

NATFLU CAPSULES 75MG

OSELTAMIVIR PHOSPHATE CAPSULES

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What Natflu is used for?

NATFLU capsules is used for adults, adolescents, and children 1 year old or older.

NATFLU is used for adults, adolescents, 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.

NATFLU can also be prescribed for adults and adolescents, age for **preventing flu**, on a case-by-case basis – for instance, if you have been in contact with someone who has flu.

NATFLU may be prescribed for adults & adolescents 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.

How NATFLU works

NATFLU 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 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.

Before you use NATFLU

When you must not use it
Do not take NATFLU if:

- You have had an allergic reaction to NATFLU or any ingredients listed at the end of this leaflet.
- The package is torn or shows signs of tampering.
- The expiry date (EXP) printed on the pack has passed.

If you are not sure if you should be taking NATFLU, talk to your doctor

Before you start to use it

Tell your doctor if:

- You are pregnant or plan to become pregnant. It is not known whether NATFLU is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take NATFLU when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.
- You are breast-feeding or plan to breast-feed. NATFLU may

pass into breast milk. Your doctor will discuss the risks and benefits of using NATFLU if you are breastfeeding.

- You have any other health problems, especially the following:
 - Kidney failure, kidney impairment or kidney disease.
- You are allergic to any other medicines, foods, dyes or preservatives.

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

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 medicine may interact with NATFLU if taken together:

- probenecid (used to treat gout)

How to use NATFLU

-How much to take

Adult and Children (>13 years old, >40kg and able to swallow capsules)

The recommended doses

For treating flu, take one capsule two times a day. It is usually convenient to take one dose in the morning and one in the evening. It is important to complete the whole 5-day course, even if you start to feel better quickly.

For preventing flu or after being exposed to an infected person, take 75mg once a day for 10 days. It is best to take this in the mornings with breakfast.

Elderly

No dose adjustment is required.

Patients with Liver Problems

No dose adjustment required for

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mild and moderate liver dysfunction patients.

Patients with Kidney Problems

For treating flu:

Your doctor may reduce the dose to 75mg twice daily for 5 days according to the severity of your kidney problem.

For preventing flu:

Your doctor may reduce the dose to 75mg once daily depending on the severity of your kidney problem.

Immunocompromised patients

For treating flu:

No dose adjustment is necessary. Your treatment should be initiated as soon as possible within the first two days of onset of symptoms of influenza.

For preventing flu:

No dose adjustment is necessary. Your doctor will advice to take NATFLU for 12 weeks.

Always let your doctor knows if you have any medical condition such as kidney problem, so that your doctor can decide the dose that suits you.

-When to take it

NATFLU capsules can be taken with or without food, although taking it with food can reduce the chance of feeling or being sick (nausea or vomiting).

Swallow the capsules whole with water.

Take NATFLU capsules as soon as possible, ideally within the first two days of the start of flu symptoms.

-How long to take it

For treating flu: 5-days

For preventing flu: 10 days or as prescribed by your doctor.

If you forget to use it

Do not take a double dose to make up for a forgotten capsule. Consult your doctor or pharmacist if you are not sure what to do.

-If you take too much (overdose)

Stop taking NATFLU capsules and contact your doctor or pharmacist immediately.

At present, there has been no experience with overdose. There are reports on nausea and/or vomiting only.

While you are using it

Things you must do

Tell your doctor if you have kidney failure or impairment or any other problems with your kidneys. Tell all doctors, dentists and pharmacists who are treating you that you are taking NATFLU. Tell your doctor if you become pregnant while taking NATFLU. Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Tell your doctor if you feel your symptoms have worsened after starting NATFLU.

