

**PATIENT INFORMATION LEAFLET**

## PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

### Osetamivir (as phosphate) 45 mg Capsules\*

**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 health care provider.
- 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 health care provider. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What Osetamivir (as phosphate) 45 mg Capsules is and what it is used for
2. What you need to know before you take Osetamivir (as phosphate) 45 mg Capsules
3. How to take Osetamivir (as phosphate) 45 mg Capsules
4. Possible side effects
5. How to store Osetamivir (as phosphate) 45 mg Capsules
6. Contents of the pack and other information

#### 1. WHAT OSELTAMIVIR (AS PHOSPHATE) 45 MG CAPSULES IS AND WHAT IT IS USED FOR

- Osetamivir (as phosphate) 45 mg Capsules 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.
- Osetamivir (as phosphate) 45 mg Capsules 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.
- Osetamivir (as phosphate) 45 mg Capsules 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.
- Osetamivir (as phosphate) 45 mg Capsules contains osetamivir, 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 sudden fever (temperature more than 37.8 °C), cough, runny or stuffy nose, headaches, muscle ache and extreme tiredness. These symptoms can also be caused by other infections. True influenza occurs only during annual outbreaks (epidemics) when flu viruses are spreading in the

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\* Trade names are not prequalified by WHO. This is under the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

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 OSELTAMIVIR (AS PHOSPHATE) 45 MG CAPSULES**

### **Do not take Osetamivir (as phosphate) 45 mg Capsules:**

- if you are allergic to osetamivir, or to any of the other ingredients of this medicine (listed in Section 6).

Talk to your health care provider if this applies to you.

### **Warnings and precautions**

Talk to your health care provider before taking Osetamivir (as phosphate) 45 mg Capsules:

- 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 Osetamivir (as phosphate) 45 mg Capsules, tell a health care provider **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.

### **Osetamivir (as phosphate) 45 mg Capsules is not a flu vaccine**

Osetamivir (as phosphate) 45 mg Capsules is not a vaccine - it treats infection or prevents the flu virus spreading. A vaccine gives you antibodies against the virus. Osetamivir (as phosphate) 45 mg Capsules will not change the effectiveness of a flu vaccine and you might be prescribed both by your health care provider.

### **Other medicines and Osetamivir (as phosphate) 45 mg Capsules**

Tell your health care provider 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 a number of conditions including rheumatoid arthritis)
- phenylbutazone (used to treat pain and inflammation)
- probenecid (used to treat gout)

### **Pregnancy and breastfeeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your health care provider for advice before taking this medicine.

This can help your health care provider decide if Osetamivir (as phosphate) 45 mg Capsules right for you.

### **Driving and using machines**

Osetamivir (as phosphate) 45 mg Capsules has no effect on your ability to drive or use machines.

### 3. HOW TO TAKE OSELTAMIVIR (AS PHOSPHATE) 45 MG CAPSULES

Always take this medicine exactly as your health care provider has told you. Check with your health care provider if you are not sure.

Take Oseltamivir (as phosphate) 45 mg Capsules 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 full 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 weak immune system, treatment will continue for up to 6 or 12 weeks.

**The recommended dose is based on the patient's body weight.** A liquid (an *oral suspension*) made up from Oseltamivir (as phosphate) 45 mg Capsules can be used by people who find it hard to take capsules or if Oseltamivir (as phosphate) 45 mg Capsules does not contain the right dose of oseltamivir for you. You must use the amount of oral suspension prescribed by your health care provider.

#### Adults and adolescents aged over 13 years

Body weight	Treating flu: Dose for 5 days	Preventing flu: Dose for 10 days
40 kg or more	75 mg <sup>1</sup> twice daily	75 mg <sup>1</sup> once daily

1. The 75-mg dose can be made up of a 30-mg capsule and a 45-mg capsule; alternatively, a 75-mg capsule may be used

#### Children aged 1 to 12 years

Body weight	Treating flu: Dose for 5 days	Preventing flu: Dose for 10 days
10 to 15 kg	30 mg twice daily	30 mg once daily
15 kg to 23 kg	45 mg twice daily	45 mg once daily
23 kg to 40 kg	60 mg twice daily	60 mg once daily
40 kg or more	75 mg <sup>1</sup> twice daily	75 mg <sup>1</sup> once daily

1. The 75-mg dose can be made up of a 30-mg capsule and a 45-mg capsule; alternatively, a 75-mg capsule may be used

#### Infants aged less than 1 year

The decision to give Oseltamivir (as phosphate) 45 mg Capsules to infants aged under 1 year should be based on the health care provider's judgment after considering the potential benefit any potential harm to the infant. Only limited information is available for infants aged less than 2 years, and there are no data for infants aged less than 1 month.

