

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Oseltamivir (as phosphate) Capsules 75 mg*

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, health care provider 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, health care provider or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Oseltamivir (as phosphate) Capsules 75 mg is and what it is used for
2. What you need to know before you take Oseltamivir (as phosphate) Capsules 75 mg
3. How to take Oseltamivir (as phosphate) Capsules 75 mg
4. Possible side effects
5. How to store Oseltamivir (as phosphate) Capsules 75 mg
6. Contents of the pack and other information

1. WHAT OSELTAMIVIR (AS PHOSPHATE) CAPSULES 75 mg IS AND WHAT IT IS USED FOR

Oseltamivir (as phosphate) Capsules 75 mg is generally used for adults, adolescents, infants and children 1 year old and older.

- Oseltamivir (as phosphate) Capsules 75 mg is used for **treating flu** (*influenza*). It can be used when you have flu symptoms, and the flu virus is going round in your community.
- Oseltamivir (as phosphate) Capsules 75 mg can also be used for **preventing flu**, for example, if you have been in contact with someone who has flu.
- Oseltamivir (as phosphate) Capsules 75 mg may be used 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.

During a flu pandemic, Oseltamivir (as phosphate) Capsules 75 mg can also be used to **treat or prevent flu in babies below 1 year of age**. Doctors or health care providers should make decisions on whether to use Oseltamivir (as phosphate) Capsules 75 mg in babies of this age, based on the severity of the disease caused by the flu virus and the baby's state of health, to ensure that the baby is likely to benefit from the medicine.

Oseltamivir (as phosphate) Capsules 75 mg 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.

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

Oseltamivir (as phosphate) Capsules 75 mg
(Mylan Laboratories Ltd), IN011

WHOPAR Part 3

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 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) CAPSULES 75 mg

Do not take Oseltamivir (as phosphate) Capsules 75 mg:

- if you are allergic (*hypersensitive*) to oseltamivir, or to any of the other ingredients of Oseltamivir (as phosphate) Capsules 75 mg (listed in Section 6).

Warnings and precautions

Before you take Oseltamivir (as phosphate) Capsules 75 mg, make sure your doctor or health care provider 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 Oseltamivir (as phosphate) Capsules 75 mg, tell a doctor or 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.

Oseltamivir (as phosphate) Capsules 75 mg is not a flu vaccine

Oseltamivir (as phosphate) Capsules 75 mg is not a vaccine—it treats infection or prevents the flu virus spreading. A vaccine gives you antibodies against the virus. Oseltamivir (as phosphate) Capsules 75 mg will not change the effectiveness of a flu vaccine and you might be prescribed both by your doctor.

Oseltamivir (as phosphate) Capsules 75 mg contains FD&C yellow # 6 (Sunset yellow FCF), which may cause allergic reactions.

Other medicines and Oseltamivir (as phosphate) Capsules 75 mg

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

Pregnancy and breastfeeding

You must tell your doctor or health care provider if you are pregnant, if you think you are pregnant or if you are trying to get pregnant. This can help your doctor or health care provider decide if Oseltamivir (as phosphate) Capsules 75 mg is right for you.

Oseltamivir (as phosphate) Capsules 75 mg WHOPAR Part 3
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The effects of Oseltamivir (as phosphate) Capsules 75 mg on breast-fed infants are not known. You must tell your doctor or health care provider if you are breast-feeding so that your doctor or health care provider can decide if Oseltamivir (as phosphate) Capsules 75 mg is right for you.

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

Driving and using machines

Oseltamivir (as phosphate) Capsules 75 mg has no effect on your ability to drive or use machines.

3. HOW TO TAKE OSELTAMIVIR (AS PHOSPHATE) CAPSULES 75 mg

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

Take Oseltamivir (as phosphate) Capsules 75 mg 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) Capsules 75 mg can be used by people who find it hard to take capsules or if Oseltamivir (as phosphate) Capsules 75 mg does not contain the right dose of oseltamivir for you. You must use the amount of oral suspension prescribed by your doctor or health care provider.

Adults and adolescents aged over 13 years

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

Children aged 1 to 12 years

Body weight	Treating flu: <i>Dose for 5 days</i>	Preventing flu: <i>Dose for 10 days</i>
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 twice daily	75 mg once daily

Infants aged less than 1 year

The decision to give Oseltamivir (as phosphate) Capsules 75 mg to infants aged under 1 year should be based on the doctor's or 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
Birth to 1 month	2 mg/kg twice daily	2 mg/kg once daily
1 month to 3 months	2.5 mg/kg twice daily	2.5 mg/kg once daily
3 months to 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:

$$3 \times 8 = 24 \text{ mg twice daily}$$

Method of administration

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

Oseltamivir (as phosphate) Capsules 75 mg can be taken with or without food, but taking it with food can reduce the chance of feeling or being sick (nausea or vomiting).

