

OMIFLU CAPSULE

Oseltamivir (75mg)

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What OMIFLU is used for

OMIFLU is used for the treatment of influenza in children 6 to 12 months of age during pandemic influenza outbreak, for treatment of influenza in adults and children age 1 year and above. OMIFLU is also indicated for post exposure prevention in adults and children age 1 year and above following contact with clinically diagnosed influenza case when influenza virus is circulating in the community.

How OMIFLU works

OMIFLU contains oseltamivir which belongs to a group of medicines called neuraminidase inhibitors. These medicines prevent the influenza virus from spreading inside the body. They help to ease or prevent the symptoms of the influenza virus infection.

Influenza, usually called flu, is an infection caused by a virus. The signs of flu often include a sudden fever (more than 37.8°C), cough, runny or stuffy nose, headaches, muscle aches and extreme tiredness. These symptoms can also be caused by other infections. True influenza infection only occurs during annual outbreaks (epidemics) when flu viruses are spreading in the local community. Outside epidemic periods, flu-like symptoms are usually caused by a different type of illness.

OMIFLU is not a flu vaccine

OMIFLU is not a vaccine: it treats infection, or prevents the flu virus

spreading. A vaccine gives you antibodies against the virus. OMIFLU will not change the effectiveness of a flu vaccine, and you might be prescribed both by your doctor.

Before you use OMIFLU

- When you must not use it

Do not take OMIFLU if:

- you are allergic (*hypersensitive*) to OMIFLU or any ingredients listed at the end of this leaflet. Talk to your doctor if this applies to you.
- Do not take OMIFLU.

- Before you start to use it

Tell your doctor if:

- you have problems with your kidneys. If so, your dose may need adjustment
- you are allergic to any other medicines.
- you have a severe medical condition, which may require immediate hospitalization
- your immune system is not working
- you have chronic heart disease or respiratory disease

Pregnancy and breast-feeding

You must tell your doctor if you are pregnant, if you think you are pregnant or if you are trying to get pregnant so that your doctor can decide if OMIFLU is right for you. The effects on breast-fed infants is unknown. You must tell your doctor if you are breast-feeding so that your doctor can decide if OMIFLU is right for you.

If you have not told your doctor about any of the above, tell them before you start taking OMIFLU.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, or have recently taken any. This includes medicines obtained without a prescription.

The following medicines are particularly important:

- Chlorpropamide (used to treat diabetes)
- Methotrexate (used to treat e.g. rheumatoid arthritis)
- Phenylbutazone (used to treat pain and inflammation)
- Probenecid (used to treat gout)

How to use OMIFLU

Take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- How much to use

Treatment should begin within the first or second day of onset of symptoms of influenza.

TREATMENT OF INFLUENZA

Adults and adolescents 13 years and over

The recommended oral dose of OMIFLU for adults and adolescents ≥13 years is a 75 mg capsule twice daily for 5 days.

Children

Children weighing > 40 kg who can swallow capsules, may also receive treatment with a 75 mg capsule twice daily as an alternative to the recommended dose of OMIFLU suspension.

The recommended oral dose of OMIFLU for children ≥ 1 year of age is:

Body weight	Recommended dose for 5 days
10 to 15 kg	30 mg twice daily
>15 to 23 kg	45 mg twice daily
>23 to 40 kg	60 mg twice daily
>40 kg	75 mg twice daily

The recommended oral dose of OMIFLU for infants 6-12 months of age

The recommended oral dose of OMIFLU for infants 6 to 12 months is 3 mg/kg twice daily, for 5 days. These dosing recommendations are not intended for infants who have a post-conceptual age of less than 36 weeks.

The recommended oral dose of OMIFLU for children 6-12 months of age is:

Body weight	Recommended dose for 5 days
3 kg	9 mg twice daily
4 kg	12 mg twice daily
5 kg	15 mg twice daily
6 kg	18 mg twice daily
7 kg	21 mg twice daily
8 kg	24 mg twice daily
9 kg	27 mg twice daily
10 kg	30 mg twice daily

The recommended duration for immunocompromised patients is 10 days.

PREVENTION OF INFLUENZA

Adults and adolescents 13 years and over

The recommended oral dose of OMIFLU for prevention of influenza following close contact with an infected individual is 75mg once daily for 10 days. Therapy should begin within two days of exposure. The recommended dose for prevention during a community outbreak of influenza is 75 mg once daily for up to 6 weeks (or up to 12 weeks in immunocompromised patients).