Things you must not do

Do not stop taking NATFLU or change the dose without first checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays. Do not give NATFLU to anyone else, even if they have the same condition as you. Do not use NATFLU to treat any other complaints unless your doctor tells you to. Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how NATFLU affects you.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor if you notice any of the following and they worry you:

- nausea (feeling like vomiting)
- vomiting

The following are rare but serious side effects:

- Anaphylactic reaction (severe, potentially life-threatening allergic reactions)
- Hepatitis (inflammation of the liver).
- Gastrointestinal bleeding
- Physiological disorders
- Thrombocytopenia (low platelet count)

This is not a complete list of possible side effects for NATFLU capsule; please contact your doctor or pharmacist if you encounter any other side effects or if you are not sure.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

You may report any side effects or

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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 and disposal of NATFLU

Storage

Keep the medicine in a place where the temperature stays below 30°C. Protect from light. Do not store NATFLU Capsule or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines. Keep NATFLU Capsule where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking NATFLU Capsule or the capsule have passed their expiry date, ask your pharmacist what to do with any that are left over. Return any unused medicine to your pharmacist.

Product description

What it looks like:

White to off white powder filled in size '2' capsules with yellow colour cap imprinted with '75mg' with blue colour ink and grey colour body imprinted with 'NAT' with blue colour ink.

Ingredients:

The active substance is:

Oseltamivir Phosphate USP equivalent to Oseltamivir 75mg

The other ingredients are:

Pregelatinized starch
Croscarmellose sodium
Povidone K – 30

Talc

Sodium Stearyl fumarate

Capsule shell – Bovine Source

MAL

Manufacture

Natco Pharma Ltd

Kothur, Ranga Reddy (District)

Telangana – 509 228, India

Product Registration Holder

Perniagaan Normahas Sdn Bhd

3, 5 & 7, Jalan 12/10, Taman Koperasi Polis Fasa 1, Mukim Batu, 68100, Kuala Lumpur

Date of revision: 07/06/2021

Serial Number: NPRA (R2)
20/108

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INFORMATION FOR THE USER

If you need a liquid medicine, but its not available, a suspension can be made up at the pharmacy from Natflu capsules. This pharmacy preparation is the preferred option.

If the pharmacy preparation is not available either, you can make liquid Natflu from these capsules at home.

The dose is the same for treating or preventing flu. The difference is how often it is given.

MAKING LIQUID NATFLU AT HOME

USING 75MG CAPSULES

- If you have the right capsule for the dose needed (a 75mg dose), you will 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.
- If you need smaller doses, making liquid Natflu from capsules involves extra steps. This is suitable for younger children and babies: they usually need a Natflu dose of less than 30mg.

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

To make a 75mg dose, you need:

- One 75mg Natflu capsule
- Sharp scissors
- One small bowl
- Teaspoon (5ml spoon)
- Water
- Sweet food to hide the bitter taste of the powder, example are: chocolate or cherry syrup, and dessert toppings such as caramel or fudge sauce. Or you can make sugar water: mix a teaspoon of water with

three-quarters (3/4) of a teaspoon of sugar.

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.

Look at the right column to check the number of capsules you will need to give the patients for a single dose. The amount is the same whether treating or preventing flu.

You should use only 75mg capsules for 75mg doses. Do not try to make a 75mg dose by using the contents of 30mg or 45mg capsules.

Weight	Dose of Natflu	Number of capsules
40kg and over	75mg	1 capsule

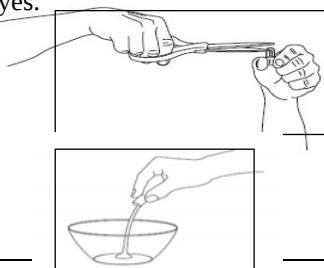
Not for children who weigh less than 40kg

You will need to prepare a dose of less than 75mg for children who weigh less than 40 kg. *see below:*

Step 2: Pour all the powder into a bowl

Hold a 75mg capsule upright over a bowl and carefully snipp off the rounded tip with scissors.

Pour all of the powder into the bowl. Be careful with the powder, because it may irritate your skin and eyes.

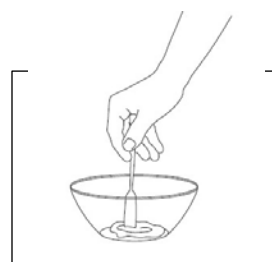


Step 3: Sweeten the powder and give the dose

Add a small amount – no more than one teaspoonful – of sweet food to the powder in the bowl.

This is to hide the bitter taste of the Natflu powder.

Stir the mixture well.



