

FLUVIR (Oseltamivir Phosphate Capsules)

Oseltamivir Phosphate 30mg, 45mg, 75mg

What is in this leaflet

1. What FLUVIR is used for
2. How FLUVIR works
3. Before you use FLUVIR
4. How to use FLUVIR
5. While you are using it
6. Side effects
7. Storage and Disposal of FLUVIR
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

1. What FLUVIR is used for

FLUVIR is used for the treatment of influenza in children 6 to 12 months of age during pandemic influenza outbreak, for treatment of influenza in adults and children age 1 year and above. FLUVIR is also indicated for post exposure prevention in adults and children age 1 year and above following contact with clinically diagnosed influenza case when influenza virus is circulating in the community.

2. How FLUVIR works

FLUVIR contains oseltamivir which belongs to a group of medicines named neuraminidase inhibitors. These medicines prevent the influenza virus from spreading inside the body. They help to ease or prevent the symptoms of the influenza 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.

FLUVIR is not a flu vaccine

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

3. Before you use FLUVIR

- When you must not take it

Do not take or receive FLUVIR if:

- **you are allergic** (*hyper-sensitive*) to oseltamivir or any of the other ingredients of FLUVIR. **Talk to your doctor** if this applies to you. **Do not take FLUVIR.**

- Before you start to take it

Tell your doctor if:

- you are **allergic to other medicines**
- you have **problems with your kidneys**. If so, your dose may need adjustment
- you have a **severe medical condition**, which may require immediate hospitalisation
- your **immune system** is not working
- you have chronic **heart disease** or **respiratory disease**

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 FLUVIR is right for you. The effects on breast-fed infants is unknown. You must tell your doctor if you are breast-feeding so that your doctor can decide if FLUVIR is right for you.

If you have not told your doctor about any of the above, tell them before you start taking FLUVIR.

- Taking other medicines

Tell your doctor or pharmacist 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 e.g., rheumatoid arthritis)
- Phenylbutazone (used to treat pain and inflammation)
- Probenecid (used to treat gout)

4. How to use FLUVIR

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

- How much to use:

Treatment should begin within the first or second day of onset of symptoms of influenza.

Treatment of influenza

Adults and adolescents 13 years and over

The recommended oral dose of FLUVIR capsules in adults and adolescents ≥ 13 years is a 75 mg capsule twice daily for 5 days.

Children

Children weighing > 40 kg who can swallow capsules, may also receive treatment with a 75 mg capsule twice daily.

The recommended oral dose of FLUVIR for children ≥ 1 year of age is:

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

The recommended oral dose of

FLUVIR for infants 6-12 months of age

The recommended oral dose of FLUVIR for children 6 to 12 months is 3 mg/kg twice daily, for 5 days. These

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dosing recommendations are not intended for infants who have a post-conceptual age of less than 36 weeks.

The recommended oral dose of FLUVIR for children 6-12 months of age is:

Body weight	Recommended dose for 5 days
3 kg	9 mg twice daily
4 kg	12 mg twice daily
5 kg	15 mg twice daily
6 kg	18 mg twice daily
7 kg	21 mg twice daily
8 kg	24 mg twice daily
9 kg	27 mg twice daily
10 kg	30 mg twice daily

The recommended duration for immunocompromised patients is 10 days.

Prevention of influenza

Adults and adolescents 13 years and over

The recommended oral dose of FLUVIR for prevention of influenza following close contact with an infected individual is 75 mg once daily for 10 days. Therapy should begin within two days of exposure. The recommended dose for prevention during a community outbreak of influenza is 75 mg once daily for up to 6 weeks (or up to 12 weeks in immunocompromised patients).

Children ≥ 1 year of age

Children weighing > 40 kg, who are able to swallow capsules, may also receive prevention dose with a 75 mg capsule once daily for 10 days.

The recommended prevention oral dose of FLUVIR for children ≥ 1 year of age is:

Body weight	Recommended dose for 10 days
10 to 15 kg	30 mg once daily
> 15 to 23 kg	45 mg once daily
> 23 to 40 kg	60 mg once daily
> 40 kg	75 mg once daily

- How to take it:

Swallow the capsules whole with water. Do not break or chew the capsules. FLUVIR 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 make a liquid form of FLUVIR from these capsules.

When Oseltamivir oral suspension is not available

During situation when commercially manufactured oseltamivir powder for oral suspension is not readily available, adults, adolescents or children who are unable to swallow capsules may receive appropriate doses of FLUVIR prepared by a pharmacist or prepared at home by parents or caregivers.

Please consult your pharmacist before self-preparing FLUVIR.

Open the capsule and pour the content of capsules into a suitable small amount (1 teaspoon maximum) of sweetened food product such as sugar water, chocolate syrup, cherry syrup, dessert toppings (like caramel or fudge sauce) to mask the bitter taste. The mixture should be stirred and the entire contents given to the patient. The mixture must be swallowed immediately after its preparation.

