

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

*https://extranet.who.int/prequal/sites/default/files/documents/75%20SRA%20clarification_February2017_0.pdf

Information for the patient

[IN020 trade name][†]
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 questions about the medicine, 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 seem to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [IN020 trade name] is and what it is used for
2. What you need to know before you take [IN020 trade name]
3. How to take [IN020 trade name]
4. Possible side effects
5. How to store [IN020 trade name]
6. Contents of the pack and other information

1. What [IN020 trade name] is and what it is used for

- [IN020 trade 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.
- [IN020 trade 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.
- [IN020 trade 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.
- [IN020 trade 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 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.

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

2. What you need to know before you take [IN020 trade name]

Do not take [IN020 trade name]:

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

Talk to your healthcare provider if this applies to you.

Warnings and precautions

Talk to your healthcare provider before taking [IN020 trade name]:

- 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 properly or if you are taking medications to suppress your immune system (e.g. after an organ transplant or treatment for an auto-immune disease)
- if you have chronic heart disease or respiratory disease.

During treatment with [IN020 trade name], tell a healthcare 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.

[IN020 trade name] is not a flu vaccine

[IN020 trade name] is not a vaccine - it treats infection or prevents the flu virus spreading. A vaccine gives you antibodies against the virus. [IN020 trade name] will not change the effectiveness of a flu vaccine and you might be prescribed both by your healthcare provider.

Other medicines and [IN020 trade name]

Tell your healthcare 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 several conditions including rheumatoid arthritis)
- phenylbutazone (used to treat pain and inflammation)
- probenecid (used to treat gout)

Pregnancy and breastfeeding

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

The effects on breastfed infants are not known. If you are breastfeeding, ask your healthcare provider for advice before taking this medicine.

Your healthcare provider can decide if [IN020 trade name] is right for you.

Driving and using machines

[IN020 trade name] has no effect on your ability to drive or use machines.

3. How to take [IN020 trade name]

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

Take [IN020 trade 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 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 [IN020 trade name] can be used by people who find it hard to take capsules or if [IN020 trade name] does not contain the right dose of oseltamivir for you. You must use the amount of oral suspension prescribed by your healthcare 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 ¹ twice daily	75 mg ¹ once daily

¹The 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 kg to 15 kg	30 mg twice daily	30 mg twice daily
15 kg to 23 kg	45 mg twice daily	45 mg twice daily
23 kg to 40 kg	60 mg twice daily	60 mg twice daily
40 kg or more	75 mg ¹ twice daily	75 mg ¹ twice daily

¹The 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 [IN020 trade name] to infants aged under 1 year should be based on the healthcare provider's judgment after considering the potential benefit versus 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.

The recommended treatment dose for infants 0 - 12 months of age is 3 mg/kg twice 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.

Body weight*	Treating flu Dose for 5 days	Preventing flu Dose for 10 days
3 kg	9 mg twice daily	9 mg once daily
4 kg	12 mg twice daily	12 mg once daily
5 kg	15 mg twice daily	15 mg once daily
6 kg	18 mg twice daily	18 mg once daily

Body weight*	Treating flu Dose for 5 days	Preventing flu Dose for 10 days
7 kg	21 mg twice daily	21 mg once daily
8 kg	24 mg twice daily	24 mg once daily
9 kg	27 mg twice daily	27 mg once daily
10 kg	30 mg twice daily	30 mg once daily

* This table is not intended to contain all possible weights for this population. For all patients under the age of 1 year, 3 mg/kg should be used to determine dose regardless of the weight of the patient.

How to take [IN020 trade name]

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

[IN020 trade name] 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, 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 [IN020 trade name] than you should

Stop taking [IN020 trade name] and contact your healthcare provider immediately.

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

Overdose has been reported more frequently when [IN020 trade name] was given to children than to adults and adolescents. Care is needed when preparing a liquid from [IN020 trade name] for children and when giving [IN020 trade name] to children.

