

Flumivir®

Oseltamivir phosphate

What is Flumivir®?

Flumivir®: Each 1ml of reconstituted suspension contains oseltamivir phosphate equivalent to oseltamivir 12mg.

Each 1g of powder for oral suspension contains oseltamivir phosphate equivalent to oseltamivir 22.5mg.

Excipients: Sorbitol, xanthan gum, sodium benzoate, saccharin sodium, acesulfame potassium, titanium dioxide, sodium dihydrogen citrate, simethicone emulsion 30%, orange dry flavor, tutti frutti flavor.

Why should you take Flumivir®?

- Flumivir® is prescribed to you for treating or preventing influenza.
- Flumivir® 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.

What should you know about Flumivir®?

Before you take Flumivir®, make sure your prescribing physician knows if you have hereditary fructose intolerance. This medicine contains sorbitol which is a form of fructose.

What is the recommended dosage of Flumivir®?

Treatment

For infants below 12 months of age

The recommended treatment dose for infants less than 12 months is between 2 mg/kg twice daily and 3 mg/kg twice daily during a pandemic influenza outbreak. This is based upon limited pharmacokinetic data indicating that these doses provide plasma drug exposures in the majority of patients similar to those shown to be clinically efficacious in older children and adults. The following weight-adjusted dosing regimens are recommended for treatment of infants below 1 year of age:

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

* There is no data available regarding the administration of Flumivir® to infants less than one month of age.

Administration of Flumivir® to infants less than one year of age should be based upon the judgment of the physician after considering the potential benefit of treatment versus any potential risk to the infant.

For infants 1 year of age and older and Children 2 to 12 years of age)

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

Body Weight	Recommended dose for 5 days (Treatment)
Less than or equal to 15kg	30mg twice daily
More than 15 kg and up to 23 kg	45 mg twice daily
More than 23 kg and up to 40 kg	60 mg twice daily
More than 40 kg	75 mg twice daily (75 mg is made up of a 30 mg dose plus a 45 mg dose)

Prevention

For infants below 12 months of age

The recommended prophylaxis dose for infants less than 12 months during a pandemic influenza outbreak is half of the daily treatment dose. This is based upon clinical data in children > 1 year of age and adults showing that a prophylaxis dose equivalent to half the daily treatment dose is clinically efficacious for the prevention of influenza. The following weight-adjusted dosing prophylaxis regimens are recommended for infants below 1 year of age:

Age	Recommended dose for 10 days
> 3 months to 12 months	3 mg/kg once daily
> 1 month to 3 months	2.5 mg/kg once daily
0 to 1 month*	2 mg/kg once daily

* There is no data available regarding the administration of Flumivir® to infants less than one month of age.

Administration of Flumivir® to infants less than one year of age should be based upon the judgment of the physician after considering the potential benefit of prophylaxis versus any potential risk to the infant.

For infants 1 year of age and older and Children 2 to 12 years of age)

Flumivir® can also be used to prevent influenza following exposure to an infected individual, such as family members.

Flumivir® should be taken once daily for 10 days. It is best to take this dose in the mornings with breakfast.

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)
Less than or equal to 15kg	30mg once daily
More than 15 kg and up to 23 kg	45 mg once daily
More than 23 kg and up to 40 kg	60 mg once daily
More than 40 kg	75 mg once daily (75 mg is made up of a 30 mg dose plus a 45 mg dose)

Children weighing more than 40 kg and can swallow capsules may take a 75 mg dose of Flumivir® capsules once daily for 10 days.

Your physician will recommend the length of time to continue taking Flumivir®, if it is prescribed to prevent influenza.

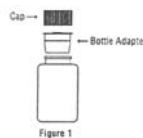
How is Flumivir® taken?

Always take Flumivir® exactly as your physician has told you. You should check with your physician or pharmacist if you are not sure.

Take Flumivir® as soon as you get the prescription as this will help to slow the spread of the influenza virus in the body.

a) HOW TO PREPARE THE ORAL SUSPENSION:

Your pharmacist may have prepared the oral suspension for you when you collected your prescription. However, if they have not done this, then you can do it easily yourself. You only need to prepare the suspension once, at the beginning of your course. After that, all you need to do is shake the suspension well and draw up the appropriate recommended dose.



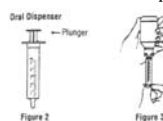
Preparation of oral suspension:

Tap the bottle several times to loosen the powder. Add 46ml of water or make up the volume with water up to the mark.

Close the bottle and shake well to obtain a homogenous suspension.

b) HOW TO MEASURE AND GIVE A DOSE OF ORAL SUSPENSION

Always shake Flumivir® oral suspension well before use!