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) Capsules 75 mg than you should

Stop taking Oseltamivir (as phosphate) Capsules 75 mg and contact a doctor, pharmacist or 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) Capsules 75 mg was given to children than to adults and adolescents. Care is needed when preparing a liquid from Oseltamivir (as phosphate) Capsules 75 mg for children and when giving Oseltamivir (as phosphate) Capsules 75 mg to children.

If you forget to take Oseltamivir (as phosphate) Capsules 75 mg

Do not take a double dose to make up for a forgotten dose of Oseltamivir (as phosphate) Capsules 75 mg.

If you stop taking Oseltamivir (as phosphate) Capsules 75 mg

There are no side effects when you stop Oseltamivir (as phosphate) Capsules 75 mg. But if Oseltamivir (as phosphate) Capsules 75 mg is stopped earlier than your doctor or health care provider told you, the symptoms of flu may come back. Always complete the course that your doctor or health care provider prescribed.

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

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) Capsules 75 mg 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) Capsules 75 mg with food reduces the frequency of these effects.

Rare side effects: get medical help at once

(Up to 1 in 1000 people are likely to get these)

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) Capsules 75 mg.

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

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"> • Headache • Nausea 	<ul style="list-style-type: none"> • Cough • Nasal congestion • Vomiting
Common side effects (may affect up to 1 in 10 people)	
<ul style="list-style-type: none"> • Bronchitis • Cold sore virus • Cough • Dizziness • Fever • Pain • Pain in limb • Runny nose • Sleeping difficulties • Sore throat • Stomach ache 	<ul style="list-style-type: none"> • 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

Adults and adolescents aged 13 to 17 years	Children aged 1 to 12 years
<ul style="list-style-type: none"> • Tiredness • Upper abdominal fullness • Upper respiratory tract infections (inflammation of the nose, throat and sinuses) • Upset stomach • Vomiting 	
<p>Uncommon side effects (may affect up to 1 in 100 people)</p>	
<ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • Inflammation of the skin • Tympanic membrane (eardrum) disorder
<p>Rare side effects (may affect up to 1 in 1000 people)</p>	
<ul style="list-style-type: none"> • Thrombocytopenia (low platelet count) • Visual disturbances 	

Infants aged less than 1 year

The reported side effects in infants 1 to 12 months old are similar to the side effects reported for older children (1 year old or older).

Infants aged less than 1 month

There is no information on the use of Oseltamivir (as phosphate) Capsules 75 mg in infants aged less than 1 month.

If any of the side effects get serious or if you notice any side effects not listed in this leaflet, tell your doctor, health care provider or pharmacist. Tell your doctor or health care provider **as soon as possible** if:

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

5. HOW TO STORE OSELTAMIVIR (AS PHOSPHATE) CAPSULES 75 mg

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 the original container.

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) Capsules 75 mg contains

Each hard capsule contains oseltamivir equivalent to 75 mg of oseltamivir.

The other ingredients are

Capsule core: Croscarmellose sodium, povidone, pregelatinised starch, sodium stearyl fumarate, talc.

Capsule shell: D&C yellow #10 (E104), FD&C yellow # 6 (Sunset yellow FCF, E110), gelatin, titanium dioxide (E171)

Printing ink: Black iron oxide (E172), potassium hydroxide, propylene glycol, shellac.

What Oseltamivir (as phosphate) Capsules 75 mg looks like and contents of the pack

Oseltamivir (as phosphate) Capsules 75 mg are hard-shell gelatin capsule with white yellow opaque cap and white opaque body imprinted axially with 'MYLAN' over 'OS3' in black ink on both cap and body. The capsules are filled with white to off-white powder.

HDPE bottle pack

Round wide mouth white HDPE bottle with white opaque polypropylene screw cap. 30 capsules per bottle.

PVC blister pack

Clear transparent PVC-Al blisters. 10 capsules per card.

Triplex blister pack

Clear transparent, PVC/PE/PVDC-Al blisters. 10 capsules per card.

Supplier and Manufacturer

Supplier

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Manufacturer

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

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This leaflet was last approved in February 2015. Section 6 updated in March 2017.

Detailed information on this medicine is available on the World Health Organization (WHO) web site:
<http://www.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 (75-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

Adults, adolescents aged over 13 years and children weighing over 40 kg who need to take 75-mg dose of oseltamivir

You need:

- **One Oseltamivir (as phosphate) Capsule 75 mg** (each containing 75 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
Over 40 kg	75 mg	One 75-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.