Children ≥ 1 year of age

Children weighing > 40 kg, who are able to swallow capsules, may also receive prevention dose with a 75 mg capsule once daily for 10 days as an alternative to the recommended dose of oseltamivir oral suspension (as below). The recommended prevention oral dose for children ≥ 1 year of age is:

Body weight	Recommended dose for 10 days
10 to 15 kg	30 mg once daily
>15 to 23 kg	45 mg once daily
>23 to 40 kg	60 mg once daily
>40 kg	75 mg once daily

- How to take it

Swallow the capsules whole with water. Do not break or chew the capsules.

OMIFLU can be taken with or without food, although taking it with food can reduce the chance of feeling or being sick (nausea or vomiting).

When Oseltamivir oral suspension is not available or for people who find it hard to take capsules, a liquid form of OMIFLU can be made from the capsules. See

INFORMATION FOR THE USER

Making Liquid OMIFLU at Home, at the end of this leaflet.

Appropriate doses of OMIFLU can be prepared by a pharmacist or prepared at home by parents or caregivers.

Please consult your pharmacist before self-preparing OMIFLU. The mixture must be swallowed immediately after its preparation.

- When to use it

Take OMIFLU as soon as possible, ideally within two days of the flu symptoms starting.

For treating flu, take two doses daily. It is usually convenient to take one dose in the morning and one in the evening. It is important to complete the whole 5-day course, even if you start to feel better quickly.

For preventing flu or after being exposed to an infected person, take one dose daily for 10 days. It is best to take this in the mornings with breakfast.

In special situations, such as widespread flu or for patients with a weak immune system, treatment will continue for up to 6 or 12 weeks.

- How long to use it

Continue taking OMIFLU for as long as your doctor tells you to stop or your course of treatment is complete

If you stop taking OMIFLU

There are no side effects when you stop OMIFLU. But if OMIFLU is stopped earlier than your doctor told you, the symptoms of flu may come back. Always complete the course that your doctor prescribed.

- If you forget to use it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your capsules as you would normally.

Do not take a double dose to make up for the dose that you missed.

- If you use too much (overdose)

Stop taking OMIFLU and contact a doctor or pharmacist immediately.

In most cases of overdose, people have not reported any side effects. When side effects were reported, they were similar to those from normal doses.

Overdose has been reported to have occurred more frequently when OMIFLU was given to children than to adults and adolescents. Caution should be exercised when preparing liquid OMIFLU for children and when administering OMIFLU capsules or liquid to children.

While you are using it

- Things you must do

Tell your doctor immediately if you notice changes in behaviour or mood (neuropsychiatric events), especially in children and adolescents. These may be signs of rare but serious side effects.

- Things you must not do

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- Things to be careful of

Driving and using machines

OMIFLU has no effect on your ability to drive or use machines.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Many of the side effects listed below may also be caused by influenza.

The following serious side effects have been rarely reported since oseltamivir has been marketed:

- Anaphylactic and anaphylactoid reactions: severe allergic reactions, with face and skin swelling, itchy rashes, low blood pressure and breathing difficulties
- Hepatic disorders (fulminant hepatitis, hepatic function disorder and jaundice): yellowing of the skin and white of the eyes, change in stool color, changes in behaviour
- Angioneurotic oedema: sudden onset of severe swelling of the skin mainly around the head and neck area, including eyes and tongue, with difficulties breathing
- Stevens-Johnson syndrome and toxic epidermal necrolysis: complicated, possibly lifethreatening allergic reaction, severe inflammation of the outer and possibly inner skin, initially with fever, sore throat, and fatigue, skin rashes, leading to blisters, peeling, shedding of larger areas of skin, possible breathing difficulties and low blood pressure
- Gastrointestinal bleeding: prolonged bleeding from the large bowel or spitting up blood
- Neuropsychiatric disorders

If you notice any of these symptoms, get medical help immediately.

The most frequently (very common and common) reported side effects of OMIFLU are feeling or being sick (nausea, vomiting), stomach ache, stomach upset, headache and pain.

These side effects mostly occur after the first dose of the medicine and will usually stop as treatment continues. The frequency of these effects is reduced if the medicinal product is taken with food.