If you forget to take [IN020 trade name]

If you forget to take a dose of [IN020 trade name], you should take the next capsule when it is time. Do not take a double dose to make up for a forgotten dose of [IN020 trade name].

If you stop taking [IN020 trade name]

There are no side effects when you stop [IN020 trade name]. But if [IN020 trade name] is stopped earlier than your healthcare provider told you, the symptoms of flu may come back. Always complete the course that your healthcare provider prescribed.

Making oseltamivir suspension at home

When commercially manufactured oseltamivir oral suspension is not available, a pharmacy compounded suspension prepared from oseltamivir capsules must be used. If the commercially manufactured oseltamivir oral suspension and the pharmacy compounded suspension are also not available, oseltamivir suspension may be prepared at home.

Instructions for preparing oseltamivir suspension at home are provided in the section, "Information for the user"

If you have any further questions on the use of this medicine, ask your healthcare 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. **If you notice any of these symptoms, get medical help immediately:**

- Anaphylactic and anaphylactoid reactions - severe allergic reactions, with face and skin swelling, itchy rashes, low blood pressure and breathing difficulties
- Liver 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 - bleeding from your stomach or intestines
- Neuropsychiatric disorders, as described below.

Very common and common side effects:

(may affect 1 in 10 people or more)

Very common and commonly reported side effects of [IN020 trade name] 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 usually stop as treatment continues. Taking [IN020 trade name] 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 neuropsychiatric events have been reported that include:

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

These side effects have been 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 [IN020 trade name].

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

Tabulated list of 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)	
Headache Nausea	Cough Nasal congestion Vomiting
Common side effects (may affect up to 1 in 10 people)	
Bronchitis Cold sore virus Runny nose Sore throat	Conjunctivitis (pink eye) Earache Headache Nausea

Adults and adolescents aged 13 to 17 years	Children aged 1 to 12 years
Inflammation of the nose throat or sinuses Cough Vomiting Stomach ache Indigestion Pain in the arm or leg Dizziness Fever Tiredness	Runny nose Stomach ache Upset stomach Indigestion
Uncommon side effects (may affect up to 1 in 100 people)	
Allergic reactions Altered level of consciousness Convulsion Irregular or fast heart beat Abnormal liver function tests Skin reactions, including inflammation or an itchy rash	Inflammation of the skin Tympanic membrane (ear drum) disorder
Rare side effects (may affect up to 1 in 1000 people)	
Low platelet count Visual disturbances Inflammation of the liver Liver failure	

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 healthcare provider. Tell your healthcare 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 unwanted effects not listed in this leaflet. If available, you can also report side effects directly through the national reporting system. By reporting side effects, you can help improve understanding about the safety of this medicine.

5. How to store [IN020 trade name]

Do not store above 30°C. Protect from moisture.

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

Do not use this medicine after the expiry date stated on the carton or blister card, after “EXP”. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your 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 [IN020 trade name] contains

- The active ingredient is oseltamavir phopshate
- The other ingredients of [IN020 trade name] are:

Capsule core:

Pregelatinised starch
Povidone
Croscarmellose sodium
Talc
Sodium stearyl fumarate

Capsule shell:

Gelatin
Iron oxide red (E172)
Iron oxide yellow (E172)
Iron oxide black (E172)
Titanium dioxide (E171)

Printing ink:

Shellac (E904)
Iron oxide black (E172)
Potassium hydroxide (E525)

What [IN020 trade name] looks like and contents of the pack

White to off-white powder, filled in size “2” hard gelatin capsules with a grey, opaque colour body with a black-coloured band, imprinted with “M” and having a light-yellow opaque colour cap imprinted with “75 mg”.

[IN020 trade name] is packed a clear, transparent PVC/PE/PVDC-Alu blister card of 10 capsules.
Pack sizes: 1, 3 or 10 blister cards packed in a carton.

