# Package Leaflet: Information for the user VIRIFLU 75 mg capsules

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. Keep this leaflet. You may need to read it again.

- If you have further questions, ask your doctor or pharmacist. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their slans of illness are

- If you get any of the side effects, talk to your doctor or

pharmaclst. This Includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet

the same as yours.

. What VIRIFLU is and what it is used for

- 2. What you need to know before you take VIRIFLU
- 4. Possible side effects

3. How to take VIRIFI U

- 5. How to store VIRIFLU
- 6. Contents of the pack and other information

### . What VIRIFLU is and what it is used for

(Including full-term newborn bables) 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.

case-by-case basis - for instance, if you have been in contact with someone who has flu.

• VIRIFLU may be prescribed for adults, adolescents, children Driving and using machines vaccine may not provide sufficient protection.

prevent the flu virus from spreading inside the body. They help to The recommended doses ease or prevent the symptoms of the flu virus Infection.

extreme tiredness. These symptoms can also be caused by other. For patients with a weak Immune system, treatment will continue the cansules. Infections. True Influenza Infection only occurs during annual for 10 days community. Outside epidemic periods, flu-like symptoms are take one dose daily for 10 days, it is best to take this in the vomitina) usually caused by a different type of illness. mornings with breakfast.

other Ingredients of VIRIFLU listed in section 6.

## Warnings and precautions:

Before you take VIRIFLU, make sure the prescribing doctor knows

- if you have a severe medical condition, which may require
- If your immune system is not working
- if you have chronic heart disease or respiratory disease

• if you notice changes in behaviour or mood (neuropsychiatric Body weight events), especially in children and adolescents). These may be signs of rare but serious side effects.

### VIRIFLU is not a flu vaccine

VIRIFLU is not a vaccine: it treats infection, or prevents the flu virus spreading. A vaccine gives you antibodies against the virus.

For patients with a weak immune system, treatment is for 10 days. VIRIFI II will not change the effectiveness of a flu vaccine, and Children 1 to 12 years you might be prescribed both by your doctor.

## Other medicines and VIRIFLIJ

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 particulariv important:

- chiorpropamide (used to treat diabetes)
- methotrexate (used to treat e.a. rheumatoid arthritis) phenylbutazone (used to treat pain and Inflammation)

The recommended dose is based on the patient's body weight.

You must use the amount of oral capsules prescribed by the

 probenecld (used to treat gout) Preanancy and breast-feeding

You must tell your doctor If you are preanant, If you think you are VIRIFLU is used for adults, adolescents, children, and infants pregnant or if you are trying to get pregnant so that your doctor can decide if VIRIFLU is right for you. The effects on breast-fed infants are unknown. You must tell your

 VIRIFI LL can also be prescribed for adults, adolescents, children. If VIRIFLU is right for you.

and infants (Including full-term newborn babies) as preventive VIRIFLU has no effect on your of treatment in exceptional circumstances - for example, if there is 3. How to take VIRIFLU a global epidemic of flu (a flu pandemic) and the seasonal flu Take this medicine exactly a with your doctor or pharmacis

VIRIFLU contains oseitamivir, which belongs to a group of Take VIRIFLU as soon as possible, Ideally within two days of the flu medicines named neuraminidase inhibitors. These medicines symptoms starting.

Influenza, usually called flu, is an infection caused by a virus. The take one dose in the morning and one in the evening. It is per kg = 24 mg slans of flu often include a sudden fever (more than 37.8 °C). Important to complete the whole 5-day course, even if you start Method of administration cough, runny or stuffy nose, headaches, muscle aches and to feel better quickly

## 2. What you need to know before you take VIRIFLU

# • If you are allergic (hypersensitive) to oseltamivir or any of the weeks.

## Talk to your doctor if this applies to you. Do not take VIRIFLU:

 If you are alleraic to other medicines • if you have problems with your kidneys. If so, your dose may

- need adjustment
- Immediate hospitalisation

Adults, and adolescents 13 years and over

### Treating flu: Treatina flu Preventina flu: dose for 5 days (Immunocompromised Patients): dose for 10 days Inflammation of the outer and possibly inner skin. Initially with • Alleraic reactions dose for 10 days\* fever, sore throat, and fatique, skin rashes, leading to blisters. • Altered level of consciousness 75 ma twice daily 75 ma once daily 75 ma twice daily

