

FLUHALT CAPSULES

Oseltamivir Phosphate Capsules 75mg

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If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What FLUHALT Capsules are used for

Your doctor has prescribed **FLUHALT Capsules** to you for the treatment or prevention of influenza.

How FLUHALT Capsules works

FLUHALT Capsules belongs to a group of medicines named “neuraminidase inhibitors”. These medicines prevent the influenza virus from spreading inside the body and so help to ease or prevent the symptoms arising from the influenza virus infection.

Influenza is an infection caused by the influenza virus. The signs (symptoms) of influenza include the sudden onset of fever (more than 37.8 °C), cough, runny or stuffy nose, headaches, muscle aches and often extreme fatigue. These symptoms may also be caused by infections other than influenza. True influenza infection only occurs during annual outbreaks (epidemics) at times when influenza viruses are spreading in the local community. Outside of the epidemic period, these symptoms will mainly be caused by a different type of infection or illness.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

FLUHALT Capsules are available in strength of 75mg.

This medicine is available only with a doctor’s prescription.

Before you use FLUHALT Capsules

When you must not take it

Do not take FLUHALT Capsules

- If you have previously had severe allergic reaction (hypersensitive) associated with the use of oseltamivir or to any of the capsule ingredients listed (symptoms of an allergic reaction may include skin rash, itching, difficulty breathing and swelling of face, lips, tongue and throat).
- If you develop severe skin reaction like blisters on your skin, mouth, eyes and genitals.

The expiry date refers to the last day of that month.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Talk to your doctor or pharmacist before taking this medicine if:

- You have kidney problems.
- You have serious bacterial infection with flu like symptoms such as malaise, fever and chills etc.
- You are suffering from heart problem and/or lung problem.
- You are immunocompromised (people incapable of developing a normal immune response, usually as a result of disease, malnutrition, or immunosuppressive therapy).
- You have flu, particularly in children and adolescents; you may be at an increased risk of seizures, confusion, or abnormal behaviour early during their illness while taking oseltamivir medication. If you or your child develop these symptoms, your doctor will decide whether to continue the treatment depending on the risk or benefit of continuing the treatment.

- Your child was born premature (< 37 weeks post menstrual age).

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and **FLUHALT Capsules** may interfere with each other. These include:

- Chlorpropamide (medicine used for treatment of sugar diabetes).
- Methotrexate (medicine used in treatment of cancer, autoimmune diseases and termination of pregnancy during early stages).
- Phenylbutazone (medicine used for treatment of chronic pain).

Kindly note that FLUHALT Capsules should not be substituted for influenza vaccination.

Patients should continue receiving their annual flu vaccination according to guidance on immunization practices.

Ideally influenza vaccine should not be administered within 2 weeks before or 48 hours after administration of oseltamivir unless your doctor tells you.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking **FLUHALT Capsules**.

How to take FLUHALT Capsules

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box ask your doctor or pharmacist for help.

How much to take

Take your medicine or give it to your child as instructed by your doctor. Check the label carefully for how much to take and how often to take.

Your pharmacist or doctor can help if you are not sure.

Take **FLUHALT Capsules** or give it to your child as soon as you get the prescription as this will help to slow the spread of the influenza virus in the body.

Swallow **FLUHALT Capsules** whole with water. Do not break or chew **FLUHALT Capsules**.

FLUHALT Capsules may not be suitable for all dosages and therefore, other suitable available strengths and/or dosage forms (e.g. suspension) of oseltamivir should be used in such cases.

The usual dose is as follows:

Treatment

Adolescents (13 to 17 years of age) and adults: For treatment of influenza take one **FLUHALT Capsules** 75 mg twice a day for five days. It is important to complete the whole 5 day course, even if you start to feel better quickly.

Infants 1 year of age and older, and children 2 to 12 years of age: The usual dose for treatment of influenza in children 1 year of age and older depends on the body weight of the child. Your child's doctor will recommend the appropriate dosage for your child according to your child's body weight.

Body Weight	Recommended dose for 5 days
15 kg	30 mg twice daily
> 15 kg to 23 kg	45 mg twice daily
> 23 kg to 40 kg	60 mg twice daily
> 40 kg	75 mg twice daily

Children who can swallow capsules may take **FLUHALT Capsules** 75 mg twice daily for 5 days.

Infants below 12 months of age: The recommended dose for your child is 2 mg/kg twice daily and 3 mg/kg twice daily during pandemic influenza outbreak. Your child's doctor will recommend the appropriate weight-adjusted dosing for your child.