- When to take it:

Take FLUVIR as soon as possible, ideally within two days of the flu symptoms starting.

For treating flu, take two doses daily. It is usually convenient to take one dose in the morning and one in the evening.

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.

- How long to use it:

Continue taking FLUVIR until your doctor tells you to stop or your course of treatment is complete.

If you stop taking FLUVIR

There are no side effects when you stop FLUVIR. But if FLUVIR 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 forget to use it:

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

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember and then go back to taking it as you would normally.

- If you use too much (overdose)

Stop taking FLUVIR 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.

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

5. While you are using it

- Things you must do

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.

- Things you must not do

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.

- Things to be careful of

Driving and using machines

FLUVIR has no effect on your ability to drive or use machines.

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6. 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:

- Thrombocytopenia (low platelet count)
- 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

If you notice any of these symptoms, get medical help immediately.

The most frequently (very common and common) reported side effects of FLUVIR 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 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 FLUVIR 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 FLUVIR.

- 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.

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 [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7. Storage and Disposal of FLUVIR

Storage

Store below 30°C.

Keep out of the reach and sight of children.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. Product Description

- What it looks like

FLUVIR 75 (Oseltamivir Phosphate Capsules 75mg):

Light yellow opaque cap / Grey opaque body size '2' hard gelatin capsules imprinted with 'H' on cap and '5' on body with blue ink, filled with white to off white granular powder.

FLUVIR 45 (Oseltamivir Phosphate Capsules 45mg):

Grey opaque cap / Grey opaque body size '4' hard gelatin capsules imprinted with 'H' on cap and '32' on body with blue ink, filled with white to off white granular powder.

FLUVIR 30 (Oseltamivir Phosphate Capsules 30mg):

Light yellow opaque cap / Light yellow opaque body size '4' hard gelatin capsules imprinted with 'H' on cap and '33' on body with blue ink, filled with white to off white granular powder.

Ingredients

Active ingredient

FLUVIR 75

Each capsule contains 98.5 mg Oseltamivir phosphate equivalent to 75 mg Oseltamivir

FLUVIR 45

Each capsule contains 59.1 mg Oseltamivir phosphate equivalent to 45 mg Oseltamivir

FLUVIR 30

Each capsule contains 39.4 mg Oseltamivir phosphate equivalent to 30 mg Oseltamivir

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List of excipients

FLUVIR 75

Capsule content: Pregelatinized starch, Croscarmellose sodium, Povidone, Talc, Sodium Stearyl Fumarate

Capsule shell: 1) Cap: Gelatin (Bovine), Water, Titanium Dioxide, Iron Oxide Yellow, Iron Oxide Red

2) Body: Gelatin (Bovine), Water, Titanium Dioxide, Iron Oxide Black

Printing ink: Dehydrated alcohol, FD&C Blue #2 Aluminium Lake, Shellac, Butyl Alcohol, Propylene Glycol, Strong Amonia Solution, Isopropyl Alcohol.

FLUVIR 45

Capsule content: Pregelatinized starch, Croscarmellose sodium, Povidone, Talc, Sodium Stearyl Fumarate

Capsule shell: 1) Cap: Gelatin (Bovine), Water, Titanium Dioxide, Iron Oxide Black; 2) Body: Gelatin (Bovine), Water, Titanium Dioxide, Iron Oxide Black

Printing ink: Dehydrated alcohol, FD&C Blue #2 Aluminium Lake, Shellac, Butyl Alcohol, Propylene Glycol, Strong Amonia Solution, Isopropyl Alcohol.

FLUVIR 30

Capsule content: Pregelatinized starch, Croscarmellose sodium, Povidone, Talc, Sodium Stearyl Fumarate

Capsule shell: 1) Cap: Gelatin (Bovine), Water, Titanium Dioxide, Iron Oxide Yellow, Iron Oxide Red; 2) Body: Gelatin (Bovine), Water, Titanium Dioxide, Iron Oxide Yellow, Iron Oxide Red

Printing ink: Dehydrated alcohol, FD&C Blue #2 Aluminium Lake, Shellac, Butyl Alcohol, Propylene Glycol, Strong Amonia Solution, Isopropyl Alcohol.

MAL number(s):

FLUVIR 75

MAL23046011AZ

FLUVIR 45

MAL23046010AZ

FLUVIR 30

MAL23046009AZ

9. Manufacturer and Product Registration Holder

Manufacturer

Hetero Labs Limited,
Unit-III, #22 – 110, I.D.A.,
Jeedimetla, Hyderabad - 500 055,
Telangana, India.

Product Registration Holder

Camber Laboratories Sdn. Bhd.
Unit E-13A-02, Menara SUEZCAP 2,
No. 2, KL Gateway, Jalan Kerinchi,
Gerbang Kerinchi Lestari,
59200 Kuala Lumpur, Malaysia.

10. Date of revision

28/11/2024

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