iPLEDGE™
Committed to Pregnancy Prevention

iPLEDGE–Committed to Pregnancy Prevention
555 North Lane, Suite 6000
Conshohocken, PA 19428

Dear Healthcare Provider,

October 06, 2006

Effective Immediately: Elimination of the 23 day lock-out period for Males and Females of Non Childbearing Potential

Previously, whether a prescription was filled or not, a patient could not start the qualification process for another prescription until 23 days after the end of their 7 day window.

The isotretinoin manufacturers are pleased to announce the following change to the iPLEDGE program, effective immediately.

What is the change?

For males and females of non childbearing potential (FNCBP) the 23 day lock out period will be eliminated.

Does this change include females of child bearing potential?

No. For females of child bearing potential the 23 day lock out period is still in effect. However, a change to this aspect of iPLEDGE is under development and will be rolled out next year. You will be notified of this change in the future.

How will this change affect prescribing procedures?

The prescribing procedures and qualification criteria for isotretinoin will remain the same for **all patients.** The elimination of the 23 day lock-out period will allow patients (males and FNCBP) the ability to have a **new prescription** filled after the 7 day window has expired. However, both the patient and prescriber must complete the qualification process again to ensure the patient has met all qualification criteria, including confirming patient counseling in the iPLEDGE system.

To confirm patient counseling for a male or FNCBP after their 7 day window has expired, select the patient in the Manage Patient screen then select the Confirm Patient Counseling button and follow the prompts. The qualification process can start immediately after a patient's 7 day window has expired. A new prescription must be provided to the patient. There will be **no** lock out period after the 7 day window has expired for males and FNCBP.

How will this change affect prescription authorization procedures?

Pharmacists must continue to authorize every isotretinoin prescription using the iPLEDGE system. No other action is required.

Where can I find out additional information?

Website

Additional information can be found by visiting the website, www.ipledgeprogram.com and selecting the FAQs button. Once on the Frequently Asked Questions page, select the Pharmacy or Prescriber topic and then select the topic entitled "Please explain the elimination of the 23-day lockout requirement for Males and Females of Non Childbearing Potential (FNCBP)".

Telephone

Call iPLEDGE at 1-866-495-0654, press 1 for English then press 1 to log in. After logging in to iPLEDGE, listen to the menu options and select the option "To listen to the Safety Notice or to hear information about iPLEDGE and isotretinoin" then select the option "To hear information about the 23 day lockout elimination for males and females of non childbearing potential".

Professional Associations

The following organizations have posted information regarding the removal of the 23 day window for males and FNCBP.

The American Academy of Dermatology Association (AADA)
http://www.aad.org/professionals/AdvocacyGovRelSkin/iso_information.htm

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Food and Drug Administration (FDA)
http://www.fda.gov/cder/drug/infopage/accutane/iPLEDGEupdate200609.htm
National Association of Chain Drug Stores (NACDS)
www.nacds.org/pharmacypractice
Children's Oncology Group (COG)
http://childrensoncologygroup.org
New Approaches to Neuroblastoma Therapy (NANT)
http://www.nant.org/13cis.shtml

We will continue to update you as changes to the iPLEDGE program occur.

SAFETY NOTICE

Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected. Because of this toxicity, isotretinoin can only be marketed under a special restricted distribution program. This program is called iPLEDGE™. Under this program, prescribers must be registered and activated with the iPLEDGE program and can prescribe isotretinoin only to registered patients who meet all the requirements of iPLEDGE. Isotretinoin can be dispensed only by a pharmacy registered and activated with iPLEDGE. Registered and activated pharmacies can only receive isotretinoin from wholesalers registered with iPLEDGE.

Patients on isotretinoin have been known to become depressed or to develop other serious mental health problems. Some people have had thoughts of hurting themselves or putting an end to their own lives. Some people tried to end their own lives and some have ended their own lives. There have been reports that people on isotretinoin were aggressive or violent. No one knows if isotretinoin caused these problems or behaviors or if they would have happened even if the person did not take isotretinoin.

Isotretinoin use has been associated with pseudotumor cerebri, a condition caused by increased pressure on the brain. This condition may occur more often in patients also taking tetracycline. Patients should be aware of other serious side effects, including problems with the pancreas, liver, stomach, bones, muscles, hearing, vision, lipids, allergic reactions, blood sugar, or red and white blood cells. The most common, less serious adverse events include dry skin, chapped lips, dry eyes, and dry nose that may lead to nosebleeds. Patients should be advised about these adverse events and routinely monitored by a doctor during treatment with isotretinoin.

Please refer to the enclosed isotretinoin package inserts for full prescribing and dispensing instructions.

Thank you for your continued commitment to the iPLEDGE program.

Sincerely yours,

Peter B. Bottini, Pharm.D., FCP
Executive Director
Product Safety and Risk Management
Mylan Pharmaceuticals Inc.

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