

Patient care and contraception consent form

For: ☐ Roaccutane® ☐ Curacne® ☐ Xeractan®

Important information and Warning

Isotretinoin treatment may cause teratogenicity to your baby if used before and during pregnancy even in low doses. There is a high risk that will cause your child suffer from severe birth defects in the following cases:
- If you are pregnant when you started Isotretinoin treatment
- If you become pregnant during Isotretinoin treatment
- If you become pregnant in a month after stopping Isotretinoin treatment.

Acknowledgment:

Isotretinoin usage has been personally explained to me by my doctor and among other medical guidance, the doctor has cleared the following information:

- 1- There is a high risk of babies’ severe birth defects (Teratogenic) In case of pregnancy during Isotretinoin treatment and in a month after stopping Isotretinoin treatment. Therefore I do not intend to become pregnant a month before starting Isotretinoin treatment, during Isotretinoin treatment and a month after stopping Isotretinoin treatment.

■ 2- I am not pregnant and do not plan to become pregnant during Isotretinoin treatment or a month after stopping Isotretinoin treatment.

■ 3- I must not take Isotretinoin If I am pregnant or If I may become Pregnant during the treatment.

■ 4- I have been Informed by my doctor that two effective birth control (Contraception) must be used in the following cases:
A. At least one month before starting Isotretinoin treatment.
B. During Isotretinoin treatment.
C. A month after stopping Isotretinoin treatment.

■ 5- I know that I must have pregnancy blood and urine tests before starting Isotretinoin treatment.

■ 6- I know that I must have pregnancy blood and urine tests within three days of my menstrual period to make sure I am not pregnant before starting Isotretinoin treatment.

■ 7- I know that I must have pregnancy blood and urine tests on monthly basis during Isotretinoin treatment and before dispensing the next dosage.

■ 8- I am fully aware of the possible contraceptive failure as explained to me by my doctor.

■ 9- I know that I must stop taking Isotretinoin and contact my doctor immediately If:
A. My menstrual period is delayed during Isotretinoin treatment.
B. I become pregnant during Isotretinoin treatment.

■ 10- I know that I must contact my doctor immediately if I become pregnant during the month after stopping Isotretinoin treatment.

■ 11- I know that it is prohibited to donate blood during Isotretinoin treatment or one month after stopping Isotretinoin treatment.

■ 12- I know that I should start the treatment within 7 days of prescription and the prescription is valid for 30 days .
- By my signature I acknowledge that all the points above have been explained and emphasized to me by my doctor and that I have clearly understood the risks of becoming pregnant during Isotretinoin treatment or one month after stopping the treatment. In addition I have been provided with Isotretinoin treatment guidance booklet.
- I acknowledge that I received the down mentioned booklets:
1 - Important information booklet on the drug Isotretinoin.
2 - Contraception booklet.
- Number of packs to be distributed:
Date:
Physician name:.....

Name & Signature:
Address:
Physician address:

- Copy for medical records
- Copy for the patient
- Copy for the company