Applicant: Teva Pharmaceuticals (Pty) Ltd	Product name: FLUMITEV 30; 45; 75 (hard capsules) Dosage form & strength: Each hard capsule contains oseltamivir phosphate equivalent to 30, 45 or 75 mg oseltamivir respectively

PATIENT INFORMATION LEAFLET:

SCHEDULING STATUS:

S4

FLUMITEV 30, hard capsules

FLUMITEV 45, hard capsules

FLUMITEV 75, hard capsules

Oseltamivir

Sugar free

Read all of this leaflet carefully before you start taking FLUMITEV:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- FLUMITEV has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT IS IN THIS LEAFLET:

1. **WHAT FLUMITEV IS AND WHAT IT IS USED FOR**
2. **WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLUMITEV**
3. **HOW TO TAKE FLUMITEV**
4. **POSSIBLE SIDE EFFECTS**
5. **HOW TO STORE FLUMITEV**
6. **CONTENTS OF THE PACK AND OTHER INFORMATION**

1. WHAT FLUMITEV IS AND WHAT IT IS USED FOR:

FLUMITEV 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.

- FLUMITEV is used for adults, adolescents and children above ≥ 1 year of age for treating flu (influenza).
- FLUMITEV may be prescribed for adults and children above ≥ 1 year of age 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.
- FLUMITEV can also be prescribed for adults and children above ≥ 1 year of age for preventing flu, on a case-by-case basis – for instance, if you have been in contact with someone who has flu.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLUMITEV:

Do not take FLUMITEV:

- if you are hypersensitive (allergic) to oseltamivir or any of the other ingredients of FLUMITEV (listed in **section 6**).

Warnings and precautions:

Take special care with FLUMITEV:

- if you have problems with your kidneys. If so, your dose may need adjustment
- if you have a severe medical condition, which may require immediate hospitalisation
- if your immune system is not working
- if you have chronic heart disease or respiratory disease.

Children and adolescents:

During treatment with FLUMITEV, tell a doctor immediately:

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

FLUMITEV is not a flu vaccine:

FLUMITEV is not a vaccine: it treats infection or prevents the flu virus spreading. A vaccine gives you antibodies against the virus. FLUMITEV will not change the effectiveness of a flu vaccine, and you might be prescribed both by your doctor.

Other medicines and FLUMITEV:

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

The following medicines are particularly important:

- 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)

FLUMITEV with food:

FLUMITEV taken with food may enhance tolerability in some patients.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking FLUMITEV.

Do not take FLUMITEV when you are pregnant or breastfeeding your baby.

Driving and using machines:

It is not always possible to predict to what extent FLUMITEV may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which FLUMITEV affects you.

FLUMITEV contains sodium stearyl fumarate:

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. HOW TO TAKE FLUMITEV:

Do not share medicines prescribed for you with any other person.

Always take FLUMITEV exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take FLUMITEV as soon as possible, ideally within two days of the flu symptoms starting.

Swallow the capsules whole with water. Do not break or chew the capsules.

People who find it hard to take capsules can use a liquid form of this medicine (oral suspension). If you need an oral suspension but it's not available from your pharmacy, you can make a liquid form of FLUMITEV from these capsules. See ***Making Liquid FLUMITEV at home*** for instructions.

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

The usual dose is:

For treating flu, take two doses daily. 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 one dose daily for 10 days. It is best to take this in the mornings with breakfast.

In special situations, such as widespread flu or for patients with a weak immune system, treatment will continue for up to 6 or 12 weeks.

The recommended dose is based on the patient's body weight. You must use the amount of oral capsules or suspension prescribed by the doctor.

Patients 13 years and over:

Body weight	**Treating flu:** *dose for 5 days*	**Preventing flu:** *dose for 10 days*
40 kg or more	75 mg twice daily	75 mg once daily

75 mg can be made up of a 30 mg capsule plus a 45 mg capsule

Children 1 to 12 years:

Body weight	**Treating flu:** *dose for 5 days*	**Preventing flu:** *dose for 10 days*
≤ 15 kg	30 mg twice daily	30 mg once daily
More than 15 kg and up to 23 kg	45 mg twice daily	45 mg once daily
More than 23 kg and up to 40 kg	60 mg twice daily	60 mg once daily
More than 40 kg	75 mg twice daily	75 mg once daily

75 mg can be made up of a 30 mg capsule plus a 45 mg capsule

Children 6 to 12 months of age:

A dosage of 3 mg/kg twice daily in children 6 to 12 months of age during a pandemic flu outbreak only, and not for seasonal flu use.