How to measure the correct amount of suspension:

1. Shake the closed bottle of Flumivir® oral suspension well before use.
2. Take the dispenser (see figure 2) and push the plunger completely down toward the tip of the dispenser. The dispenser provided with your medicine must always be used to measure to correct dose.

3. Remove the cap from the bottle of oral suspension.
4. Insert the tip of the dispenser into the bottle adapter.
5. Turn the entire unit (bottle and dispenser) upside down (see figure 3).
6. Slowly pull out the plunger to the graduation which marks the dose you need.
7. Turn the entire unit upright.
8. Slowly remove the dispenser from the bottle.
9. Push the suspension directly into the mouth by pushing down the plunger of the dispenser. Swallow the medicine. You may drink and eat something after taking the medicine.
10. Immediately after administration, take the dispenser apart and rinse both parts of the dispenser under running tap water.

What to do if you miss a dose?

Take the forgotten dose as soon as you remember. If it is almost time for your next dose, skip the dose you missed and go back to your regular schedule. Do not take two doses at the same time.

What to do in case of over dosage?

Contact your physician or pharmacist immediately.

Are there drug or food interactions with Flumivir®?

Please tell your physician or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Flumivir® can be taken with paracetamol, ibuprofen or acetylsalicylic acid. Flumivir® is not expected to alter the effect of any other medicines.

Interactions with an influenza vaccination:

Flumivir® is not a substitute for influenza vaccination. Flumivir® will not change the effectiveness of the influenza vaccine. Even if a vaccination against influenza has been given to you Flumivir® may be prescribed by your physician.

Taking Flumivir® with food and drink:

Flumivir® oral suspension can be taken with or without food, although it is recommended to take Flumivir® with food to reduce the chance of feeling or being sick (nausea or vomiting). It can also be taken with a drink of water.

What are the side effects of Flumivir®?

Like all medicines, Flumivir® can cause side effects, although not everybody gets them.

- Common side effects of Flumivir®

The most common side effects of Flumivir® are nausea, vomiting, diarrhoea, stomach ache and headache. These side effects mostly occur only 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.

- Less common side effects of Flumivir®

Adults and adolescents (children aged 13 years and older)

Other less common side effects, which may also be caused by influenza, are upper abdominal fullness, bleeding in the gastrointestinal tract, bronchitis, upper respiratory tract infections, dizziness, tiredness, sleeping difficulties, skin reactions, mild to severe liver function disorders, visual disturbances and heart rhythm abnormalities.

Influenza can be associated with a variety of neurologic and behavioural symptoms which can include events such as hallucinations, delirium, and abnormal behaviour, in some cases resulting in fatal outcomes. These events may occur in the setting of encephalitis or encephalopathy but can occur without obvious severe disease.

During Flumivir® treatment, events like convulsions and delirium (including symptoms such as altered level of consciousness, confusion, abnormal behavior, delusions, hallucinations, agitation, anxiety, nightmares) have been reported, in a very few cases resulting in accidental injury, in some instances with fatal outcome. These events were reported primarily among children and adolescents and often had an abrupt onset and rapid resolution. The contribution of Flumivir® to those events is unknown. Such neuropsychiatric events have also been reported in patients with influenza who were not taking Flumivir®.

Children (aged 1 to 12 years)

Other less common side effects, which may also be caused by influenza, are ear inflammation, inflammation of the lungs, sinusitis, bronchitis, aggravation of pre-existing asthma, nose bleeding, ear disorders, inflammation of the skin, swelling of the lymph nodes, conjunctivitis, visual disturbances and heart rhythm abnormalities.

If you or your child are often sick, you should inform your physician. You should also tell your physician if the influenza symptoms get worse or the fever continues.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician or pharmacist.

Precautions about Flumivir®

Before you take Flumivir®, make sure your prescribing physician knows if you

- are allergic to other medicines
- have problems with your kidneys

If you have been told by your physician that you have intolerance to some sugars, contact your physician before taking this medicinal product.

What are the cases in which you should not take Flumivir®?

Do not take Flumivir® if you are allergic (hypersensitive) to oseltamivir or any of the other ingredients of Flumivir®.

What should you do if you are pregnant or breastfeeding?

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

The possible effects of Flumivir® on unborn children are unknown. You must tell your physician if you are pregnant, if you think you are pregnant or if you are trying to get pregnant so that your physician can decide if Flumivir® is right for you.

The effects on nursing infants are unknown. You must tell your physician if you are breast-feeding so that your physician can decide if Flumivir® is right for you.

How to store Flumivir®?

Store dry powder below 25° C.

After reconstitution store the suspension at (2°C to 8°C) for 10 days.

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor
- Medicament: keep out of reach of children

Council of Arab Health Ministers
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Benta S.A.L.
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