



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Tamiflu (*oseltamivir*)

An overview of Tamiflu and why it is authorised in the EU

### What is Tamiflu and what it is used for?

Tamiflu is an antiviral medicine used to treat or prevent influenza (flu).

- to treat flu, it can be used in adults and children (including full-term newborns) who have the symptoms of flu, when the flu virus is circulating in the community;
- to prevent flu, it can be used in adults and children over 1 year of age who have been in contact with someone who has flu and flu is circulating in the community. This is generally done on a case-by-case basis. Tamiflu can also be used as preventative treatment in exceptional cases, for instance when the seasonal flu vaccine may not provide sufficient protection and when there is a pandemic (a global epidemic of flu). During a flu pandemic, Tamiflu can also be used to prevent flu in babies below 1 year of age.

Tamiflu cannot replace flu vaccination, and its use should be based on official recommendations.

The medicine contains the active substance oseltamivir.

### How is Tamiflu used?

Tamiflu is available as capsules (30 mg, 45 mg, and 75 mg) and as a powder that is made up into a liquid to be drunk (6 mg/ml and 12 mg/ml).

In the treatment of flu, Tamiflu must be started within two days of the onset of symptoms. The usual dose for adults and children weighing more than 40 kg is 75 mg given twice a day for 5 days. For adults with a weakened immune system (the body's natural defences), it is given for 10 days.

In the prevention of flu, Tamiflu must be started within two days of contact with someone who has flu. The usual dose for adults and children weighing more than 40 kg is 75 mg given once a day for at least 10 days after contact with an infected person. When Tamiflu is used during a flu epidemic, it is given for up to 6 weeks.

The medicine can only be obtained with a prescription. For more information about using Tamiflu, see the package leaflet or contact your doctor or pharmacist.



## **How does Tamiflu work?**

The active substance in Tamiflu, oseltamivir, acts on the flu virus, blocking some of the enzymes on its surface known as neuramidases. When the neuramidases are blocked, the virus cannot spread. Oseltamivir works on the neuramidases of both influenza A (the most common type) and influenza B viruses.

## **What benefits of Tamiflu have been shown in studies?**

### **Treatment of flu**

Tamiflu reduced the duration of the illness compared with placebo (a dummy treatment) in several studies (involving 2,413 patients aged 13 years or over, 741 elderly patients aged 65 years or over and 1,033 children aged between 1 and 12 years). Effectiveness was measured by recording symptoms (feeling feverish, muscle pain, headache, sore throat, cough, overall discomfort and runny nose). In adults, the duration of the illness was reduced from an average of 5.2 days for patients taking placebo, to 4.2 days for patients taking Tamiflu. The average reduction in the duration of the illness in children aged 1 to 6 years was 1.5 days.

### **Prevention of flu**

Tamiflu reduced the incidence of flu in people who had come into contact with the disease when one of their family members contracted flu (962 cases) or during an epidemic (1,562 people aged between 16 and 65 years, and 548 elderly people in nursing homes). The studies measured the number of cases of flu proven by laboratory tests. A study also looked at using Tamiflu in a family setting (277 families) for both the treatment of the person with flu, and the treatment or prevention of flu in those in contact with the person.

In the study carried out during an epidemic, 1% of the people taking Tamiflu developed flu after contact, compared with 5% of those taking placebo. In families with one patient who had flu, 7% of the family members in the household developed flu when receiving Tamiflu, compared with 20% of those receiving no preventative treatment.

## **What are the risks associated with Tamiflu?**

The most common side effects with Tamiflu (seen in more than 1 patient in 10) in adults and adolescents are headache and nausea (feeling sick). In children the most common side effects (seen in more than 1 patient in 10) are vomiting, cough and nasal congestion (a blocked nose). For the full list of side effects and restrictions with Tamiflu, see the package leaflet.

## **Why is Tamiflu authorised in the EU?**

When used for treatment of flu, Tamiflu reduces the duration of illness in adults and children. It can also reduce the incidence of flu in patients who had come into contact with the disease or during a pandemic. Side effects are generally mild or moderate in severity.

The European Medicines Agency decided that Tamiflu's benefits are greater than its risks and recommended that it can be authorised for use in the EU.

## **What measures are being taken to ensure the safe and effective use of Tamiflu?**

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Tamiflu have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Tamiflu are continuously monitored. Side effects reported with Tamiflu are carefully evaluated and any necessary action taken to protect patients.

## **Other information about Tamiflu**

Tamiflu received a marketing authorisation valid throughout the EU on 20 June 2002.

Further information on Tamiflu can be found on the Agency's website: [ema.europa.eu/medicines/human/EPAR/tamiflu](http://ema.europa.eu/medicines/human/EPAR/tamiflu).

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