

Package Leaflet: Information for the user

VIRIFLU 75 mg capsules

Osetamivir

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.

- If you have further questions, ask your doctor or pharmacist.

- 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.

- If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What VIRIFLU is and what it is used for
2. What you need to know before you take VIRIFLU
3. How to take VIRIFLU
4. Possible side effects
5. How to store VIRIFLU
6. Contents of the pack and other information

1. What VIRIFLU is and what it is used for

VIRIFLU is used for adults, adolescents, children and infants (including full-term newborn babies) for **treating flu (influenza)**. It can be used when you have flu symptoms, and the flu virus is known to be going round in your community.

VIRIFLU can also be prescribed for adults, adolescents, children and infants above 1 year of age for **preventing flu**, on a case-by-case basis – for instance, if you have been in contact with someone who has flu.

VIRIFLU may be prescribed for adults, adolescents, children and infants (including full-term newborn babies) as **preventive treatment** in exceptional circumstances – for example, if there is a global epidemic of flu (a flu **pandemic**) and the seasonal flu vaccine may not provide sufficient protection.

VIRIFLU contains *oseltamivir*, which belongs to a group of medicines named *neuraminidase inhibitors*. These medicines prevent the flu virus from spreading inside the body. They help to ease or prevent the symptoms of the flu 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.

2. What you need to know before you take VIRIFLU

Do not take VIRIFLU:

- If you are allergic (*hypersensitive*) to oseltamivir or any of the other ingredients of VIRIFLU listed in section 6.

Talk to your doctor if this applies to you. Do not take VIRIFLU.

Warnings and precautions:

Before you take VIRIFLU, make sure the prescribing doctor knows

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



During treatment with VIRIFLU, **tell a 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.

VIRIFLU is not a flu vaccine

VIRIFLU is not a vaccine: it treats infection, or prevents the flu virus spreading. A vaccine gives you antibodies against the virus. VIRIFLU will not change the effectiveness of a flu vaccine, and you might be prescribed both by your doctor.

Other medicines and VIRIFLU

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)

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 VIRIFLU is right for you. The effects on breast-fed infants are unknown. You must tell your doctor if you are breast-feeding so that your doctor can decide if VIRIFLU is right for you.

Ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

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

3. How to take VIRIFLU

Take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Take VIRIFLU as soon as possible, ideally within two days of the flu symptoms starting.

The recommended doses

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 patients with a weak immune system, treatment will continue for 10 days.

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.

The **recommended dose is based on the patient's body weight**. You must use the amount of oral capsules prescribed by the doctor.

Adults, and adolescents 13 years and over

Body weight	Treating flu: dose for 5 days	Treating flu (Immunocompromised Patients): dose for 10 days*	Preventing flu: dose for 10 days
40 kg or more	75 mg twice daily	75 mg twice daily	75 mg once daily

* For patients with a weak immune system, treatment is for 10 days.

Children 1 to 12 years

Body weight	Treating flu: dose for 5 days	Treating flu (Immunocompromised Patients): dose for 10 days*	Preventing flu: dose for 10 days
10 to 15 kg	30 mg twice daily	30 mg twice daily	30 mg once daily
More than 15 kg and up to 23 kg	45 mg twice daily	45 mg twice daily	45 mg once daily
More than 23 kg and up to 40 kg	60 mg twice daily	60 mg twice daily	60 mg once daily
More than 40 kg	75 mg twice daily	75 mg twice daily	75 mg once daily

* For children with a weak immune system, treatment is for 10 days.

Infants less than 1 year (0 to 12 months)

Giving VIRIFLU to infants less than 1 year old for preventing flu during a flu pandemic should be based upon the judgment of a doctor after considering the potential benefit versus any potential risk to the infant.

Body weight	Treating flu: dose for 5 days	Treating flu (Immunocompromised Patients): dose for 10 days*	Preventing flu: dose for 10 days
3 kg to 10+ kg.	3 mg per kg body weight** twice daily	3 mg per kg body weight** twice daily	3 mg per kg**, once daily

* For infants with a weak immune system, treatment is for 10 days.