Body weight	<b>Treating flu:</b> dose for 5 days	Treating flu (Immunocompromised Patients): dose far 10 days*	Preventing flu: dose for 10 days	lf Im Th
10 to 15 kg	30 mg twice daily	30 mg twice daily	30 mg once daily	ef st
More than 15 kg and up to 23 kg	45 mg twice daily	45 mg twice daily	45 mg once daily	ef us
More than 23 kg and up to 40 kg	60 mg twice daily	60 mg twice daily	60 mg once daily	ef Ro
More than 40 kg	75 mg twice daily	75 mg twice daily	75 mg once daily	D th

\* For children with a weak immune system, treatment is for 10 days.

# doctor if you are breast-feeding so that your doctor can decide infants less than 1 year (0 to 12 months)

Giving VIRIFLU to infants less than 1 year old for preventing flu during a flu pandemic should be based upon the ludament of a and infants above 1 year of age for preventing flu, on a lit vikill-Lu is right for you.

Ask your doctor or pharmacist for advice before taking this doctor after considering the potential benefit versus any potential risk to the Infant.

ur ability to drive or use machines.	Body weight	<b>Treating flu:</b> dose <i>for 5 days</i>	Treating flu (Immunocompromised Patients): dose for 10 days*	Preventing flu: dose for 10 days	re ne wi
as your doctor has told you. Check cist if you are not sure.	3 kg to 10+ kg,	3 mg per kg body weight** twice daily	3 mg per kg body welght** twice daily	3 mg per kg**, once daily	ck

\* For infants with a weak immune system, treatment is for 10 days, If you forget to take VIRIFLU \*\*ma perka = ma for each kiloaram of the infant's body weight. Do not take a double dose to make up for a forgotten capsule. Adults and adolescents 13 and over

VIRIFLU can be taken with or without food, although taking it with If you have any further questions on the use of this medicine, ask (may affect up to 1 in 10 people) outbreaks (epidemics) when flu viruses are spreading in the local For preventing flu or after being exposed to an infected person, food can reduce the chance of feeling or being sick (nausea or your doctor or pharmacist

> In special situations, such as widespread flu or for patients with a suspension. You can make a liquid form of VIRIFLU from these although not everybody gets them. Many of the side effects weak immune system, treatment will continue for up to 6 or 12 capsules. See Makina liquid VIRIFLU at home, over the page. If you take more VIRIFLU than you should

> > Stop taking VIRIFLU and contact a doctor or pharmacist since oseltamivir has been marketed:

have not reported any side effects. When side effects were pressure and breathing difficulties. reported, they were similar to those from normal doses, as listed • Hepatic disorders (fulminant hepatitis, hepatic function Overdose has been reported to have occurred more frequently eyes, change in stool color, changes in behavior.

when oseitamivir capsules were given to children than to adults • Angioneurotic oedema: sudden onset of severe swelling of the • Upper respiratory tract infections (Inflammation of the nose, and adolescents. Caution should be exercised when preparing skin mainly around the head and neck area, including eyes liquid VIRIFLU for children and when administerina VIRIFLU and tongue, with difficulties breathing. capsules or liquid VIRIFLU to children.

For treating flu. take two doses dally. It is usually convenient to For example: If a 6-month-old weighs 8 kg, the dose is 8 kg x 3 mg | you stop taking VipiFLU There are no side effects when you stop VIRIFLU. But if VIRIFLU is (may affect more than 1 in 10 people) stopped earlier than your doctor told you, the symptoms of flu. • Headache Swallow the capsules whole with water. Do not break or chew may come back. Always complete the course that your doctor . Nausea Common side effects

Bronchltls

# 4. Possible side effects

People who find it hard to take capsules can use a liquid Like all medicines, this medicine can cause side effects, The following serious side effects have been rarely reported \* Pain

 Pain In Ilmb Runny nose Anaphylactic and anaphylactoid reactions: severe alleraic