Age of infant	Treating flu: Dose for 5 days	Preventing flu: Dose for 10 days
< 12 months	3 mg/kg twice daily	3 mg/kg once daily

'mg/kg' means the number of milligrams of oseltamivir for each kilogram of the infant's body weight. For example, the dose for treating flu in an infant aged 6 months, weighing 8 kg is: 3 x 8 = 24 mg twice daily

### **Method of administration**

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

Oseltamivir (as phosphate) 45 mg Capsules can be taken with or without food, but 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 (*oral suspension*). If you need oseltamivir as a liquid (*oral suspension*) but a ready-made liquid is not available, you can make a suspension from these capsules. See below, under ‘**Making oseltamivir suspension at home**’, for instructions.

### **If you take more Oseltamivir (as phosphate) 45 mg Capsules than you should**

Stop taking Oseltamivir (as phosphate) 45 mg Capsules and contact a health care provider immediately.

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

Overdose has been reported more frequently when Oseltamivir (as phosphate) 45 mg Capsules was given to children than to adults and adolescents. Care is needed when preparing a liquid from Oseltamivir (as phosphate) 45 mg Capsules for children and when giving Oseltamivir (as phosphate) 45 mg Capsules to children.

### **If you forget to take Oseltamivir (as phosphate) 45 mg Capsules**

Do not take a double dose to make up for a forgotten dose of Oseltamivir (as phosphate) 45 mg Capsules.

### **If you stop taking Oseltamivir (as phosphate) 45 mg Capsules**

There are no side effects when you stop Oseltamivir (as phosphate) 45 mg Capsules. But if Oseltamivir (as phosphate) 45 mg Capsules is stopped earlier than your health care provider told you, the symptoms of flu may come back. Always complete the course that your health care provider prescribed.

If you have any further questions on the use of this medicine, ask your health care provider.

## **4. POSSIBLE SIDE EFFECTS**

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

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 whites 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.**

**Very common and common side effects:**

The most frequently (very common and common) reported side effects of Oseltamivir (as phosphate) 45 mg Capsules are feeling or being sick (nausea, vomiting), stomachache, stomach upset, headache and pain. These side effects mostly occur after the first dose of the medicine and usually stop as treatment continues. Taking Oseltamivir (as phosphate) 45 mg Capsules with food reduces the frequency of these effects.

**Rare but serious side effects: get medical help at once**

*(may affect up to 1 in 1000 people)*

During treatment with oseltamivir, rare events have been reported that include

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

These effects are reported mainly among children and adolescents. They often start suddenly and improve rapidly. A few cases have resulted in self-injury, some with fatal outcome. Such neuropsychiatric events have also been reported in patients with influenza who were not taking Oseltamivir (as phosphate) 45 mg Capsules.

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

**Other side effects**

**Adults and adolescents aged 13 to 17 years**

**Children aged 1 to 12 years**

**Very common side effects (may affect more than 1 in 10 people)**

- |  |   |
|--|---|
| <ul style="list-style-type: none"> <li>• Headache</li> <li>• Nausea</li> </ul> | <ul style="list-style-type: none"> <li>• Cough</li> <li>• Nasal congestion</li> <li>• Vomiting</li> </ul> |
|--|---|

**Common side effects (may affect up to 1 in 10 people)**

- |   |   |
|---|---|
| <ul style="list-style-type: none"> <li>• Bronchitis</li> <li>• Cold sore virus</li> <li>• Cough</li> <li>• Dizziness</li> <li>• Fever</li> <li>• Pain</li> <li>• Pain in limb</li> <li>• Runny nose</li> <li>• Sleeping difficulties</li> <li>• Sore throat</li> <li>• Stomach ache</li> <li>• Tiredness</li> <li>• Upper abdominal fullness</li> <li>• Upper respiratory tract infections (inflammation of the nose, throat and sinuses)</li> <li>• Upset stomach</li> <li>• Vomiting</li> </ul> | <ul style="list-style-type: none"> <li>• Conjunctivitis (red eyes and discharge or pain in the eye)</li> <li>• Ear inflammation and other ear disorders</li> <li>• Headache</li> <li>• Nausea</li> <li>• Runny nose</li> <li>• Stomach ache</li> <li>• Upper abdominal fullness</li> <li>• Upset stomach</li> </ul> |
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**Adults and adolescents aged 13 to 17 years****Children aged 1 to 12 years**

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**Uncommon side effects** (may affect up to 1 in 100 people)

