

# Concentration Lowered in Tamiflu Medication

**W**hen flu season arrives this fall, a liquid form of Tamiflu—the most widely used anti-viral flu medication—will be available in a new, lower concentration to reduce the possibility of medication errors.

The change applies to the oral suspension form of Tamiflu and not the capsule. Oral suspension is a powder form of the prescription medication that a pharmacist mixes with water to make a liquid treatment easier to take by children or adults who are unable to swallow a Tamiflu capsule.

The Tamiflu packaging of its oral suspension product says “new strength” because the concentration of medicine in the liquid has been changed from 12 mg/mL (milligrams per milliliter) to 6 mg/mL. This change in concentration means that the amount of medicine that must be taken has also changed. If taken as directed, the medicine is still as effective as it was before.

The Food and Drug Administration worked with Genentech Inc, manufacturer of Tamiflu, to create the new 6 mg/mL medication to reduce the possibility of errors in getting the correct dose. It will replace the 12 mg/mL concentration, which will no longer be manufactured but will be available until expiration.

Tamiflu is FDA-approved to treat adults and children older than 1 year who have had influenza symptoms for two days or less. Tamiflu stops the virus from spreading in the body and can help shorten the duration of such symptoms as a stuffy or runny nose, sore throat, cough and muscle aches.

Linda Lewis, medical team leader in FDA’s Division of Antiviral Products, explains that there have been no reported cases of serious side effects related to medication errors involving oral suspension Tamiflu. But there were many reports of confusion about prescribing and taking the right dose during the influenza pandemic in 2009, Lewis says.

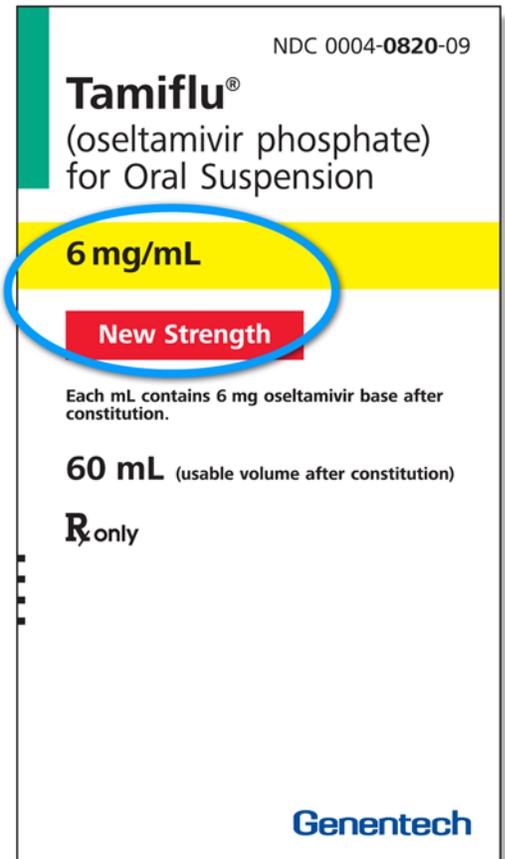
That’s because when mixed as directed, the 12 mg/mL concentration gets frothy and bubbly and it can be difficult to get the right amount. “We were concerned that the measurement of the dose was not very reliable,” Lewis says. She adds that the mixture is not frothy when the concentration is lower.

Containers of the low-concentration medication will come with new dosing instructions based on body weight.

In addition, the dosing device has been changed to a 10-milliliter oral syringe, which will make it easier to accurately measure the correct dose. The dosing device originally packaged with the 12 mg/mL suspension was marked in 30 and 45 mg, which caused confusion in measuring the liquid medication.

### Preparing for the next flu season

Because there are no quality issues with the 12 mg/mL concentration



Tamiflu, it will remain on the market until supplies run out and can be used until its expiration date.

With both dose concentrations being available during the flu season this fall, Kendall Marcus, safety deputy in FDA’s Division of Antiviral Products, cautions that pharmacists and physicians will have to be particularly careful in prescribing and dispensing the medication.

After the next flu season, only the 6 mg/mL concentration will be available.

# *“We were concerned that the measurement of the dose was not very reliable.”*

Marcus says consumers need to know the following:

- You could receive either the 6 mg/mL or the 12 mg/mL version at your local pharmacy during the next flu season. If you have any questions about how to use the product safely, speak to your pharmacist or other health care provider.
- If you have taken oral suspension Tamiflu in the past, the container and label will look different.
- The new oral dosing device is different and the volume (mL) of your dose may differ from past prescriptions.
- If you have any problems with the medication, report them to your health care provider and to FDA’s MedWatch program.

Marcus notes that pediatric strength Tamiflu capsules (30 mg and 45 mg) have not changed and are still available for children who can swallow

capsules. Another option for parents is to open the capsule and mix its contents with a flavored food, like chocolate syrup. [FDA](#)

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