Actavis

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Acknowledgement form for women of child bearing potential

Isotretinoin Actavis (isotretinoin) 10 mg and 20 mg soft capsules

Pregnancy & Foetal Exposure Prevention

This form should be completed and signed by the patient (parents or legal guardian if the patient is under the age of <[To be completed nationally - insert local age limit]>) and signed by the prescribing physician.

Patient's name/identification: _____
(Please use block letters)

Before start of treatment

My treatment with Isotretinoin Actavis has been personally explained to me by my doctor. The following points of information, among others, have been specifically discussed and made clear to me.

Read and check each box of the following points to show that you understand and accept each one.
Do not sign this form or take Isotretinoin Actavis if you continue to have questions.
Follow your doctor's advice.

☐ I understand that there is a very high risk that my baby would suffer severe birth defects if I am pregnant or become pregnant during the Isotretinoin Actavis treatment, regardless of the amount and length of treatment. For this reason I should not get pregnant during the treatment or in the month after I have discontinued the treatment.

☐ I understand that I must not take Isotretinoin Actavis if I am pregnant.

☐ I understand that I should avoid unprotected sexual relations during the Isotretinoin Actavis treatment and that I should use two methods of contraception at the same time. The only exception is if I have had a hysterectomy.

☐ I understand that I should begin using the chosen contraceptive methods at least one month before starting the treatment, without interruption, using at least one, but preferably two effective methods of contraception, including one barrier method, and continue to use effective contraception during the entire treatment and for at least one month after discontinuing the treatment.

☐ I am aware that contraceptive methods can fail.

☐ I agree to have a pregnancy test done by a doctor or competent laboratory (with a minimum sensitivity of 25 mIU/ml) before starting the treatment and also on a monthly basis during the treatment and five weeks after discontinuing the treatment.

☐ I understand that I should stop taking Isotretinoin Actavis immediately and inform my doctor right away if I become pregnant, miss my normal menstrual period, stop using contraceptive methods or have sexual relations without the two methods of contraception while I am being treated with Isotretinoin Actavis or during the month after discontinuing the medication.

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☐ I agree to talk to my doctor about any medicines or herbal products I am taking or intend to take while I am being treated with Isotretinoin Actavis, since these might interfere with the chosen contraceptive methods.

☐ I have read and understand all the documents that my doctor has given to me, including the Patient's Guide.

☐ I know that I cannot donate blood during the treatment or during the month after ending the treatment, because the blood could be given to a pregnant woman and cause malformations in the foetus.

☐ I understand that I am eligible to take Isotretinoin Actavis because:

- I had a negative pregnancy test (blood) before beginning the treatment and I should have a negative pregnancy test every month during the treatment.

- I have chosen two contraceptive methods to use at the same time (at least one is a barrier method) and that I should begin using them one month before starting the treatment.

- I have signed this informed consent form and I am aware of the preventive measures I must take.

☐ I understand that I must be monitored by a doctor on a monthly basis; I therefore agree to come to an appointment once a month (every 28 days) while the Isotretinoin Actavis treatment lasts and five weeks after discontinuing the treatment.

My doctor has answered all my questions and I know that it is my responsibility not to get pregnant during the Isotretinoin Actavis treatment and for one month after it is discontinued.

Patient's signature _____ Date _____

Signature of parents or legal guardian (if the patient is under the age of <[To be completed nationally - insert local age limit]>)

_____ Date _____

I have explained the need for the Isotretinoin Actavis treatment to my patient as well as the risks inherent in taking Isotretinoin Actavis, principally with respect to pregnancy.

Doctor's signature _____ Date _____