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|---|---|
| <ul style="list-style-type: none"><li>• Allergic reactions</li><li>• Altered level of consciousness</li><li>• Convulsion</li><li>• Heart rhythm abnormalities</li><li>• Mild to severe liver function disorders</li><li>• Skin reactions (inflammation of the skin, red and itchy rash, scaling skin)</li></ul> | <ul style="list-style-type: none"><li>• Inflammation of the skin</li><li>• Tympanic membrane (eardrum) disorder</li></ul> |
|---|---|
- 

**Rare side effects** (may affect up to 1 in 1000 people)

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|---|--|
| <ul style="list-style-type: none"><li>• Thrombocytopenia (low platelet count)</li><li>• Visual disturbances</li></ul> |  |
|---|--|
- 

**Infants aged less than 1 year**

The reported side effects in infants 0 to 12 months old are 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 health care provider. Tell your health care provider **as soon as possible** if:

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

**Reporting of side effects**

If you get any side effects, talk to your health care provider. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the local reporting system.

**5. HOW TO STORE Oseltamivir (as phosphate) 45 mg Capsules**

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

Do not use this medicine after the expiry date stated on the label. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in dry place and protect from light.

Store capsules in blisters in the provided carton to protect from light.

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

**6. CONTENTS OF THE PACK AND OTHER INFORMATION****What Oseltamivir (as phosphate) 45 mg Capsules contains**

The active substance is oseltamivir. Each hard capsule contains oseltamivir phosphate USP 59.12 mg equivalent to 45 mg of oseltamivir.

The other ingredients are:

*Capsule fill:* croscarmellose sodium, povidone, pregelatinised starch, sodium stearyl fumarate and talc.

*Capsule shell:* gelatin, iron oxide black and titanium dioxide.

*Printing ink:* FD&C Blue # 2 Aluminium Lake (Indigo Carmine) and shellac.

### **What Oseltamivir (as phosphate) 45 mg Capsules looks like and contents of the pack**

Oseltamivir (as phosphate) 45 mg Capsules are hard gelatin capsules size '4' with grey cap and grey body, containing white to off white granules, imprinted with "45 mg" on the cap and "M 54" on the body with blue ink.

Oseltamivir (as phosphate) 45 mg Capsules are available in clear PVC/PE/PVdC-Al blisters. 10 capsules per blister card, 10 cards per carton (10x10) or, 10 capsules per blister card, 1 card per carton (10x1).

### **Supplier and Manufacturer**

#### **Supplier**

Macleods Pharmaceuticals Limited  
304, Atlanta Arcade  
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Andheri (East)  
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#### **Manufacturer**

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For any information about this medicinal product, please contact the supplier.

**This leaflet was first approved in June 2017**

Section 6 updated in October 2019.

Detailed information on this medicine is available on the World Health Organization (WHO) web site:  
<https://extranet.who.int/prequal>.



## Information for the user

### Making oseltamivir suspension at home

When neither commercially manufactured nor pharmacy compounded oseltamivir suspension is available, an oseltamivir suspension can be made up at home.

- **If you have the right capsule** for the dose needed (45-mg dose), you need to open the capsule and stir its contents into one teaspoon (or less) of a suitable sweetened food product. See **Part A** of the instructions below.
- **If you need smaller doses**, making a suspension from capsules involves extra steps. This is suitable for patients weighing less than 45 kg. See **Part B** of the instructions below.

### PART A: you have the right capsule for the dose

Children aged 1 to 12 years who need to take 45-mg dose of oseltamivir

You need:

- **One Oseltamivir (as phosphate) 45 mg Capsule USP** (each containing 45 mg oseltamivir)
- **Sharp scissors**
- **One small bowl**
- **Teaspoon (5-ml spoon)**
- **Sweet food** to hide the bitter taste of oseltamivir powder  
Examples are: chocolate or cherry syrup, dessert topping such as caramel or fudge sauce. Or you can make sugar water by mixing three-quarters ( $\frac{3}{4}$ ) of a teaspoonful of sugar with a teaspoon of water.

#### 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.

Body weight	Dose of oseltamivir	Number of capsules
15 kg to 23 kg	45 mg	One 45-mg capsule

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 45-mg capsules for 45-mg doses. Do not try to make a 45-mg dose by using the contents of 30-mg capsules.

#### Step 2: pour all the powder in the bowl

Hold a 45-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 suspension and give it to the patient

Add a small amount of sweet food—no more than one teaspoon—to the powder in the bowl. This is to hide the bitter taste of the oseltamivir powder.

Stir the mixture well.

**Give the whole contents** of the bowl to the patient straightaway.

**If there is any mixture left** in the bowl, rinse the bowl with a small amount of water and get the patient to drink it all. This is to make sure that the patient gets the full dose.