- In most cases of overdose with oseitamivir capsules, people reactions, with face and skin swelling, itchy rashes, low blood Sleeping difficuitles Sore throat Stomach ache
  - Tiredness disorder and jaundice); vellowing of the skin and white of the

peeling, shedding of larger greas of skin, possible breathing Heart rhythm abnormalities difficulties and low blood pressure. GastroIntestinal bleeding prolonged bleeding from the large • Mild to severe liver function disorders Skin reactions (inflammation of the skin, red and itchy rash. bowel or spitting up blood Neuropsychiatric disorders, as described below scalina skin) you notice any of these symptoms, get medical help Rare side effects

(may affect up to 1 in 1.000 people) most frequently (very common and common) reported side • Thrombocytopenia (low platelet count) ects of oseltamivir are feeling or being sick (nauseg, vomiting), • Visual disturbances mach ache, stomach upset, headache and pain. These side Children 1 to 12 years ects mostly occur after the first dose of the medicine and will very common side effects ially stop as treatment continues. The frequency of these (may affect more than 1 in 10 people) ects is reduced if the medicinal product is taken with food.

• Cough

### e but serious effects: get medical help at once Nasal congestion ese may affect up to 1 In 1.000 people) Vomlting

na oseltamivir treatment, rare events have been reported Common side effects

- Convulsions and delirium, including altered level of consclousness
- Confusion, abnormal behavior
- Delusions, hallucinations, agitation, anxiety, nightmares These are reported primarily among children and adolescents • Runny nose and often started suddenly and resolved rapidly. A few cases • Stomach ache resulted In self-injury, some with fatal outcome, Such • Upper abdominal fullness neuropsychiatric events have also been reported in patients . Upset stomach
- with influenza who were not taking oseltamivir. Uncommon side effects Patients, especially children and adolescents, should be (may affect up to 1 in 100 people)
- closely monitored for the behavioral changes described above. If you notice any of these symptoms, especially in younger

  • Tympanic membrane (eardrum) disorder people, get medical help immediately. Infants less than 1 year

# Very common side effects

old are mostly similar to the side effects reported for older children (1 year old or older), Additionally, diarrhoea and diaper rash have been reported.

(may affect up to 1 in 10 people)

Ear Inflammation and other ear disorders

If any of the side effects get serious, or If you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

The reported side effects of oseltamivir in Infants 0 to 12 months

if you or your child are repeatedly sick, or

Conjunctivitis (red eyes and discharge or pain in the eye)

 if the influenza symptoms get worse or the fever continues. Tell your doctor as soon as possible.

## 5. How to store VIRIFLU

- Keep this medicine out of the sight and reach of children. - Do not use this medicine after the expiry date which is stated
- on the blister and the outer packaging. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep away from humidity - Do not use this medicine if you notice visible signs of deterioration.
- Do not throw away any medicines via wastewater. Ask your Upper abdominal fullness pharmacist how to throw away medicines you no longer use. These measures will help protect the environment. throat and sinuses)
- Upset stomach

Cold sore virus

Vomltlna

- Stevens-Johnson syndrome and toxic epidermal necrolysis: Uncommon side effects complicated, possibly life-threatening alleraic reaction, severe (may affect up to 1 in 100 people)
- Each capsule contains Oseltamivir phosphate equivalent to 75mg of Oseltamivir

Contents of the pack and other information

The active substance is Oseltamivir.

What VIRIFLU contains

- The other Ingredients are: Pregelatinized starch, talc.
- povidone, croscarmellose sodium, sodium stearyl fumarate. Capsule shell content: gelatin, Indigotine (E132), Titanium dioxide (E171)

## What VIRIFLU looks like and contents of the pack

VIRIFLU capsules are white and blue capsules. VIRIFLU is available in boxes containing 10 capsules. Marketing Authorisation Holder and Manufacturer

Pharmaline s.a.l. - Lebanon P.O. Box90201 Jdeldet-El-Metn, Lebanon Contact us: pharmaline@maligaroup.com Rea. No. for VIRIFLU 75 ma In Lebanon: 24341/06

### This is a medicament

for you.

- 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. One small bowl Do not by yourself interrupt the period of treatment prescribed
- Teaspoon (5 ml spoon) Do not repeat the same prescription without consulting your
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers Union of Arab Pharmacists

The leaflet was last revised in May 2020.