Age	Recommended dose for 5 days
> 3 months to 12 months	3 mg/kg twice daily
>1 month to 3 months	2.5 mg/kg twice daily
0 to 1 month	2 mg/kg twice daily

If your child is less than one year of age, your child's doctors will decide if this medicine is right for your child.

Prevention

FLUHALT Capsules 75 mg can also be used for prevention of influenza following exposure to an infected individual, such as family members.

Adolescents (13 to 17 years of age) and adults: **FLUHALT Capsules** 75 mg should be taken once daily for 10 days when used to prevent influenza following exposure to an infected individual, such as family members.

Infants 1 year of age and older and children 2 to 12 years of age: Children weighing more than 40 kg and can swallow capsules may take **FLUHALT Capsules** 75 mg once daily for 10 days.

The usual dose for prevention of influenza in children depends on the body weight of the child (see table below).

Body Weight	Recommended dose for 10 days (Prevention)
15 kg	30 mg once daily
> 15 kg to 23 kg	45 mg once daily
> 23 kg to 40 kg	60 mg once daily
> 40 kg	75 mg once daily

Your child's doctor will recommend the appropriate weight-adjusted dosing for your child.

Infants below 12 months of age: The recommended prophylaxis dose for infants less than 12 months of age

during a pandemic influenza outbreak is half of the daily treatment dose.

Age	Recommended dose for 10 days (Prevention)
> 3 months to 12 months	3 mg/kg twice daily
>1 month to 3 months	2.5 mg/kg twice daily
0 to 1 month	2 mg/kg twice daily

Your child's doctor will recommend the appropriate weight-adjusted dosing prophylaxis for your child.

If your child is less than one year of age your child's doctor will consider and the potential benefit of prophylaxis versus any potential risk with **FLUHALT Capsules** to your child.

You should not give your child **FLUHALT Capsules** if your child was born premature (< 37 weeks post menstrual age).

For prevention of influenza during community outbreak **FLUHALT Capsules** 75 mg once daily is prescribed for 6 weeks.

When oseltamivir powder for oral suspension is not available

When commercially manufactured oral suspension is not available, a pharmacy preparation from **FLUHALT Capsules** can be used. If the pharmacy preparation is not available either, Your or your child's doctor may instruct you to prepare **FLUHALT Capsules** doses at home mixing its contents with no more than one teaspoon of a suitable sweetened food product. The bitter taste can be masked by products such as sugar water, chocolate syrup, cherry syrup, dessert toppings (like caramel or fudge sauce). The mixture should be stirred and given entirely to the patient. The mixture must be swallowed immediately after its preparation.

The pharmacy preparation is the preferred option in infants below 12 months of age.

Taking FLUHALT Capsules with food or drink

Swallow **FLUHALT Capsule** with water. FLUHALT Capsules can be taken with or without food, although it is recommended to take FLUHALT with food to reduce the chance of feeling or being sick (nausea or vomiting).

If you forget to take FLUHALT Capsules

If you forget to take your medicine at the right time, take them as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses. To help you remember to take your medicine, try to get into the habit of taking it at the same time each day.

If you have the impression that the effect of this medicine is too strong or too weak, talk to your doctor or pharmacist.

Follow all directions given to you by your doctor and pharmacist carefully. These instructions may differ from the information contained in this leaflet.

If you do not understand the directions on the pack, ask your doctor or pharmacist for help.

When to take it

Treatment with **FLUHALT Capsules** should be started as soon as possible within first 2 days of onset of symptoms of influenza

If you take too much (overdose)

If you take more **FLUHALT Capsules** than you should, contact your doctor or go to a hospital straight away. Take this leaflet or some capsules with you so your doctor will know what you have taken.

Immediately telephone your doctor or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much FLUHALT Capsules.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention. Keep telephone numbers of these facilities handy.

While you are taking FLUHALT CAPSULE

Things you must do

You must stop using **FLUHALT Capsules** if:

- If you have previously had severe allergic reaction (hypersensitive) associated with the use of oseltamivir or to any of the capsule ingredients.

If you experience any of the above while taking **FLUHALT Capsules**, you need to seek medical attention urgently.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking FLUHALT Capsules.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use FLUHALT Capsules, to treat any other complaints unless your doctor says to.

Things to be careful of

You must tell your doctor if you are pregnant, if you think you are pregnant or if you are planning to get pregnant, so that your doctor can decide if this medicine is right for you.

The effects on nursing infants are unknown. You must tell your doctor if you are breast-feeding or planning to breast-feed so that your doctor can decide if this medicine is right for you.

If you experience dizziness or change in vision when taking **FLUHALT Capsules**, do not drive or operate machinery.

Side Effects

Like all medicines, **FLUHALT Capsules** may cause side effects although not everybody gets them.

