



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## [EPAR summary for the public](#)

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# Tamiflu

## oseltamivir

This is a summary of the European public assessment report (EPAR) for Tamiflu. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Tamiflu.

### What is Tamiflu?

Tamiflu is an antiviral medicine available as capsules (30 mg, 45 mg, and 75 mg) and as a powder that is made up into an oral suspension (6 mg/ml and 12 mg/ml). It contains the active substance oseltamivir.

### What is Tamiflu used for?

Tamiflu is used to treat or prevent influenza (flu):

- in the treatment of flu, it can be used in adults and children (including full-term newborns) who have the symptoms of flu, when the flu virus is known to be circulating in the community;
- in the prevention of flu, it can be used in adults and children over one year of age who have been in contact with someone who has flu. 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 one year of age.

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

The medicine can only be obtained with a prescription.



## How is Tamiflu used?

In the treatment of flu, Tamiflu must be started within two days of the onset of symptoms. It is given as one dose twice a day for five days.

In the prevention of flu, Tamiflu must be started within two days of contact with someone who has flu. It is given as one dose once a day for at least 10 days after contact with an infected person. When Tamiflu is used during a flu epidemic, this dose can be given for up to six weeks.

The dose of Tamiflu is 75 mg in patients aged 13 years and over, and in children aged between one and 12 years who weigh more than 40 kg. For children who weigh less than 40 kg, the dose is adjusted according to their weight using the lower-dose capsules (30 or 45 mg). Full-term babies up to 1 year of age should be given the oral suspension in a dose of 3 mg per kg body weight (the dose to use in premature babies has not been determined). Older patients who cannot swallow capsules may also receive the appropriate dose of the oral suspension.

If the powder for oral suspension is not available, the pharmacist can make up a solution using the contents of the capsules, or the contents of the capsules can be mixed into sweetened food at home. The solution made up by a pharmacist is preferable to a home preparation as a pharmacist can measure the dose more accurately.

The doses may need to be lower in patients who have kidney problems. See the package leaflet for full details.

## How does Tamiflu work?

The active substance in Tamiflu, oseltamivir, acts specifically 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.

## How has Tamiflu been studied?

Tamiflu has been compared with placebo (a dummy treatment) in studies of the treatment of flu (2,413 patients aged 13 years or over, 741 elderly patients aged 65 years or over and 1,033 children aged between one and 12 years). The effectiveness was measured using a score card to record symptoms (feeling feverish, muscle pain, headache, sore throat, cough, overall discomfort and runny nose).

In the prevention of flu, Tamiflu was studied in patients who had been exposed to 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 him or her.

Studies have also been carried out to show that the recommended doses of Tamiflu in full-term babies up to one year of age produce similar levels of the medicine in the blood as the effective doses for older patients.

## **What benefit has Tamiflu shown during the studies?**

In the treatment studies in adults (aged 18 years or over), Tamiflu reduced the duration of the illness 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 disease in children aged one to six years was 1.5 days.

In the prevention studies, Tamiflu reduced the incidence of flu among the people in contact with a flu patient. 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 flu patient, 7% of the family members in the household developed flu when receiving Tamiflu, compared with 20% of those receiving no preventative treatment.

## **What is the risk associated with Tamiflu?**

The most common side effects with Tamiflu (seen in more than 1 patient in 10) when used for treatment and prevention of influenza 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 all side effects and restrictions with Tamiflu, see the package leaflet.

## **Why has Tamiflu been approved?**

The CHMP decided that Tamiflu's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

A risk management plan has been developed to ensure that Tamiflu is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Tamiflu, including the appropriate precautions to be followed by healthcare professionals and patients.

## **Other information about Tamiflu**

The European Commission granted a marketing authorisation valid throughout the European Union for Tamiflu on 20 June 2002.

The full EPAR for Tamiflu can be found on the Agency's website [ema.europa.eu/Find\\_medicine/Human\\_medicines/European\\_Public\\_Assessment\\_Reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_Public_Assessment_Reports). For more information about treatment with Tamiflu, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

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