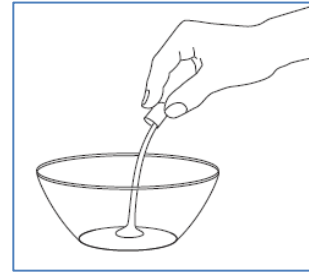
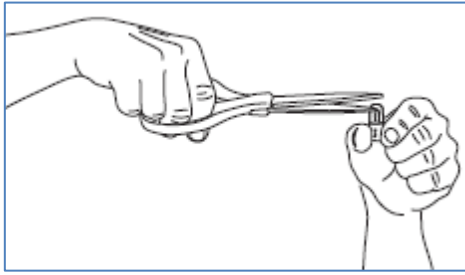
You should use only 75-mg capsules for 75-mg doses.

Step 2: pour all the powder in the 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 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 osetamivir 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 40 kg** who need to take smaller doses of osetamivir

You need:

- **One Osetamivir (as phosphate) Capsule 75 mg** (containing 75 mg osetamivir)
- **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 osetamivir powder

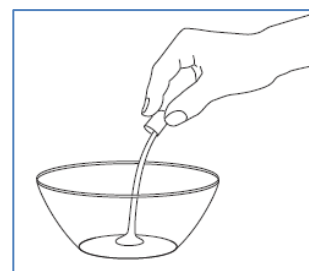
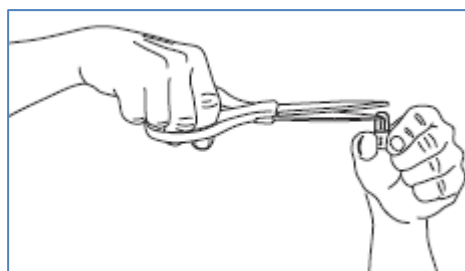
Examples are: chocolate or cherry syrup, dessert topping such as caramel or fudge sauce. Or you can make sugar water by mixing three-quarters ($\frac{3}{4}$) of a teaspoonful of sugar with a teaspoon of water.

Step 1: pour all the powder into the bowl

Hold a 75-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

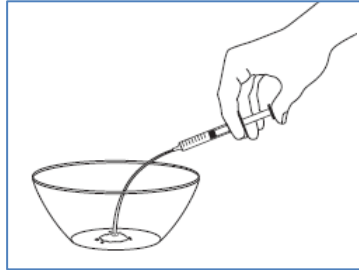
Be careful with the powder, because it may irritate your skin or eyes.



Step 2: add water to dilute the medicine

Use the larger dispenser to draw up **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 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

Find the table for your child's age. There are three—birth to 1 month; 1 month to 3 months; and 3 months to 12 months.

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.

Infant from birth to 1 month (oseltamivir dose 2 mg/kg)

Weight (nearest)	Oseltamivir dose	How much mixture to draw up	Dispenser size to use (measurements of 0.1 ml)
3 kg	6 mg	1.0 ml	1-ml (or 2-ml)
3.5 kg	7 mg	1.2 ml	1-ml (or 2-ml)
4 kg	8 mg	1.3 ml	1-ml (or 2-ml)
4.5 kg	9 mg	1.5 ml	1-ml (or 2-ml)

Infant aged 1 month to 3 months (oseltamivir dose 2.5 mg/kg)

Weight (nearest)	Oseltamivir dose	How much mixture to draw up	Dispenser size to use (measurements of 0.1 ml)
4 kg	10 mg	1.7 ml	2-ml (or 3-ml)
4.5 kg	11.25 mg	1.9 ml	2-ml (or 3-ml)
5 kg	12.5 mg	2.1 ml	3-ml
5.5 kg	13.75 mg	2.3 ml	3-ml
6 kg	15 mg	2.5 ml	3-ml
6.5 kg	16.25 mg	2.7 ml	3-ml

Infant aged 3 months to 12 month (oseltamivir dose 3 mg/kg)

Weight (nearest)	Oseltamivir dose	How much mixture to draw up	Dispenser size to use (measurements of 0.1 ml)
6 kg	18 mg	3 ml	3-ml (or 5-ml)
6.5 kg	19.5 mg	3.3 ml	
7 kg	21 mg	3.5 ml	5-ml
8 kg	24 mg	4 ml	5-ml
9 kg	27 mg	4.5 ml	5-ml
10 kg or more	30 mg	5 ml	5-ml

Children over 1 year, weighing less than 40 kg

Weight (nearest)	Oseltamivir dose	How much mixture to draw up	Dispenser size to use (measurements of 0.5 ml)
10–15 kg	30 mg	5 ml	5-ml
15–23 kg	45 mg	7.5 ml	10-ml
23–40 kg	60 mg	10 ml	10-ml

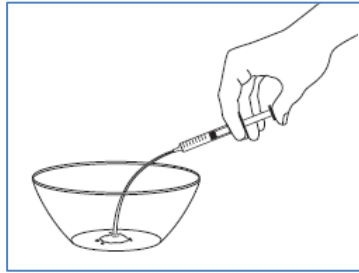
Step 4: draw up the liquid mixture

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.