Supplier and Manufacturer

Supplier

MSN Laboratories Private Limited
“MSN House”, Plot No. C-24
Industrial Estate
Sanath Nagar
Hyderabad,
Telangana 500 018, India

Tel. No.: +91-40-30438660
Fax No.: +91-40-30438798
Email: formulation@msnlabs.com

Manufacturer

MSN Laboratories Private Limited
Formulations Division, Unit-II
Survey Nos. 1277, 1319 to 1324
Nandigama (Village & Mandal)
Rangareddy District
Telangana 509228, India

Tel. No.: +91-40-30449200
Fax No.: +91-40-30449211
Email: formulation@msnlabs.com

For any information about this medicine, contact the local representative of the supplier .

This leaflet was last revised in September 2020

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

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Information for the user

For people who find it hard to take capsules, including very young children, a liquid medicine called an oral suspension is preferred, if available.

If you need the oral suspension, but it is not available, your pharmacy can prepare it for you. The pharmacy preparation is the preferred option.

If the pharmacy preparation is not available either, you can make an oseltamivir suspension from capsules at home according to the instructions given below.

Making oseltamivir suspension at home

- **If you have the right capsule** for the dose needed (75 mg dose), you will need to 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 of age. See **Part A** of the instructions below.
- **If you need smaller doses**, making oseltamivir suspension from capsules involves extra steps. This is suitable for patients weighing less than 30 kg. See **Part B** of the instructions below.

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

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

To make a 75 mg dose you need:

- **One capsule of [IN020 trade name]** (containing 75 mg oseltamivir)
- **Sharp scissors** (preferred, if available)
- **One small bowl**
- **Teaspoon (5-ml spoon)**
- **Sweet food** to hide the bitter taste of oseltamivir powder, e.g., sweet porridge 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
40 kg and over	75 mg	One 75 mg 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 in the bowl

- Wash your hands thoroughly
- Hold a 75 mg capsule upright over a bowl and carefully snip off the rounded tip with scissors.
If you do not have scissors, you can hold the capsule on both ends, and gently twist and pull to open the capsule.
- Pour all 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: If you need to give a smaller dose

Infants aged under 1 year (weighing up to 10 kg) and **children weighing less than 40 kg:**

To make a smaller single dose you need:

- **One capsule of [IN020 trade name]** (containing 75 mg oseltamivir)
- **Sharp scissors** (preferred, if available)
- **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, e.g., sweet porridge 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

- Wash your hands thoroughly
- Hold a 75 mg capsule upright over one of the bows and carefully snip off the rounded tip with scissors.

If you do not have scissors, you can hold the capsule on both ends, and gently twist and pull to open the capsule.

- Pour **all** 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

- 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.

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

Weight (nearest)	Oseltamivir dose	How much mixture to draw up
3.0 kg	9.0 mg	1.5 mL
3.5 kg	10.5 mg	1.8 mL
4.0 kg	12.0 mg	2.0 mL
4.5 kg	13.5 mg	2.3 mL
5.0 kg	15.0 mg	2.5 mL
5.5 kg	16.5 mg	2.8 mL
6.0 kg	18.0 mg	3.0 mL
6.5 kg	19.5 mg	3.3 mL
7.0 kg	21.0 mg	3.5 mL

Weight (nearest)	Oseltamivir dose	How much mixture to draw up
7.5 kg	22.5 mg	3.8 mL
8.0 kg	24.0 mg	4.0 mL
8.5 kg	25.5 mg	4.3 mL
9.0 kg	27.0 mg	4.5 mL
9.5 kg	28.5 mg	4.8 mL
10.0 kg	30.0 mg	5.0 mL

Children over 1 year, weighing less than 40 kg

Weight (nearest)	Oseltamivir dose	How much mixture to draw up
10-15 kg	30 mg	5 mL
15-23 kg	45 mg	7.5 mL
23-40 kg	60 mg	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.