Rare but serious effects: get medical help at once (*These may affect up to 1 in 1,000 people*)

During OMIFLU treatment, rare events have been reported that include:

- Convulsions and delirium, including altered level of consciousness
- Confusion, abnormal behaviour
- Delusions, hallucinations, agitation, anxiety, nightmares

These are reported primarily among children and adolescents and often started suddenly and resolved rapidly. A few cases resulted in self-injury, some with fatal outcome. Such neuropsychiatric events have also been reported in patients with influenza who were not taking OMIFLU.

- Patients, especially children and adolescents, should be closely monitored for the behavioural changes described above.

If you notice any of these symptoms, especially in younger people, get medical help immediately.

Adults and adolescents 13 and over

Very common side effects

(*may affect more than 1 in 10 people*)

- Headache
- Nausea.

Common side effects

(*may affect up to 1 in 10 people*)

- Bronchitis
- Cold sore virus
- Cough
- Dizziness
- Fever
- Pain
- Pain in limb
- Runny nose
- Sleeping difficulties
- Sore throat
- Stomach ache
- Tiredness
- Upper abdominal fullness
- Upper respiratory tract infections (inflammation of the nose, throat and sinuses)
- Upset stomach
- Vomiting

Uncommon side effects

(*may affect up to 1 in 100 people*)

- Allergic reactions
- Altered level of consciousness
- Convulsion
- Heart rhythm abnormalities
- Mild to severe liver function disorders
- Skin reactions (inflammation of the skin, red and itchy rash, scaling skin).

Rare side effects

(*may affect up to 1 in 1,000 people*)

- Thrombocytopenia (low platelet count)
- Visual disturbances

Children 1 to 12 years

Very common side effects

(*may affect more than 1 in 10 people*)

- Cough
- Nasal congestion
- Vomiting

Common side effects

(*may affect up to 1 in 10 people*)

- Conjunctivitis (red eyes and discharge or pain in the eye)
- Ear inflammation and other ear disorders
- Headache
- Nausea
- Runny nose
- Stomach ache
- Upper abdominal fullness
- Upset stomach

Uncommon side effects

(*may affect up to 1 in 100 people*)

- Inflammation of the skin
- Tympanic membrane (eardrum) disorder

Infants less than 1 year

The reported side effects in infants 6 to 12 months old are mostly similar to the side effects reported for older children (1 year old or older). Additionally, diarrhoea and diaper rash have been reported.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist. However,

- If you or your child are repeatedly sick, or
- If the influenza symptoms get worse or the fever continues

Tell your doctor as soon as possible.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of OMIFLU**- Storage**

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description**- What it looks like**

OMIFLU CAPSULE 75mg is a size '2' capsule, yellow / white colour, with 'DUO 861' marking. Capsule content is white to off white crystalline powder.

- Ingredients

- Active ingredient:
 - Oseltamivir
- Inactive ingredients
 - Croscarmellose sodium
 - Starch
 - Magnesium stearate
 - Polyvinylpyrrolidone
 - Talc

- MAL number:

MAL07090926AZ

Manufacturer

DUOPHARMA (M) SDN. BHD.
Lot. 2599, Jalan Seruling 59, Kawasan 3,
Taman Klang Jaya, 41200 Klang,
Selangor Darul Ehsan, Malaysia.

Product Registration Holder

DUOPHARMA (M) SDN. BHD.

Lot. 2599, Jalan Seruling 59, Kawasan 3,
Taman Klang Jaya, 41200 Klang,
Selangor Darul Ehsan, Malaysia.

Date of revision

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INFORMATION FOR THE USER**Making Liquid OMIFLU at Home****Using 75 mg Capsules**

- **If you have the right capsule** for the dose needed (a 75 mg dose), you will open the capsule and stir its contents into one teaspoon (or less) of a suitable sweetened food product. This is usually suitable for children over 1 year. **See the upper set of instructions.**
- **If you need smaller doses**, making liquid OMIFLU from capsules involves extra steps. This is suitable for younger children and babies: they usually need a OMIFLU dose of less than 30 mg. **See the lower set of instructions.**

Adults, adolescents 13 years and over, and children weighing 40 kg and over

To make a 75 mg dose, you need:

- One 75 mg OMIFLU capsule
- Sharp scissors
- One small bowl
- Teaspoon (5 ml spoon)
- Water
- Sweet food to hide the bitter taste of the powder. Examples are: chocolate or cherry syrup, and dessert toppings such as caramel or fudge sauce. Or you can make sugar water: mix a teaspoon of water with three-quarters (3/4) of a teaspoon of sugar.

