EXEMPTION FOR PATIENTS
WITH SERIOUS MEDICAL REASONS WHO CAN BECOME PREGNANT

Follow these steps to request an exemption from the iPLEDGE® REMS requirements for a patient who can become pregnant with serious medical reasons.

NOTE: The intent of this form is to request an exemption from the iPLEDGE REMS requirements for a non-pregnant patient with serious medical reason(s) who is unable to obtain an isotretinoin prescription by completing the requirements in the iPLEDGE REMS at this time. It is not intended to replace the requirements of the iPLEDGE REMS.

1. Complete a new Exemption for Patients with Serious Medical Reasons who can Get Pregnant form. Print the completed form, sign and date.

2. Fax the form (all pages) to 866-486-7001. When form is completed online, it does not need to be faxed in.

Call 877-475-3345 if you need any assistance with the exemption request. If an agent is not immediately available, please leave contact information, and the call will be returned. Please note that this phone number must only be used for requesting exemptions for patients with serious medical reasons. No other iPLEDGE questions or issues will be handled through this number.

NOTE: This form MUST be filled out and signed by the requesting prescriber. All required information (*) must be provided. Please FAX this completed form to 866-486-7001.

*Prescriber ID  |  [click here and enter the prescriber's iPLEDGE ID]
*Prescriber Name |  [click here and enter the prescriber's name]
*Patient ID   |  [click here and enter the patient's iPLEDGE ID]
*Patient Date of Birth |  [click here and enter the patient's date of birth]
*Office Telephone Number |  [click here and enter your telephone number]
*Office Fax Number   |  [click here and enter your fax number]

Forms received after 8PM Eastern Time will be processed on the next business day. Forms received after 8PM Eastern Time on a Friday will be processed the following Monday (or Tuesday, if Monday is a federal holiday).
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☐ Exemption Option 1 - Tanner Stage 1 or 2

By selecting this option I attest that all of the following apply to this patient:

- Classified as Tanner Stage 1 (pre-pubertal patient) or Stage 2 (patient who has not yet experienced menarche or breast development)
- Not considered to be a patient who can become pregnant
- Not currently pregnant
- I will evaluate whether this patient can become pregnant while receiving isotretinoin and I will notify the iPLEDGE REMS within 10 business days of any change in the patient’s pregnancy status

☐ Exemption Option 2 - Expedite Start of Treatment

By selecting this option I attest that all of the following apply to this patient:

- Medical condition necessitates that the patient be exempt from the initial wait period
- Not currently pregnant
- Required to take monthly pregnancy tests
- Required to successfully complete monthly comprehension testing
- I understand that the patient will have 7 days to obtain the prescription from the date of the monthly pregnancy test specimen collection

☐ Exemption Option 3 – Cognitively and/or Physically Impaired

By selecting this option I attest that all of the following apply to this patient:

- Medical condition necessitates that the patient be exempt from the initial wait period and the monthly comprehension testing
- Not currently pregnant
- Required to take monthly pregnancy tests
- I understand that the patient will have 7 days to obtain the prescription from the date of the

Please make certain that you maintain medical documentation supporting the reason(s) for this exemption. The iPLEDGE REMS may require a copy.

- The medical exemption process is governed by the iPLEDGE Non-Compliance Action Policy. Intentional misuse of the medical exemption process may result in Permanent Deactivation from the iPLEDGE REMS resulting in a permanent loss of isotretinoin prescribing privilege.
- I attest that I am both qualified and have performed the necessary medical evaluation(s) to determine that the medical exemption is appropriate for this patient based on the iPLEDGE REMS requirements.

*Signature  __________________________

*Date of Request ____________________

PLEASE FAX COMPLETED COPY TO 866-486-7001