

## Package Leaflet: Information for the user

### Oseltamivir Zentiva 75 mg harde capsules oseltamivir

**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 any 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 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 <product name> is and what it is used for
2. What you need to know before you take <product name>
3. How to take <product name>
4. Possible side effects
5. How to store <product name>
6. Contents of the pack and other information

#### **1. What <product name> is and what it is used for**

- <product name> 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.
- <product name> 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.
- <product name> 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.

<product name> 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 <product name>**

##### **Do not take <product name>:**

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

**Talk to your doctor** if this applies to you. **Do not take <product name>.**

### Warnings and precautions:

Before you take <product name>, 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 <product name>, **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.

### <product name> is not a flu vaccine

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

### Other medicines and <product name>

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. 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 <product name> 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 <product name> is right for you.

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

### Driving and using machines

<product name> has no effect on your ability to drive or use machines.

### <Product name> contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

## 3. How to take <product name>

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

Take <product name> 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 or suspension 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.

\*\*75 mg can be made up of a 30 mg capsule plus a 45 mg capsule.

#### 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.

\*\*75 mg can be made up of a 30 mg capsule plus a 45 mg capsule.

#### Infants less than 1 year (0 to 12 months)

Giving <product name> to infants less than 1 year old for preventing flu during 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

$8 \text{ kg} \times 3 \text{ mg per kg} = 24 \text{ mg}$

#### Method of administration

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

<product name> 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 medicine; an oseltamivir powder for oral suspension may be available, however not under this tradename. If you need an oral suspension, but it's

not available from your pharmacy, you can make a liquid form from the capsules. See ***Making liquid oseltamivir at home***, over the page.

**If you take more <product name> than you should**

Stop taking <product name> 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, as listed in section 4.

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

**If you forget to take <product name>**

Do not take a double dose to make up for a forgotten capsule.

**If you stop taking <product name>**

There are no side effects when you stop <product name>. But if <product name> 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 have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### **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 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 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
- 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 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 oseltamivir.

- 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 0 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.**

#### **Reporting of side effects**

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

### **7. How to store <product name>**

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 carton and blister after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

#### Storage of the pharmacy compounded suspension

Shelf life of 10 days when stored below 25°C.

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

### **8. Contents of the pack and other information**

#### **What <product name> contains**

- Each hard capsule contains oseltamivir phosphate equivalent to 75 mg of oseltamivir.
- The other ingredients are:  
Capsule contents: pregelatinised starch, povidone K-30, croscarmellose sodium, talc, and sodium stearyl fumarate.  
Capsule shell: gelatin, titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172).  
Printing ink – Black ink TEK SW 9008: shellac, propylene glycol, concentrated ammonia solution, black iron oxide (E172), potassium hydroxide.

## What <product name> looks like and contents of the pack

### <product name> 75 mg hard capsules

Size “2” hard gelatin capsules with grey opaque colour body with black colour band, imprinted with “M” and light yellow opaque colour cap imprinted with “75 mg”. The size is approximately 17.66 mm.

<product name> hard capsules are available in blister packs of 10.

## Houder van de vergunning voor het in de handel brengen en fabrikant

### Houder van de vergunning voor het in de handel brengen:

Zentiva, k.s.

U kabelovny 130

Dolní Měcholupy,

102 37 Praag 10

Tsjechië

### Fabrikant:

*Pharmadox Healthcare Ltd*

KW20A Kordin Industrial Park

Paola, PLA3000

Malta

### In het register ingeschreven onder:

Oseltamivir Zentiva 75 mg harde capsules – RVG 124070

### Dit medicijn is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland, Frankrijk, Duitsland, Spanje

Oseltamivir Zentiva

**Deze bijsluiter is voor het laatst goedgekeurd in december 2023.**

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### Information for the user

**For people who find it hard to take capsules**, including very young children, an oseltamivir powder for oral suspension may be available, however not under this tradename.

If you need a liquid medicine, but it's not available, a suspension can be made up at the pharmacy from <product name> capsules (see *Information for healthcare professionals*). This pharmacy preparation is the preferred option.

If the pharmacy preparation is not available either, you can make liquid oseltamivir 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 oseltamivir 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 <product name> from capsules involves extra steps. This is suitable for younger, lighter children and babies: they usually need a <product name> 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<product name> 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. Do not try to make a 75 mg dose by using the contents of 30 mg or 45 mg capsules.

Weight	Dose of <product name>	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.

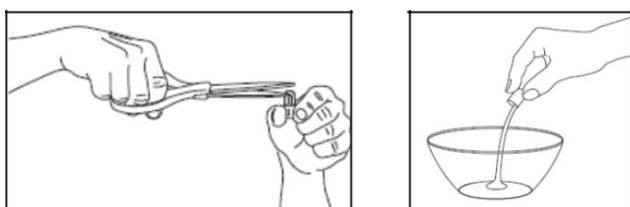
*See below.*

### Step 2: Pour all the powder into a bowl

Hold a **75 mg capsule** upright over a bowl and carefully 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.