**mg per kg = mg for each kilogram of the infant's body weight.

For example: If a 6-month-old weighs 8 kg, the dose is 8 kg x 3 mg per kg = 24 mg

Method of administration

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

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

People who find it hard to take capsules can use a liquid suspension. You can make a liquid form of VIRIFLU from these capsules. See **Making liquid VIRIFLU at home**, over the page.

If you take more VIRIFLU than you should

Stop taking VIRIFLU and contact a doctor or pharmacist immediately.

In most cases of overdose with oseltamivir capsules, people have not reported any side effects. When side effects were reported, they were similar to those from normal doses, as listed in section 4.

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

4. Possible 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 behavior.
- Angioneurotic oedema: sudden onset of severe swelling of the skin mainly around the head and neck area, including eyes and tongue, with difficulties breathing.

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Stevens-Johnson syndrome and toxic epidermal necrolysis: complicated, possibly life-threatening 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.

Mild to severe liver function disorders

Gastrointestinal bleeding: prolonged bleeding from the large bowel or spitting up blood.

Neuropsychiatric disorders, as described below.

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

The most frequently (very common and common) reported side effects of oseltamivir 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 oseltamivir treatment, rare events have been reported that include:

- Convulsions and delirium, including altered level of consciousness
- Confusion, abnormal behavior
- 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-harm, some with fatal outcome. Such neuropsychiatric events have also been reported in patients with influenza who were not taking oseltamivir.
- Patients, especially children and adolescents, should be closely monitored for the behavioral 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

5. How to store VIRIFLU

- Keep this medicine out of the sight and reach of children.

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

- Do not store above 30°C. Keep away from humidity.

- Do not use this medicine if you notice visible signs of deterioration.

- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

What VIRIFLU looks like and contents of the pack

VIRIFLU capsules are white and blue capsules.

VIRIFLU is available in boxes containing 10 capsules.

Marketing Authorisation Holder and Manufacturer

Pharmaline s.a.l. – Lebanon

P.O. Box90201, Jdeidet-El-Metr, Lebanon

Contact us: pharmaline@maliagroup.com

Reg. No. for VIRIFLU 75 mg In Lebanon: 24341/06

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6. Contents of the pack and other information

What VIRIFLU contains

- The active substance is Osetamivir.
- Each capsule contains Osetamivir phosphate equivalent to 75mg of Osetamivir.

- The other ingredients are: Pregelatinized starch, talc, povidone, croscarmellose sodium, sodium stearyl fumarate. Capsule shell content: gelatin, Indigotine (E132), Titanium dioxide (E171) looks

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Information for the user

For people who find it hard to take capsules, including very young children:

If you need a liquid medicine, a suspension can be made up at the pharmacy from VIRIFLU capsules. This pharmacy preparation is the preferred option.

If the pharmacy preparation is not available, you can make liquid VIRIFLU from these capsules at home.

The dose is the same for treating or preventing flu. The difference is how often it is given.

Making liquid VIRIFLU at home

• If you have the right capsule strength 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 VIRIFLU from capsules involves extra steps. This is suitable for younger children and babies: they usually need a VIRIFLU 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 VIRIFLU 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.

Step 2: 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 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 VIRIFLU powder. Stir the mixture well.

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 VIRIFLU. Mix the sweet food and VIRIFLU liquid well.

Step 6: Give the whole contents of the second bowl

(VIRIFLU 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.

Step 7: Throw away any unused liquid left in the first bowl

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

Step 8: Give the whole contents of the second bowl

(VIRIFLU 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.

Step 9: Throw away any unused liquid left in the first bowl

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Step 7: Throw away any unused liquid left in the first bowl

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

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Step 9: Throw away any unused liquid left in the first bowl

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

Step 10: Give the whole contents of the second bowl