Give the whole contents of the bowl to the patient straight away.

If there is some mixture left in the bowl, rinse the bowl with a small amount of water and get the patient to drink it all.

Repeat this procedure every time you need to give the medicine.

Infants 6-12 months old, and children weighing less than 40kg.

To make a smaller single dose, you need:

- One 75mg Natflu capsule
- Sharp scissors
- Two small bowls
- One large oral dose dispenser to measure out water – a 5 or 10ml dispenser.
- One small oral dose dispenser

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showing measurements of 0.1ml to give the dose

- Teaspoon (5ml spoon)
- Water

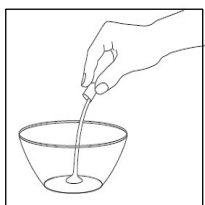
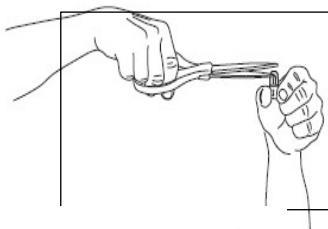
Sweet food to hide the bitter taste of the powder, example are: chocolate or cherry syrup, and dessert toppings such as caramel or fudge sauce. Or you can make sugar water: mix a teaspoon of water with three-quarters (3/4) of a teaspoon of sugar.

Step1: pour all the powder into a bowl

Hold a 75mg capsule upright over one of the bowl and carefully snip off the rounded tip with scissors. Be careful with the powder: it may irritate your skin and eyes.

Pour all of the powder into the bowl, whatever the dose you are making.

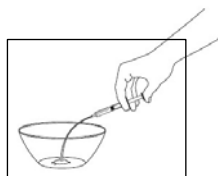
The amount is the same whether you are treating or preventing flu.



Step 2: Add water to dilute the medicine

Use the larger dispenser to draw up 12.5ml water.

Add the water to the powder in the bowl.



Stir the mixture with the teaspoon for about 2 minutes.



Don't worry if not all of the powder dissolves. The undissolved powder is just inactive ingredients.

Step 3: choose the correct amount for your child's weight

Look up the child's weight on the left side of the table.

The column on the right of the table shows how much of the liquid mixture you will need to draw up.

Infants 6-12 months old:

Child's weight (nearest)	How much mixture to draw up
3kg	1.5ml
3.5kg	1.8ml
4kg	2.0ml
4.5 kg	2.3ml
5kg	2.5ml
5.5kg	2.8ml
6kg	3.0ml
6.5kg	3.3ml
7kg	3.5ml
7.5kg	3.8ml
8kg	4.0ml
8.5kg	4.3ml
9kg	4.5ml

9.5kg	or	4.8ml
10kg above		5.0ml

Children 1 year or older, weighing less than 40kg.

Child's Weight (nearest)	How much mixture to draw up
Upto 15kg	5.0ml
15 to 23 kg	7.5ml
23 to 40kg	10.0ml

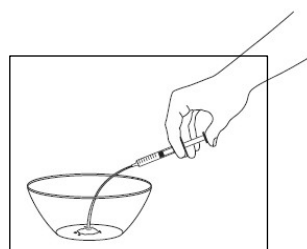
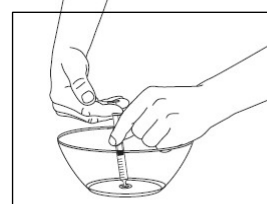
Step 4: Draw up the liquid mixture

Make sure you have the right size dispenser.

Draw up the correct amount of liquid mixture from the first bowl.

Draw it up carefully so as not to include air bubbles.

Gently squirt the correct dose into the second bowl.



Step 5: sweeten and give to the child

Add a small amount – no more than one teaspoonful – of a sweet food to the second bowl.

This is to hide the bitter taste of the Natflu.

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Mix the sweet food and Natflu liquid well.



Give the whole contents of the second bowl (Natflu liquid mixture with sweet food added) to the child straight away.\

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. For children unable to drink from a bowl, spoonfeed or use a bottle to feed the child the remaining liquid.

Give the child something to drink.

Throw away any unused liquid left in the first bowl.

Repeat this procedure every time you need to give the medicine.