Very serious side effects

If any of the following happen to you or your child, stop taking FLUHALT Capsules and tell your doctor immediately or go to the casualty department at your nearest hospital.

- Rashes, hives, itching, chest constriction, shortness of breath or swelling of face, lips, tongue, hands / feet, fainting, high temperature (anaphylaxis, angioedema).
- Severe skin rashes which may include blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals [Stevens-Johnson syndrome, toxic epidermal necrolysis].

These are very serious side effects. If you have them you may have had a serious allergic reaction. You may need urgent medical attention or hospitalization.

Serious side effects

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following in you or your child:

- Convulsions and confusional state (delirium) [including symptoms such as altered level of consciousness, abnormal behaviour, false belief or opinion (delusions), seeing feeling or hearing things that are not there (hallucinations), agitation, anxiety, nightmares]
- Cough, chest pain, fever, and difficulty in breathing due to lung infection (Pneumonia)
- Wheezing, coughing, chest tightness and shortness of breath (Asthma)
- Wheezing, coughing, chest tightness and shortness of breath due to obstruction of the inflamed airways (acute bronchitis)
- Heart problems (heart rhythm abnormalities), chest pain radiating to left shoulder or feeling

of tightness or heaviness in chest (unstable angina).

- Severe diarrhoea (which may contain blood or mucous) accompanied with stomach cramps (pseudomembranous colitis).
- Yellowing of the skin or eyes, abdominal pain, unexplained fatigue, dark colored urine or pale colored stools; these may be manifestations of a liver problem.

Other side effects

Tell your doctor if you notice any of the following in you or your child:

- Cough, sore throat, runny nose, nasal congestion, headache, low grade fever, facial pressure and sneezing (upper respiratory tract infections)
- Cough sore throat, increased sputum production, runny nose, nasal congestion, fever, feeling tired etc (bronchitis)
- Difficulty falling asleep,
- Runny nose, stuffy nose, bleeding from nose.
- Stomach pain, being sick (vomiting), feeling sick (nausea),
- Diarrhoea (loose stools), upset stomach or indigestion (dyspepsia)
- Feeling unsteady or giddy (dizziness)
- Spinning sensation (vertigo)
- Tiredness
- Generalized Pain
- Headache/facial pain or pressure, runny nose due to inflammation of the paranasal sinuses (sinusitis)
- Ear pain due to middle ear infection, tympanic membrane disorder
- Headache
- Seeing strange or unusual sights (hallucinations)
- Rash and itching due to inflammation of the skin (Dermatitis)
- Hives (Urticaria)
- Scaly and itchy rashes with blistering, weeping, or peeling of the skin (Eczema)
- Tiredness, headaches, being short of breath when exercising,

dizziness and looking pale (anemia)

- Bone fracture
- Fever
- Sore throat and pain during swallowing due to collection of pus beside the tonsil (peritonsillar abscess)
- Swelling of the lymph nodes
- Swelling of the face or tongue,
- Shivering and/or mental confusion due to decreased body temperature (hypothermia)
- Visual disturbances, discharge with itching of the eyes with crusty eyelids.
- Excessive thirst increased appetite with weight loss, feeling tired, drowsy, weak, depressed, irritable and generally unwell and passing large amount of urine.

If you notice any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage

Keep FLUHALT Capsules where children cannot reach it. A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

Keep FLUHALT Capsules in a cool, dry place where the temperature stays below 30°C. Heat and dampness can destroy some medicines.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Keep FLUHALT Capsules in the original blister pack until it is time to take them. If you take the capsules out of the pack they may not keep well.

Storage of the pharmacy-compounded suspension (10 mg/mL)

Room temperature storage conditions: Stable for 3 weeks (21 days) when stored at room temperature “do not store above 25 °C”.

Refrigerated storage conditions: Stable for 6 weeks when stored at 2 °C to 8 °C.

Disposal

If your doctor tells you to stop taking FLUHALT Capsules or the capsules have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What FLUHALT Capsules looks like **FLUHALT CAPSULE 75 mg**

Size ‘2’ capsule with yellow cap and light grey body printed in blue ink with OS 75 on both cap and body, containing white to off white powder.

Ingredients

Active ingredient:

Oseltamivir Phosphate

Inactive ingredients:

Croscarmellose Sodium, Povidone, Pregelatinised Starch, Purified Talc, Purified Water, Sodium Stearyl Fumarate.

MAL NO: MAL06061317AZ

Manufacturer and Product Registration Holder

RANBAXY (MALAYSIA) SDN. BHD.

Lot 23, Bakar Arang Industrial Estate, 08000 Sungai Petani, Kedah, Malaysia.

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