Your pharmacy will compound the suspension to be administered to your child.

Your doctor will tell you how long your treatment with FLUMITEV will last. If you have the impression that the effect of FLUMITEV is too strong or too weak, tell your doctor or pharmacist.

If you take more FLUMITEV than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take FLUMITEV:

Do not take a double dose to make up for forgotten individual doses.

If you stop taking FLUMITEV:

There are no side effects when you stop FLUMITEV. But if FLUMITEV is stopped earlier than your doctor told you, the symptoms of flu may come back. Always complete the course that your doctor prescribed.

4. POSSIBLE SIDE EFFECTS:

FLUMITEV can have side effects.

Not all side effects reported for FLUMITEV are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FLUMITEV, please consult your healthcare provider for advice.

If any of the following happens, stop taking FLUMITEV and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to FLUMITEV. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- liver disorders (fulminant hepatitis, hepatic function disorder and jaundice): yellowing of the skin and white of the eyes, change in stool colour, changes in behaviour
- angioneurotic oedema: sudden onset of severe swelling of the skin mainly around the head and neck area, including eyes and tongue, with difficulties breathing
- convulsions and delirium, including altered level of consciousness, neuropsychiatric disorders, especially children and adolescents, should be closely monitored for the behavioural changes described above.
- gastrointestinal bleeding: prolonged bleeding from the large bowel or spitting up blood
- Stevens-Johnson syndrome and toxic epidermal necrolysis: complicated,

possibly life-threatening allergic reaction, severe inflammation of the outer and possibly inner skin, initially with fever, sore throat, and fatigue, skin rashes, leading to blisters, peeling, shedding of larger areas of skin, possible breathing difficulties and low blood pressure

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- bronchitis
- cold sore virus
- upper respiratory tract infections (inflammation of the nose, throat and sinuses)
- flu
- headache
- sleeping difficulties
- cough
- runny nose, stuffy nose
- sore throat
- nausea
- vomiting
- indigestion
- stomachache
- runny tummy
- back pain
- joint pain, muscle pain

- painful menstruation
- fever
- pain
- pain in limb
- tiredness
- dizziness
- fever or abrupt onset with one or more of: chills, headache, malaise, myalgia, cough, pharyngitis, other respiratory complaints, and presented for throat culture

Less frequent side effects:

- thrombocytopenia (low platelet count)
- delusions, hallucinations, agitation, anxiety, nightmares
- confusion, abnormal behaviour, self-injury
- convulsion, change in level of consciousness
- bleeding in the digestive system, disease in the gut called haemorrhagic colitis
- visual disturbances
- heart rhythm abnormalities
- mild to severe liver function disorders
- skin reactions (inflammation of the skin, red and itchy rash, scaling skin)
- hives, skin or mouth lesions that have a pink-red centre surrounded by a pale ring border and an outer pink-red ring

Children 1 to 12 years:

Frequent side effects:

- ear infection, ear inflammation and other ear disorders

- bronchitis, lung infection, inflammation of a nasal sinus
- a disease affecting the lymph nodes
- headache
- conjunctivitis (red eyes and discharge or pain in the eye)
- cough
- stuffy nose
- runny nose
- breathing difficulties (asthma)
- bleeding nose (epistaxis)
- vomiting
- nausea
- stomachache, runny tummy
- indigestion

Less frequent side effects:

- inflammation of the skin
- tympanic membrane (eardrum) disorder.

Post-marketing experience:

Frequency unknown:

- fits
- abnormal and inappropriate behaviour, including abnormal motor behaviour
- disturbances in consciousness
- seeing or hearing things that aren't real (hallucinations and delirium)
- allergy
- allergic skin reactions including dermatitis, rash, eczema, hives

- inflammation of the liver
- gastrointestinal bleedings, in particular, haemorrhagic colitis (characterized by abdominal cramping, bloody diarrhea).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of FLUMITEV.

5. HOW TO STORE FLUMITEV:

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Store in original packaging until required for use.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION:

What FLUMITEV contains:

Each hard capsule contains oseltamivir phosphate equivalent to 30, 45 or 75 mg of oseltamivir respectively.

The other ingredients are:

Capsule contents: croscarmellose sodium, povidone (K-29/32), pregelatinized starch (derived from maize starch), sodium stearyl fumarate and talc.

