

Emergency Use Authorization (EUA) of IV Zanamivir for Treatment of Influenza Fact Sheet for Recipients

During this public health emergency involving H7N9 influenza, also known as the flu, you are being given a medicine called intravenous (IV) **zanamivir** because your healthcare provider has determined you or your child have the flu. IV zanamivir (pronounced 'zan-AM-i-veer') is not approved by the Food and Drug Administration (FDA), but IV zanamivir has been authorized by the FDA to treat certain people hospitalized with H7N9 flu. IV zanamivir may help you or your child recover more quickly and reduce the chance of serious illness from flu. If you have questions, talk to a doctor or healthcare provider about receiving IV zanamivir.

This fact sheet provides information about important known and possible risks and benefits of the use of IV zanamivir during the current H7N9 flu public health emergency.

What is an influenza pandemic?

An influenza pandemic is the spread of a new influenza A virus worldwide that is very different from current and recently circulating human seasonal influenza A viruses. H7N9 flu is a new flu virus causing severe illness in people. Like seasonal flu, H7N9 spreads from person-to-person and can existing chronic medical conditions to become worse.

What are the signs and symptoms of H7N9 flu virus in people?

People infected with flu, including H7N9 flu, can have symptoms that include fever, cough, sore throat, runny or stuffy nose, body aches, headache, chills and fatigue. Some people may have diarrhea and vomiting. Severe illnesses and death have occurred as a result of flu infections associated with this virus.

What is IV zanamivir?

IV zanamivir is a medicine that has not been approved by the FDA and is therefore considered to be 'investigational'. However, IV zanamivir has been studied in adults and children hospitalized with flu. IV zanamivir has been shown to be safe in people who received this medicine. Based on available information, IV zanamivir may help treat severe flu and reduce the chance of serious illness from the flu, especially for people who can't take other approved flu medications. The FDA has authorized emergency use of IV zanamivir during the current influenza pandemic for the following:

- **Treatment** of children and adults who are hospitalized with severe/complicated influenza who need to be treated with a drug by IV
- **Treatment** of children and adults who are resistant to other flu medicines such as oseltamivir and peramivir

Who should NOT receive IV zanamivir?

IV zanamivir should not be used in people with a history of allergic reaction to zanamivir or its ingredients and should also not be given to infants born prematurely. Tell your doctor if you or your child has kidney disease.

How is IV zanamivir given?

IV zanamivir is given through a needle placed in a vein, also known as intravenous or IV. The medicine is given through the vein for approximately 30 minutes, two times each day for 5 days or more, depending on what your doctor or healthcare provider thinks is best for you.

What are common side effects of IV zanamivir?

The most common side effects reported from people treated with IV zanamivir are diarrhea, nausea, and vomiting. Some people may experience changes in liver enzyme levels. Allergic reactions or severe rash may potentially occur. Your doctor will monitor you closely for these changes.

These side effects may go away after you stop receiving IV zanamivir. These are not all the possible side effects of IV zanamivir. It is possible that not all of the side effects are known at this time.

What are possible serious side effects of IV zanamivir?

Not a lot of people have taken IV zanamivir for 5 days or longer. It is possible that serious and unexpected side effects may occur. People should be aware of the risk of brief pain, bleeding, bruising, soreness, swelling and possible infection of the skin where the needle enters. Also, people with influenza may be at an increased risk for confused thinking, hallucinations, or significant changes in behavior such as irritability, anxiety or reduced awareness of your environment. Tell your doctor right away if you experience:

- Closing of the throat or trouble breathing
- Swelling of the lips, tongue or face

- Severe itching or rash, especially hives and wheals (red, swollen bumps on the skin)

Are there any risks related to pregnancy or nursing mothers?

There have been no studies giving IV zanamivir to pregnant women or nursing mothers. For a mother and fetus, the benefit of receiving IV zanamivir may be greater than the risk from the treatment. If you are pregnant or nursing, discuss your options and specific situation with your doctor.

What if I am or my child is taking other medicines?

Tell your doctor or healthcare provider about any medications you are taking.

What other medicines can I or my child receive instead of IV zanamivir?

There are other FDA-approved medicines like oseltamivir (Tamiflu®) and peramivir (Rapivab®) to help treat H7N9 flu and a vaccine to help prevent H7N9 flu. Your doctor will let you know if alternative medicines would be beneficial. The risks and benefits of those medicines will be explained in separate instructions.

What if I decide not to take IV zanamivir?

It is your choice whether or not to take IV zanamivir. The flu can become severe and lead to serious complications such as pneumonia or respiratory failure. Some people have died from the current flu virus. If you choose not to take IV zanamivir, your symptoms may last longer and may lead to a more serious illness. Even if you take IV zanamivir, there is still a chance that you may get sicker and develop complications from the flu.

Risk-Benefit Statement

Although IV zanamivir is an investigational medicine and has some potential and serious side effects, the expected benefit of IV zanamivir in helping to treat influenza and reduce the risk of serious complications or death associated with influenza virus A exposure outweighs the risks.

What else do I need to know about IV zanamivir?

A federal program called the Countermeasures Injury Compensation Program (CICP) may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by some medicines or vaccines. If you have been injured by IV zanamivir used to treat H7N9 flu during this emergency, you can learn more about this program by visiting www.hrsa.gov/cicp or by calling 1-855-266-2427 (toll-free).

How do I report side effects or medication errors?

Tell your doctor or healthcare provider right away if you have any side effects that bother you or that do not go away. You can also report side effects or medication errors to MedWatch at www.fda.gov/medwatch or 1-800-FDA-1088.

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