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 capsules 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 capsules 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 capsules.
INITIAL: _____

2. I understand that I must not become pregnant while taking acitretin capsules and for at least 3 years after the end of my treatment with acitretin capsules.
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 capsules, and for 2 months after I stop taking acitretin capsules.
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 capsules, for the entire time of therapy with acitretin capsules, and for at least 3 years after stopping acitretin capsules.
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 capsules 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 capsules. I understand that if the second pregnancy test is negative, I must start taking my acitretin capsules within 7 days of the specimen collection. I will then have pregnancy tests on a monthly basis during therapy with acitretin capsules as instructed by my prescriber. In addition, for at least 3 years after I stop taking acitretin capsules, I will have a pregnancy test every 3 months.
INITIAL: _____

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

14. If I do become pregnant while on acitretin capsules or at any time within 3 years of stopping acitretin capsules, I understand that I should report my pregnancy to Alembic at 1-866-210-9797 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 H.A.E.R.T. brochure. My prescriber has answered all my questions about acitretin capsules. I understand that it is my responsibility to follow my doctor's instructions, and not to get pregnant during treatment with acitretin capsules or for at least 3 years after I stop taking acitretin capsules.

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

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

Prescriber signature: _____ Date: _____

Alembic Pharmaceuticals, Inc.
550 Hills Drive, Suite 104B
Bedminster, NJ 07921, USA

Patient Copy

May 2024

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May 2024