

OSMIVIR CAPSULE

Osetamivir (75mg)

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What Osmivir Capsule 75mg is used for

Osmivir Capsule 75mg is used for the treatment and prevention of influenza. The preventive treatment will only be given following contact with a clinically diagnosed influenza case when influenza virus is circulating in the community.

How Osmivir Capsule 75mg works

Osmivir Capsule 75mg consists of active ingredient Osetamivir.

Osetamivir is a prodrug of osetamivir carboxylate, an inhibitor of the enzyme neuraminidase which has a role in the infectivity and replication of Influenza A and B viruses.

Before you use Osmivir Capsule 75mg

-When you must not use it:

Do NOT take Osmivir Capsule 75mg if:

- You have known hypersensitivity/allergy reaction to osetamivir or other ingredients in this medicine.

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

-Before you start to use it:

Please tell your doctor if you are suffering or have ever suffered from any of the following conditions or illnesses:

- Kidney impairment.
- Severe medical condition.
- Chronic respiratory and heart disease.
- Low immune system

Pregnancy and Breastfeeding

Please 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 Osmivir Capsule 75mg is right for you. There is limited information on children breast-fed by mothers taking osetamivir. You must tell your doctor if you are breast-feeding so that your doctor can decide if Osmivir Capsule 75mg is right for you.

- Taking other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Your doctor may need to change the dose of the other medications or take other precautions.

In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below taken at the same time with Osmivir Capsule 75mg:

- Vaccine (Live influenza virus)
- Probenecid (used to treat gout)
- Chlorpropamide (used to treat diabetes)
- Methotrexate (used to treat e.g. rheumatoid arthritis)
- Phenylbutazone (used to treat pain and inflammation)

How to take Osmivir Capsule 75mg

-How much to use:

Your doctor or pharmacist can advise you how many doses are needed each day and for how long you may need to take it. This depends on your condition and whether or not you are taking any other medicines.

The recommended dosages are as follows:

Treatment of Influenza

Adults and adolescents 13 years of age and older:

The recommended oral dose of Osmivir Capsule 75mg is a 75mg capsule twice daily for 5 days.

Children 1 to 12 years of age:

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

The recommended oral dose of Osmivir Capsule 75mg for children ≥ 1 year of age is:

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

Infant 6 to 12 months of age:

The recommended doses for infant for 6 to 12 months of age is 3mg/kg twice daily for 5 days. This dosing recommendation is not intended for premature infants, who have post-conceptual age less than 36 weeks.

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

The recommended duration in immunocompromised patient is 10 days.

Post exposure prevention:

Adults and adolescent 13 years of age and older:

The recommended dose for prevention of influenza following close contact with an infected individual is a 75mg capsule once daily for 10 days is recommended. It should begin within 2 days of close contact. The recommended dose for prevent prevention outbreak is a 75 mg Osmivir Capsule once daily for up to 6 weeks (or up to 12 weeks in immunocompromised patient).

Children 1 to 12 years of age:

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

The recommended oral dose of Osmivir Capsule 75mg for children ≥ 1 year of age is:

Body weight (kg)	Recommended dose for 5 days
10 to 15	30 mg once daily
> 15 to 23	45 mg once daily

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> 23 to 40	60 mg once daily
> 40	75 mg once daily

Individuals with renal impairment

Your doctor may reduce the dosage according to the severity of your kidney problem and creatinine clearance reading.

Individuals with liver impairment

Dosage adjustment is not necessary in patients with liver impairment.

Immunocompromised patient

The recommended duration for immunocompromised patient is 10 days. No dose adjustment is necessary.

-When to use it:

Osmivir Capsule 75mg can be taken with or without food. The chance of feeling sick can be reduced when taken with food.

Treatment with Osmivir Capsule 75mg should be started as soon as possible or within one to 2 days after the first symptoms of influenza.

-How long to use it:

Continue taking Osmivir Capsule 75mg for as long as your doctor recommends unless problem arise. If that happens, check with your doctor.

-If you forget to use it:

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose):

Contact your doctor or pharmacist immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The symptoms of over dosage include nausea, vomiting and dizziness.

In case of over dosage Osmivir Capsule 75mg should be discontinued. Over dosage should be handled with prompt

elimination of unabsorbed drug and all other appropriate measures.

Before you use Osmivir Capsule 75mg

Before you start to use Osmivir Capsule 75mg it contains TARTRAZINE / FD & C YELLOW No.5 / MA Yellow A 2 / Aluminic Lake. This is a colouring agent, which may cause allergic reactions.

While you are using Osmivir Capsule 75mg

-Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Osmivir Capsule 75mg.
- Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give Osmivir Capsule 75mg to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

- Driving and using machines can cause drowsiness, which can make you less alert and reduce your driving ability. So you should be careful about using machines or driving while on Osmivir Capsule 75mg.

Side effects

Like all medicines, Osmivir Capsule 75mg can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any of the side effects after taking this medicine:

The following side effects have been rarely reported since Osmivir Capsule 75mg have been marketed:

- Anaphylactic and anaphylactoid reactions
- Hepatic disorders (fulminant hepatitis, hepatic function disorder and jaundice)

- Angioneurotic oedema
- Stevens-Johnson syndrome and toxic epidermal necrolysis
- Gastrointestinal bleeding
- Neuropsychiatric disorders.

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

Adults and adolescents

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
- Herpes simplex
- Nasopharyngitis
- Upper respiratory tract infection
- Sinusitis
- Insomnia
- Cough
- Sore throat
- Rhinorrhea
- Vomiting
- Abdominal pain
- Dyspepsia
- Dizziness, fatigue

Uncommon side effects

(may affect up to 1 in 100 people)

- Hypersensitivity reaction
- Altered level of consciousness
- Convulsion
- Cardiac arrhythmia
- Elevated liver enzymes
- Eczema
- Dermatitis (including allergic and atopic dermatitis)
- Rash
- Urticaria
- Tympanic disorder

Rare side effects

(may affect up to 1 in 1000 people)

- Thrombocytopenia (low platelet count)
- Visual disturbance

You may report any side effects or adverse drug reactions directly to the

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National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.moh.gov.my [Consumers → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Osmivir Capsule 75mg

-Storage:

Store in a dry place below 30°C. Protect from light.

-Disposal:

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

Product description

-What it looks like:

Two pieces, opaque yellow/opaque white coloured size '2' hard gelatine capsule containing white to off white powder.

-Ingredients:

-Active Ingredient:

Oseltamivir Phosphate.

-Inactive Ingredients:

Croscarmellose sodium, purified talc, sodium stearyl fumarate, povidone and pregelatinised starch.

-MAL No.:

MAL06100581AZ

Manufacturer and Product Registration Holder

Royce Pharma Manufacturing Sdn.Bhd.
PT 1663, Nilai Industrial Estate,
71800 Nilai, Negeri Sembilan, Malaysia.

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27/10/2025

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