**Repeat these three steps every time you need to give the medicine.**

### PART B: you need to give a smaller dose

**Infants aged under 1 year** (weighing up to 10 kg) and **children weighing less than 23 kg** who need to take smaller doses of oseltamivir

You need:

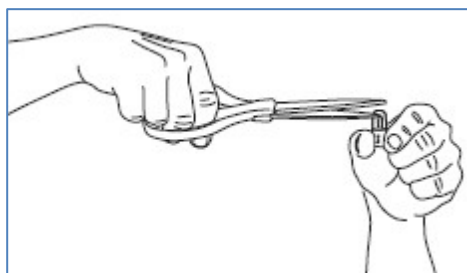
- **One Oseltamivir (as phosphate) 45 mg Capsule USP** (containing 45 mg oseltamivir)
- **Sharp scissors**
- **Two small bowls**
- **One large oral dose dispenser** to measure out water a—5-ml or 10-ml dispenser
- **One small oral dose dispenser** showing measurements of 0.1 ml, to give the dose
- **Teaspoon (5-ml spoon)**
- **Water**
- **Sweet food** to hide the bitter taste of oseltamivir powder  
Examples are: chocolate or cherry syrup, dessert topping such as caramel or fudge sauce. Or you can make sugar water by mixing three-quarters ( $\frac{3}{4}$ ) of a teaspoonful of sugar with a teaspoon of water.

#### Step 1: pour all the powder into the bowl

Hold a 45-mg capsule upright over one of the bowls and carefully snip off the rounded tip with scissors.

Pour **all** of the powder into the bowl, whatever dose you are making

Be careful with the powder, because it may irritate your skin or eyes.



#### Step 2: add water to dilute the medicine

Use the larger dispenser to draw up **7.5 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 the powder does not dissolve completely. The undissolved powder is just inactive ingredients.

**Step 3: Measure out the correct amount for your child's age and weight**

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

Then look under 'How much mixture to draw up' which shows how much of the liquid mixture you need to draw up. The last column suggests suitable dispenser size to use.

**Infants less than 1 year (including full-term newborn babies) (oseltamivir dose 3 mg/kg)**

<b>Weight (nearest)</b>	<b>Oseltamivir dose</b>	<b>How much mixture to draw up</b>	<b>Dispenser size to use (measurements of 0.1 ml)</b>
3 kg	9 mg	1.5 ml	2-ml (or 3-ml)
3.5 kg	10.5 mg	1.8 ml	2-ml (or 3-ml)
4 kg	12 mg	2.0 ml	3-ml
4.5 kg	13.5 mg	2.3 ml	3-ml
5 kg	15 mg	2.5 ml	3-ml
5.5 kg	16.5 mg	2.8 ml	3-ml
6 kg	18 mg	3.0 ml	3-ml (or 5-ml)
6.5 kg	19.5 mg	3.3 ml	5-ml
7 kg	21 mg	3.5 ml	5-ml
7.5 kg	22.5 mg	3.8 ml	5-ml
8 kg	24 mg	4.0 ml	5-ml
8.5 kg	25.5 mg	4.3 ml	5-ml
9 kg	27 mg	4.5 ml	5-ml
9.5 kg	28.5 mg	4.8 ml	5-ml
10 kg	30 mg	5.0 ml	5-ml

**Children over 1 year, weighing less than 23 kg**

<b>Weight (nearest)</b>	<b>Oseltamivir dose</b>	<b>How much mixture to draw up</b>	<b>Dispenser size to use (measurements of 0.5 ml)</b>
10–15 kg	30 mg	5 ml	5-ml
15–23 kg	45 mg	7.5 ml	10-ml

**Step 4: draw up the liquid mixture**

Make sure you have the right size of dispenser

Draw up the correct amount of liquid mixture from the first bowl. Make sure there are no bubbles in the mixture when you measure the amount drawn up.



Gently squirt the correct dose from the dispenser into the second bowl.



**Step 5: sweeten and give to the child**

Add a small amount of sweet food—no more than one teaspoon—to the second bowl. This is to hide the bitter taste of the oseltamivir.

Mix the sweet food and oseltamivir liquid well.

**Give the whole contents** of the second bowl (oseltamivir in the sweet food) to the child straightaway.

**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. If the child cannot drink from the bowl, use a spoon or use a bottle to feed the child the remaining liquid. This is to make sure that the child gets the full dose.

Give the child something to drink after taking the medicine.

**Throw away any liquid left in the first bowl.**

**Repeat these five steps every time you need to give the medicine.**