

Information for Healthcare Professionals - Authorization of Use of Expired Tamiflu for Oral Suspension

Source:

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm184770.htm>

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FDA is authorizing the use of certain lots of expired Tamiflu for Oral Suspension as part of the federal government's response to the 2009 H1N1 Influenza public health emergency.

In July 2009, FDA authorized 4 lots of Tamiflu for Oral Suspension for use beyond their labeled expiration dates. FDA is now authorizing [additional lots](#) in an effort to ensure that Tamiflu for Oral Suspension is available for patients during this public health emergency. The lots of Tamiflu for Oral Suspension that are being authorized are part of the Strategic National Stockpile and have been tested through the federal government's Shelf-Life Extension Program (SLEP).

Under SLEP, FDA conducts scientific testing and analysis to determine if certain drugs are acceptable for use beyond their expiration date. During testing, FDA comprehensively evaluates each lot to assure the quality and stability of the product. Through the SLEP testing process, FDA has determined that data support the use of these lots of Tamiflu for Oral Suspension beyond their expiration dates.

The lots of Tamiflu for Oral Suspension now authorized by FDA for use beyond their expiration dates are not required to be relabeled with information about the use of the products beyond their expiration dates. Therefore, healthcare professionals and patients might receive Tamiflu for Oral Suspension that is beyond its expiration date. In addition, fact sheets for both patients and healthcare professionals will be made available by public health officials. These fact sheets will contain information about the authorized use of these products beyond their expiration dates.

These decisions to authorize the use of certain lots of Tamiflu for Oral Suspension beyond their expiration dates are based on rigorous scientific testing and analysis. Healthcare professionals may wish to discuss this information with patients to inform them that the medication they have been given is authorized for use based on scientific testing and analysis.

Considerations for Healthcare Professionals:

- **Be aware that specific lots of Tamiflu for Oral Suspension have been authorized for use beyond their expiration dates**
- **Understand that FDA has determined that data support the use of certain lots of Tamiflu for Oral Suspension beyond their expiration dates**
- **Consider discussing this information with patients to help them understand this information and address any concerns they may have about these products**
- **For any Tamiflu that is beyond its expiration date, you may verify if it has been authorized for use through the following website:**
<http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm>
- **Consider discussing with patients, families, and caregivers the benefits of taking antiviral medications in relation to the potential risks of untreated illness**

Information for Patients, Families, and Caregivers:

- FDA has determined that certain lots of Tamiflu for Oral Suspension are authorized for use beyond their expiration dates based on scientific testing and analysis
- Discuss any concerns you have about using Tamiflu for Oral Suspension with your healthcare professional
- Make sure to follow all directions given by your healthcare professional when using Tamiflu for Oral Suspension
- If you want to look up the lot number for your Tamiflu to see if it is authorized for use beyond its expiration date, go to <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm> and look for your lot number in the table under “Tamiflu Lots Whose Expiration Date Has Been Extended”

For more information from the Arizona Board of Pharmacy, please visit our website at <http://azpharmacy.gov/faqs.asp> or for questions on Arizona’s Strategic National Stockpile, please contact Kaitlin Henslee at (602)350-0081 or Lisa Speissegger at (602)448-7628.

This document has been reviewed and authorized for use by:

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