## Information for the user

### For people who find it hard to take capsules, including very vouna children: If you need a liquid medicine, a suspension can be made up at

the pharmacy from VIRIFLU capsules. This pharmacy preparation is the preferred option If the pharmacy preparation is not available, you can make

liquid VIRIFI II 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 VIRIFLU at home

- If you have the right capsule strength for the dose needed (a Give the whole contents of the bowl to the patient straight 75 mg dose), you will open the capsule and stirits contents into one teaspoon (or less.) of a suitable sweetened food product. If there is some mixture left in the bowl, rinse the bowl with a small This is usually suitable for children over 1 year. See the upper set amount of water and get the patient to drink it all. of instructions Repeat this procedure every time you need to give
- If you need smaller doses, making liquid VIRIFI II from capsules medicine Involves extra steps. This is sultable for younger children and Infants less than 1 year, and children weighing less than 40 kg babies: they usually need a VIRIFLU dose of less than 30 mg. See To make a smaller single dose, you need: the lower set of instructions.

### One 75 ma VIRIFLU capsule Adults, adolescents 13 years and over, and children weighing 40 Sharp scissors

Two small bowls

ml, to give the dose

Teaspoon (5 ml spoon)

ml dispenser

- ka and over To make a 75 ma dose, you need:
- One 75 ma VIRIFLU capsule Sharp sclssors

same whether treating or preventing flu

40 kg and over 75 mg 1 capsule

Not for children who weigh less than 40 kg

who welch less than 40 kg. See below.

Step 2: Pour all the powder into a bowl

Pour all of the powder into the bowl.

the rounded to with scissors.

- Sweet food to hide the bitter taste of the powder.

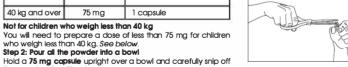
Dose of VIRIFLU Number of capsules

• Examples are: chocolate or cherry syrup, and dessert toppings Examples are: chocolate or cherry syrup and dessert toppings such as caramel or fudge sauce. Or you can make sugar water: such as caramel or fudge sauce. Or you can make sugar water: mix a teaspoon of water with three-auarters (3/4) of a teaspoon mlx a teaspoon of water with three-quarters (3/4) of a teaspoon

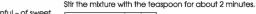
### Step 1: Check the dose is correct Step 1: Pour all the powder into a bowl

To find the correct amount to use, find the patient's weight on Hold a 75 ma capsule upright over one of the bowls and the left of the table carefully snip off the rounded tip with scissors. Be careful with the Look at the right column to check the number of capsules you powder: It may Irritate your skin and eyes. will need to give the patient for a single dose. The amount is the Pour all of the powder into the bowl, whatever the dose you are

The amount is the same whether you are treating or preventing



Step 2: Add water to dilute the medicine Use the larger dispenser to draw up 12.5 ml water. Be careful with the powder, because it may irritate your skin and Add the water to the powder in the bowl



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 VIRIFLU powder. 2 mins Stir the mixture well.

Step 3: Sweeten the powder and give the dose



• One large oral dose dispenser to measure out water - a 5 or 10

• One small oral dose dispenser showing measurements of 0.1

Sweet food to hide the bitter taste of the VIRIFI II.

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.

Child's weight

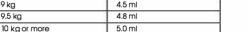
Infants less than 1 year (including full-term newborn bables)

How much mixture to draw up	William St.
1.5 ml	
1.8 ml	
2.0 ml	
2.3 ml	Give the whole c
0.51	mixture with sweet

t 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 aet the child to drink it ali. For

Give the child something to drink.

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



2.8 ml

3.3 ml

3.5 ml

3.8 ml

4.3 ml

	Child's weight (nearest)	to draw up	
	Up to 15 kg	5.0 ml	
	15 to 23 kg	7.5 ml	
3	23 to 40 kg	10.0 ml	

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 VIRIFI U Mix the sweet food and VIRIFLU liquid well.





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

Throw away any unused liquid left in the first bowl.

Rev. 05/2020 905324-A

Children 1 year or older, welghing less than 40 kg

