



Tips from Prescribers Who Have Had Success in Obtaining Post-Treatment Pregnancy Tests in the iPLEDGE Program

In Anticipation that this Will Be the Patient's Last Appointment, Prescribers Should:

1. Provide the patient with the isotretinoin prescription
2. Schedule an appointment for at least 30 days later
 - a. During this visit, obtain a pregnancy test and discuss the need for continued contraception for one more month and the importance of the 30-day post treatment pregnancy test.

The iPLEDGE Program wants to emphasize to prescribers the importance of scheduling the post-treatment follow-up appointment with patients to obtain the required post-treatment pregnancy tests.

Post-treatment Pregnancy Tests Are Only Being Obtained at a Rate of 8%

iPLEDGE Sponsors and the FDA actively monitor the completion of both the initial post-treatment pregnancy tests and the 30 day post-treatment pregnancy tests for females of childbearing potential (FCBP). The data shows a downward trend over the last four iPLEDGE years.

Scheduling the Post-treatment Pregnancy Tests

Discussions with iPLEDGE Scientific Advisory Board members indicate that there is not a consistent practice among the prescribing community in scheduling post-treatment appointments to obtain the post-treatment pregnancy tests.

One method that is used to secure the initial post-treatment pregnancy test is to set the next follow-up appointment with FCBPs at least 30 days later and make arrangements for the patient to obtain the post-treatment pregnancy test at 30 days. Providing that this 'last month of treatment' goes according to the prescriber's plan, the prescriber tells the patient at that visit that she has successfully completed her isotretinoin therapy and obtains pregnancy test results, and makes arrangements for the patient to obtain the 30 day post-treatment pregnancy test. The prescriber then counsels the patient on the importance of her continued contraception for the next month and emphasizes the importance of obtaining one final pregnancy test in 30 days.

Mechanisms in Place to Remind and Help Obtain the Post-treatment Pregnancy Tests

The iPLEDGE Program currently includes mechanisms and processes to follow up with prescribers and FCBP when the post-treatment pregnancy tests are not entered into the system. Specifically, when the post-treatment pregnancy tests are late, the prescriber is presented with a visible and persistent reminder on the Action Required List (ARL) that details the information and actions required for the patient.

It is a requirement of prescribers in the iPLEDGE Program to make every effort to obtain post-treatment pregnancy tests.



Please refer to the isotretinoin package inserts for full prescribing and dispensing instructions at:

- Absorica: <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=8d54aab5-3349-4a41-8533-0a566fd7bbaa>
- Amnesteem: <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=b2cb63c9-f825-4991-9a2c-6260f1bbcc2c>
- Claravis: <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=a31fd109-d0fd-4ab9-ba98-a3d64333c18d>
- Myorisan: <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=51ff6346-9256-4c01-9f52-417d13f2df05>
- Sotret: <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=d5a26c5e-9c3e-4781-8c08-62b91d21a68d>
- Zenatane: <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=27b3cf26-f22e-5b70-1c24-009933b7c6ee>