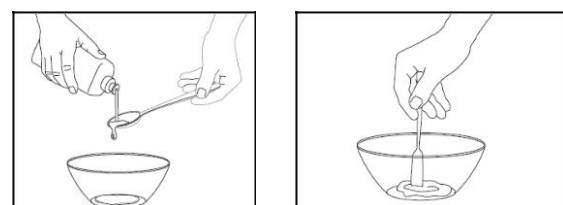


### Step 3: Sweeten the powder and give the dose

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 <product name> 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 less than 1 year, and children weighing less than 40 kg

To make a smaller single dose, you need:

- **One 75 mg capsule** <product name> capsule
- **Sharp scissors**
- **Two small bowls**
- **One large oral dose dispenser** to measure out water – a 5 ml 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 <product name>.

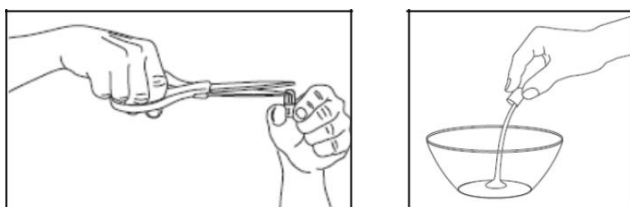
Examples are: chocolate or cherry syrup and dessert toppings such as caramel or fudge sauce.

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 less than 1 year (including full-term newborn babies)

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

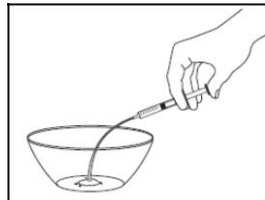
#### Step 4: Draw up the liquid mixture

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.

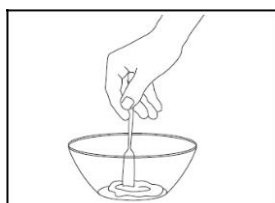
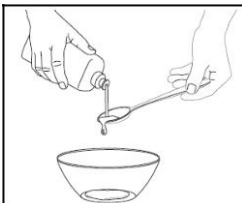


#### Step 5: Sweeten and give to the child

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 <product name>.

Mix the sweet food and <product name> liquid well.



**Give the whole contents** of the second bowl (<product name> 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.

**Information for healthcare professionals only**

**Patients who are unable to swallow capsules:**

Commercially manufactured powder for oral suspension (6mg/ml) is the preferred product for paediatric and adult patients who have difficulties swallowing capsules or where lower doses are needed. In the event that a powder for oral suspension is not available, the pharmacist may compound a suspension (6 mg/ml) from capsules. If the pharmacy compounded suspension is also not available, patients may prepare the suspension from capsules at home.

**Oral dose dispensers** (oral syringes) of appropriate volume and grading should be provided for administering the pharmacy compounded suspension, and for the procedures involved in the home preparation. In both cases, the correct volumes should preferably be marked on the dispensers. For home preparation, separate dispensers should be provided for taking the correct volume of water and for measuring the oseltamivir-water mixture. For measuring 12.5 ml of water a 10 ml dispenser should be used.

The appropriate dispenser sizes for taking the correct volume of oseltamivir suspension (6 mg/ml) are shown below.

**Infants less than 1 year (including full term new born babies):**

<b>Dose</b>	<b>Amount of oseltamivir suspension</b>	<b>Dispenser size to use (grading 0.1 ml)</b>
9 mg	1.5 ml	2.0 ml (or 3.0 ml)
10 mg	1.7 ml	2.0 ml (or 3.0 ml)
11.25 mg	1.9 ml	2.0 ml (or 3.0 ml)
12.5 mg	2.1 ml	3.0 ml
13.75 mg	2.3 ml	3.0 ml
15 mg	2.5 ml	3.0 ml
16.25 mg	2.7 ml	3.0 ml
18 mg	3.0 ml	3.0 ml (or 5.0 ml)
19.5 mg	3.3 ml	5.0 ml
21 mg	3.5 ml	5.0 ml
22.5 mg	3.8 ml	5.0 ml
24 mg	4.0 ml	5.0 ml
25.5 mg	4.3 ml	5.0 ml
27 mg	4.5 ml	5.0 ml
28.5 mg	4.8 ml	5.0 ml
30 mg	5.0 ml	5.0 ml

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

<b>Dose</b>	<b>Amount of oseltamivir suspension</b>	<b>Dispenser size to use (grading 0.1 ml)</b>
30 mg	5.0 ml	5.0 ml (or 10.0 ml)
45 mg	7.5 ml	10.0 ml
60 mg	10.0 ml	10.0 ml