Capsule shell: gelatine, iron oxide yellow (E172), titanium dioxide (E171) and iron oxide black (172).

Printing ink: shellac glaze - 45 % (20 % esterified), ammonium hydroxide 28 % (E527), black iron oxide (E172) and propylene glycol (E1520).

What FLUMITEV looks like and contents of the pack:

FLUMITEV 30 mg:

Each hard capsule consists of a rich yellow body and cap bearing the black imprint. 'OS 30'. Capsule size: 4

The capsule contains a white granulated powder.

FLUMITEV 45 mg:

The hard capsule consists of a white opaque body and cap bearing the black imprint 'OS 45'. Capsule size: 4

The capsule contains a white granulated powder.

FLUMITEV 75 mg:

The hard capsule consists of a white opaque body and a rich yellow cap bearing the black imprint 'OS 75'. Capsule size: 2

The capsule contains a white granulated powder.

FLUMITEV will be packed in PVC/PE/PVdC/Al blisters or HDPE containers with LDPE lid (and a desiccant).

Holder of Certificate of Registration:

Teva Pharmaceuticals (Pty) Ltd

Maxwell Office Park

Magwa Crescent West

Waterfall City

Midrand

Gauteng

South Africa

2090

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This leaflet was last revised in:

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Registration numbers:

FLUMITEV 30: 56/20.2.8/1035

FLUMITEV 45: 56/20.2.8/1036

FLUMITEV 75: 56/20.2.8/1037

Access to the corresponding Professional Information:

Website: *https://www.teva.co.za/*

The Professional Information can also be obtained from:

Teva Pharmaceuticals (Pty) Ltd,

Maxwell Office Park,

Magwa Crescent West,

Waterfall City,

Midrand,

Gauteng,

South Africa,

2090

Tel.: +27 11 055 0200

Information for the user:

For people who find it hard to take capsules, including very young children, a liquid medicine may be available.

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

Making Liquid FLUMITEV at home:

If you have the right capsule for the dose needed (a 30 mg or a 60 mg dose; a 45 mg dose; or a 75 mg 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.

Children 1 to 12 years:

1. To make a 30 mg or a 60 mg dose, you need:

- One or two 30 mg FLUMITEV capsule(s)

2. To make a 45 mg dose, you need:

- One 45 mg FLUMITEV capsule

3. To make a 75 mg dose, you need:

- One 75 mg FLUMITEV capsule
- Sharp scissors
- One small bowl
- Teaspoon (5 ml spoon)
- Water
- Sweet food to hide the bitter taste of the powder.

Examples 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 patient for a single dose. The amount is the same whether treating or preventing flu.

- **1.** You should use only 30 mg capsules for 30 mg and 60 mg doses. Do not try to make a 45 mg or 75 mg dose by using the contents of 30 mg capsules. Use the appropriate size capsule instead.
- **2.** You should use only 45 mg capsules for 45 mg doses. Do not try to make a 30 mg, 60 mg or 75 mg dose by using the contents of 45 mg capsules. Use the appropriate size capsule instead.

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

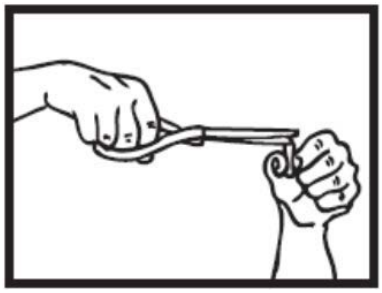
Weight	Dose of FLUMITEV	Number of capsules
Up to 15 kg	30 mg	1 capsule **(Do not use 45 mg or 75 mg capsules)**
15 kg up to 23 kg	45 mg	1 capsule **(Do not use 30 mg or 75 mg capsules)**
23 kg up to 40 kg	60 mg	2 capsules **(Do not use 45 mg or 75 mg capsules)**
40 kg and over	75 mg	1 capsule **(Do not use 30 mg or 45 mg capsules)** ***Not for children who weigh less than 40 kg**

Step 2: Pour all the powder into a bowl:

- **1.** Hold a **30 mg capsule** upright over a bowl and carefully snip off the rounded tip with scissors. Pour all of the powder into the bowl.
- Open a second capsule for a 60 mg dose. Pour all of the powder into the bowl. Be careful with the powder, because it may irritate your skin and eyes.

- **2.** Hold a **45 mg capsule** upright over a bowl and carefully snip 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.

- **3.** Hold a **75 mg capsule** upright over a bowl and carefully snip 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 FLUMITEV 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.