORMATION:

For more information, visit the
Acitretin P.P.E.T. Program website at:
www.sigmapharm.com/PPET

**24-HOUR, TOLL-FREE, AUTOMATED
BIRTH CONTROL COUNSELING:**
1-855-273-0150

**IF YOU BECOME PREGNANT OR
HAVE A SIDE EFFECT FROM
TAKING ACITRETIN:**
1-855-273-0150 (Sigmapharm)
OR
1-800-332-1088 (1-800-FDA-1088)



Sigmapharm Laboratories, LLC
PL(B)083-04 REV.1017

Sigmapharm's Acitretin Capsules, USP P.P.E.T. Patient Survey: A Patient's Guide to Participation



**Pregnancy Prevention
is Essential
with Treatment**



Sigmapharm's Acitretin

**CAUSES
BIRTH DEFECTS**



**DO NOT
GET PREGNANT**



Why Should You Participate?

Your doctor has asked you to participate in the Acitretin P.P.E.T. Patient Survey because you are able to become pregnant and were prescribed acitretin.

Your participation will be simple: you will periodically complete a short survey questionnaire while you are taking acitretin and for three years after you stop.

Sharing this valuable information on the effectiveness of the Acitretin **P.P.E.T** Program will help other women safely use acitretin in the future.



Your Participation in the Survey

We will contact you each time the survey is to be completed – you won't have to remember! You will have the option of completing the survey on paper or online. Completing the survey will only take a few minutes.

While you are taking acitretin, you will be asked to complete a brief survey once every three months.

After you stop taking acitretin, you will be asked to complete the survey two times a year for three years.

You will be paid for your time after you complete each survey.



Your Privacy

We understand the importance of your privacy. Your participation in the survey is completely confidential. Only the researchers and those working with the researchers managing the survey will know your identity. Your name and contact information will not be shared with others, and the answers you provide will never be identified with you in any presentation of the survey results.

How to Contact Us

If you have questions about the Acitretin P.P.E.T. Patient Survey please call 1-855-273-0150.

Please see the back of this brochure for phone numbers to report a side effect or pregnancy, or for information about birth control or contraception.

Thank You

Thank you for participating in the Acitretin P.P.E.T. Patient Survey. The information you provide will help ensure the safe use of acitretin now and in the future.

ACITRETIN SCHEDULE FOR PREGNANCY PREVENTION & SAFE PREGNANCY PLANNING					
	1 MONTH BEFORE TREATMENT	BEFORE TREATMENT	DURING TREATMENT WITH ACITRETIN	2 MONTHS AFTER TREATMENT	3 YEARS AFTER TREATMENT
2 FORMS OF BIRTH CONTROL					
2 NEGATIVE PREGNANCY TESTS					
ONGOING PREGNANCY TESTS	Each month before receiving prescription and every 3 months for 3 years after stopping treatment				
P.P.E.T. SURVEY			 A SURVEY EVERY THREE MONTHS		 A SURVEY EVERY SIX MONTHS
NO ALCOHOL					
NO BLOOD DONATION					
SIGN INFORMED CONSENT					



SigmaPharm
LABORATORIES

SIGMAPHARM'S ACITRETIN CAPSULES, USP P.P.E.T: Pregnancy Prevention is Essential with Treatment

PATIENT SURVEY REGISTRATION

Purpose of the Survey

The **Acitretin P.P.E.T. (Pregnancy Prevention is Essential with Treatment)** patient survey is a short, easy-to-answer questionnaire that gathers information about how women who can get pregnant use acitretin, the importance of pregnancy prevention and patient understanding of the risks associated with using acitretin.

What to Expect

You will be asked to complete a survey when you register, every three months while you are taking acitretin and then twice a year for three years after you stop taking acitretin. We will remind you when a survey is ready for you to complete. Each survey will take only a few minutes of your time. You will complete your first survey on paper, but have your choice of completing future surveys on paper or via the Internet. If you choose "Internet" below and provide your e-mail address, you will be sent an e-mail with instructions on how to complete future surveys online.

Your Privacy

Your participation in the survey and any answers that you provide are completely confidential. Only the researchers and those working with the researchers managing the survey will know your identity. Your name and contact information will not be shared with others, and the answers you provide will never be identified with you in any presentation of the survey results.

Payment

We appreciate your participation in the **Acitretin P.P.E.T.** patient survey. To compensate you for your time, we will send you a \$25 Stipend.

How to Register

Registration is simple. Just fill out the form below, and be sure to sign and date it. Then, place it in the provided postage-paid envelope along with your completed survey and drop it in the mail. Be sure to let us know how you would like to receive future surveys.

Participant Information (please print)

I agree to participate in the **Acitretin P.P.E.T.** patient survey

Name _____
Last First Middle Initial

Address _____
Street Apt # City State Zip Code

Telephone _____ Best time to call: _____ am/pm

Doctor's Name _____

Doctor's Address _____
Street City State Zip Code

Most recent date that you began treatment with acitretin ____/____/____
Month Day Year

Signature _____ Date _____

How would you like to
complete future surveys?

☐ Paper Form
☐ Internet

Your E-mail Address: _____

Misplaced your envelope? Send your form and your survey to: Sigmapharm Laboratories, LLC
Attn: P.P.E.T. Program
PO BOX 162, Morrisville, NC 27560