Step 1: Check the dose is correct

To find the correct amount to use, find the patient's weight on the left of the table. Look at the right column to check the number of capsules you will need to give the patient for a single dose. The amount is the same whether treating or preventing flu.

You should use only 75 mg capsules for 75 mg doses.

Weight	Dose of Omiflu	Number of capsules
40 kg and over	75 mg	1 capsule

Not for children who weigh less than 40 kg

You will need to prepare a dose of less than 75 mg for children who weigh less than 40 kg. See below.

Step 2: Pour all the powder into a bowl

Hold a 75 mg capsule upright over a bowl and careful snip off the rounded tip with scissors.

Pour all of the powder into the bowl. Be careful with the powder, because it may irritate your skin and eyes.

Step 3: Sweeten the powder and give the dose

Add a small amount – no more than one teaspoonful – of sweet food to the powder in the bowl. This is to hide the bitter taste of the OMIFLU powder. Stir the mixture well.

Give the whole contents of the bowl to the patient straight away.

If there is some mixture left in the bowl, rinse the bowl with a small amount of water and get the patient to drink it all.

Repeat this procedure every time you need to give the medicine.

Infants 6-12 months old, and children weighing less than 40 kg

To make a smaller single dose, you need:

- One 75 mg OMIFLU capsule
- Sharp scissors
- Two small bowls
- One large oral dose dispenser to measure out water – a 5 or 10 ml dispenser
- One small oral dose dispenser showing measurements of 0.1 ml, to give the dose
- Teaspoon (5 ml spoon)
- Water
- Sweet food to hide the bitter taste of the OMIFLU. Examples are:

chocolate or cherry syrup and dessert toppings such as caramel or fudge sauce. Or you can make sugar water: mix a teaspoon of water with three-quarters (3/4) of a teaspoon of sugar.

Step 1: Pour all the powder into a bowl

Hold a 75 mg capsule upright over one of the bowls and carefully snip off the rounded tip with scissors.

Be careful with the powder: it may irritate your skin and eyes. Pour all of the powder into the bowl, whatever the dose you are making. The amount is the same whether you are treating or preventing flu.

Step 2: Add water to dilute the medicine

Use the larger dispenser to draw up 12.5 ml water. Add the water to the powder in the bowl.

Stir the mixture with the teaspoon for about 2 minutes.

Don't worry if not all of the powder dissolves. The undissolved powder is just inactive ingredients.

Step 3: Choose the correct amount for your child's weight

Look up the child's weight on the left side of the table.

The column on the right of the table shows how much of the liquid mixture you will need to draw up.

Infants 6-12 months old::

Child's weight (nearest)	How much mixture to draw up
3 kg	1.5 ml
3.5 kg	1.8 ml
4 kg	2.0 ml
4.5 kg	2.3 ml
5 kg	2.5 ml
5.5 kg	2.8 ml
6 kg	3.0 ml

6.5 kg	3.3 ml
7 kg	3.5 ml
7.5 kg	3.8 ml
8 kg	4.0 ml
8.5 kg	4.3 ml
9 kg	4.5 ml
9.5 kg	4.8 ml
10 kg or more	5.0 ml

Children 1 year or older, weighing less than 40 kg:

Child's weight (nearest)	How much mixture to draw up
Up to 15 kg	5.0 ml
15 to 23 kg	7.5 ml
23 to 40 kg	10.0 ml

Step 4: Draw up the liquid mixture

Make sure you have the right size dispenser. Draw up the correct amount of liquid mixture from the first bowl. Draw it up carefully so as not to include air bubbles. Gently squirt the correct dose into the second bowl.

Step 5: Sweeten and give to the child

Add a small amount – no more than one teaspoonful – of a sweet food to the second bowl. This is to hide the bitter taste of the OMIFLU. Mix the sweet food and OMIFLU liquid well.

Give the whole contents of the second bowl (OMIFLU liquid mixture with sweet food added) to the child straight away. If there is anything left in the second bowl, rinse the bowl with a small amount of water and get the child to drink it all. For children unable to drink from a bowl, spoon feed or use a bottle to feed the child the remaining liquid.

Give the child something to drink. Throw away any unused liquid left in the first bowl.

Repeat this procedure every time you need to give the medicine.