PATIENT AGREEMENT/INFORMED CONSENT FOR FEMALE PATIENTS

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 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 one 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, injectable/implantable/insertable/topical (patch) hormonal birth control products, and IUDs (intrauterine devices). Secondary: Latex 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). 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 my prescriber can give me a referral for a free contraception (birth control) counseling session and pregnancy testing. INITIAL:_____
13. I understand that on a monthly basis during therapy with acitretin and every 3 months for at least 3 years after stopping treatment with acitretin that I should receive counseling from my prescriber about contraception (birth control) and behaviors associated with an increased risk of pregnancy. INITIAL:_____
14. 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:_____
15. 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:_____

Education and Pregnancy Prevention for Acitretin Program

EPPA™

Prescriber Copy

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EPPA™

Patient Copy