OMIFLU CAPSULE

Oseltamivir (75mg)

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What OMIFLU is used for

OMIFLU is used for the treatment and prevention of influenza (an infection caused by the influenza virus). The preventive treatment will only be given following contact with a clinically diagnosed influenza case when influenza virus is circulating in the community. It has no effect on the common cold or other respiratory virus infections.

How OMIFLU works

OMIFLU belongs to a group of medicines called neuraminidase inhibitors. These medicines attack the influenza virus and prevent it from spreading inside your body.

Before you use OMIFLU

- When you must not use it

Do not take OMIFLU if:

- you have had an allergic reaction to OMIFLU 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 OMIFLU, talk to your doctor.

- <u>Before you start to use it</u>

Tell your doctor if:

- you are pregnant or plan to become pregnant. It is not known whether OMIFLU is harmful to an unborn baby when taken by a pregnant woman. If there is a need to take OMIFLU 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. OMIFLU may pass into breast milk. Your doctor will discuss the risks and benefits of using OMIFLU 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 OMIFLU.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you have bought from a pharmacy, supermarket or health food shop.

These medicines may be affected by OMIFLU, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking OMIFLU.

How to use OMIFLU

- How much to use

Take OMIFLU exactly as your doctor has prescribed.

TREATMENT OF INFLUENZA

The recommended oral dose of OMIFLU for adults and adolescents is 75 mg twice a day for 5 days.

PREVENTION OF INFLUENZA

The recommended oral prevention dose of OMIFLU for adults and adolescents is 75mg once a day.

- When to use it

Treatment with OMIFLU should be started as soon as possible, but no later than 48 hours after the first symptoms of influenza.

For influenza treatment, OMIFLU should be taken in the morning and in the evening.

For influenza prevention, OMIFLU should be taken once a day.

Taking your medicine at the same time each day will help you remember when to take the capsules.

- How long to use it

Continue taking your medicine for as long as your doctor tells you.

- If you forget to use it

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 your capsules as you would normally.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

- <u>If you use too much</u> (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency Department (Casualty) at your nearest hospital if you think that you or anyone else may have taken too much OMIFLU Tablet.

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

You may need urgent medical attention.

The following are some symptoms of overdose which may or may not occur:

- nausea (feeling like vomiting)
- vomiting

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 OMIFLU.

Tell your doctor if you become pregnant while taking OMIFLU.

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 OMIFLU.

Things you must not do

Do not stop taking OMIFLU 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 OMIFLU to anyone else, even if they have the same condition as you.

Do not use OMIFLU 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 OMIFLU 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
- stomach ache
- dizziness
- headache
- fatigue
- skin rash
- hepatitis (inflammation of the liver)
- unstable angina (chest discomfort)
- anaemia (lack of red blood cell)
- convulsion (fit/seizure)
- depressed level of consciousness
- abnormal behaviour
- hallucination (perception of something not present)
- delirium (severe confusion)

Taking OMIFLU with food may reduce the potential of side effect.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug directly reactions to the National Centre for Adverse Drug Monitoring by calling Tel: 03-78835550, or visiting the portal.bpfk.gov.my website (Consumers \rightarrow Reporting).

Storage and Disposal of OMIFLU

- Storage

Keep the medicine in a place where the temperature stays below 30 degrees Celsius. Protect from light.

Do not store OMIFLU Tablet 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 OMIFLU Tablet 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.

- <u>Disposal</u>

If your doctor tells you to stop taking OMIFLU Tablet or the tablets 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

OMIFLU CAPSULE 75mg is a size '2' capsule, yellow / white colour, with 'DUO 861' marking.

- <u>Ingredients</u>

Active ingredient:

• Oseltamivir

Inactive ingredients:

- Croscarmellose sodium
- Starch
- Magnesium stearate
- Polyvinylpyrrolidone
- Talc

- <u>MAL number</u>

MAL07090926A

Manufacturer

DUOPHARMA (M) SDN. BHD. (42491-M) Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan, Malaysia.

Product Registration Holder

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