If you have questions about the iPLEDGE REMS or need help enrolling, call 1-866-495-0654 Monday – Friday, 8:00 AM – 8:00 PM ET.

To report side effects, contact the iPLEDGE REMS at 866-495-0654 or FDA at 800-FDA-1088 or www.fda.gov/medwatch.
Prescribers can only activate their enrollment by affirming that they meet requirements and will comply with all iPLEDGE REMS requirements by attesting to the following points:

- I know the risk and severity of fetal injury/birth defects from isotretinoin.
- I know the risk factors for unplanned pregnancy and the effective measures for avoidance of unplanned pregnancy.
- I have the expertise to provide the patient with detailed pregnancy prevention counseling, or I will refer the patient to an expert for such counseling, reimbursed by the manufacturer.
- I will comply with the iPLEDGE REMS requirements described in the booklet, iPLEDGE REMS Prescriber Guide.
- Before beginning treatment of patients who can become pregnant with isotretinoin, and on a monthly basis, the patient will be counseled to avoid pregnancy by using two forms of contraception simultaneously and continuously for at least one month prior to initiation of isotretinoin treatment, during isotretinoin treatment and for one month after discontinuing isotretinoin treatment, unless the patient commits to continuous abstinence, not having any sexual contact with a partner that could result in pregnancy.
- I will not prescribe isotretinoin to any patient who can become pregnant until verifying the patient has a negative screening pregnancy test and monthly negative CLIA-certified (Clinical Laboratory Improvement Amendment) pregnancy tests. Patients should have a pregnancy test at the completion of the entire course of isotretinoin and another pregnancy test one month later.
- I will report any pregnancy case that I become aware of while the patient who can become pregnant is on isotretinoin or one month after the last dose to the pregnancy registry.

I attest to the statements above.
I do not attest to the statements above.