PATIENT INFORMATION LEAFLET FOR

CIPLA OSELTAMIVIR

SCHEDULING STATUS:

S4

CIPLA OSELTAMIVIR (75 mg capsules)

Oseltamivir

Sugar free

Read all of this leaflet carefully before you start taking CIPLA OSELTAMIVIR

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CIPLA OSELTAMIVIR 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 CIPLA OSELTAMIVIR is and what it is used for

CIPLA OSELTAMIVIR contains oseltamivir which belongs to a group of medicines called antivirals. These medicines act by preventing the influenza virus from spreading inside the body, thereby helping ease or prevent symptoms of influenza virus infection.

CIPLA OSELTAMIVIR is indicated for:

- Treatment of influenza in adults and children ≥ 1 year of age.
- Pandemic use: CIPLA OSELTAMIVIR is indicated for the treatment of infants 6 to 12 months of age during a pandemic influenza outbreak only, and not for endemic (seasonal) influenza use.
- Prophylaxis (prevention) of influenza in adults and children ≥ 1 year of age.

2. What you need to know before you take CIPLA OSELTAMIVIR

Do not take CIPLA OSELTAMIVIR:

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

Warnings and precautions

Take special care with CIPLA OSELTAMIVIR:

- If you notice changes in your behaviour or mood (neuropsychiatric events) such as convulsions (seizures), hallucinations, delirium (disturbed state of mind) and disturbances in consciousness, within the first few days of taking CIPLA OSELTAMIVIR. You should inform your doctor as you should be carefully monitored for these adverse effects.
- If you have kidney problems as your dose of CIPLA OSELTAMIVIR may need to be adjusted.

- If you have a severe medical condition which may require immediate hospitilisation.
- If your immune system is weakened.
- If you any have chronic medical conditions which may affect your heart and lungs.

Other medicines and CIPLA OSELTAMIVIR

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

Tell your doctor if you are taking the following:

- Chlorpropamide (used to treat diabetes)
- Methotrexate (an immune suppressant)
- Phenylbutazone (used to treat pain and inflammation)
- Probenecid (used to treat gout).

CIPLA OSELTAMIVIR with food and drink

CIPLA OSELTAMIVIR may be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, 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 CIPLA OSELTAMIVIR**.**

The safety and efficacy of CIPLA OSELTAMIVIR during pregnancy and lactation have not been established.

Pregnancy

No studies have been conducted on the use of CIPLA OSELTAMIVIR in pregnant women.

Breastfeeding

Safety in humans has not been demonstrated in children of breastfeeding women using CIPLA OSELTAMIVIR. Mothers on treatment with CIPLA OSELTAMIVIR should not breastfeed their infants.

Fertility

There is no evidence that CIPLA OSELTAMIVIR has an effect on male or female fertility.

Driving and using machines

It is not known whether CIPLA OSELTAMIVIR affects one's ability to drive and use machines. However, if symptoms such as delirium or fever are experienced while taking CIPLA OSELTAMIVIR, you should not drive or use machines until symptoms disappear.

It is not always possible to predict to what extent CIPLA OSELTAMIVIR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CIPLA OSELTAMIVIR affects them.

3. How to take CIPLA OSELTAMIVIR

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

Always take CIPLA OSELTAMIVIR exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

CIPLA OSELTAMIVIR should be taken within 2 days of influenza (flu) symptoms starting.

Treatment of influenza

Adults and adolescents

In adults and adolescents ≥ 13 years of age, the recommended oral dose of CIPLA OSELTAMIVIR is one 75 mg capsule twice daily for 5 days.

Children

Treatment with one 75 mg capsule twice daily for may also be administered to children > 40 kg who are able to swallow capsules.

*Children ≥ 1 year of age who are not able to swallow capsules (refer to **Patients who are unable to swallow capsules** below)*

Body weight	Recommended dose for 5 days
≤ 15 kg	30 mg twice daily
> 15 to 23 kg	45 mg twice daily
> 23 to 40 kg	60 mg twice daily
> 40 kg	75 mg twice daily

*The recommended oral dose of CIPLA OSELTAMIVIR for children 6 to 12 months of age who are not able to swallow capsules (refer to **Patients who are unable to swallow capsules** below)*

Dosage in children 6 to 12 months is 3mg/kg twice daily.

Body weight (kg)	CIPLA OSELTAMIVIR (mg)
6	18
7	21
8	24
9	27
≥ 10	30

Use the smallest graduated oral syringe that will accurately deliver the appropriate volume.

The recommended treatment dose for infants 6 to 12 months is 3 mg/kg twice daily for 5 days, during a pandemic influenza outbreak only, and not for endemic (seasonal) influenza use.

Prophylaxis (prevention) of influenza

Adults and adolescents

For the prophylaxis of influenza following close contact with an infected individual the recommended oral dose of CIPLA OSELTAMIVIR is 75 mg once daily for at least 10 days. (

Prophylactic therapy should be initiated within two days of exposure.

During a community outbreak of influenza, the recommended dose for prophylaxis is 75 mg once daily. Safety and efficacy have been demonstrated for up to six weeks. Protection lasts for the duration of prophylactic treatment.

Children ≥ 1 year of age

Children weighing > 40 kg, who are able to swallow capsules, may also receive prophylaxis with

a 75 mg capsule once daily, for 10 days.

*The recommended prophylactic oral dose of CIPLA OSELTAMIVIR for children ≥ 1 year of age who are not able to swallow capsules (refer to **Patients who are unable to swallow capsules** below)*

Body weight	Recommended dose for 5 days
≤ 15 kg	30 mg once daily
> 15 to 23 kg	45 mg once daily
> 23 to 40 kg	60 mg once daily
> 40 kg	75 mg once daily

Kidney impairment

Please inform your doctor if you suffer from kidney problems as your dose may need to be adjusted for treatment or prophylaxis of influenza with CIPLA OSELTAMIVIR.

Liver impairment

Please inform your doctor if you suffer from liver problems. No dose adjustment is required for patients with mild or moderate hepatic dysfunction (liver problems). Safety has not been established in patients with severe hepatic impairment (liver problems).

Immuno-compromised patients

Seasonal prophylaxis (prevention) in immune-compromised patients 1 year of age and older is recommended for 12 weeks. No dose adjustment is necessary.

Elderly

Dose adjustment is not necessary for elderly patients who require treatment or prophylaxis (prevention) for influenza.

Children

Since the safety and efficacy of CIPLA OSELTAMIVIR in children under 1 year have not been established, CIPLA OSELTAMIVIR should not be used in children under 1 year of age, other than during a pandemic influenza outbreak.

Patients who are unable to swallow capsules

Adults, adolescents or children who are unable to swallow capsules may receive appropriate doses of CIPLA OSELTAMIVIR by opening capsules and pouring the contents of capsules into a suitable, small amount [1 teaspoon (5 mL) maximum] of sweetened food product such as regular or sugar-free chocolate syrup, honey (only for children two years or older), light brown or table sugar dissolved in water, dessert toppings, sweetened condensed milk, apple sauce or yoghurt to mask the bitter taste. The mixture should be stirred, and the entire contents taken. The mixture must be swallowed immediately after its preparation.

When using the 75 mg capsules: For patients requiring 30 to 60 mg doses, follow these instructions to ensure proper dosing:

- One CIPLA OSELTAMIVIR capsule must be held over a small bowl, the capsule must be carefully pulled open and the powder poured into the bowl.
- 5 mL water must be added to the powder using a graduated syringe and the mixture stirred for approximately two minutes.
- The correct amount of mixture must be drawn up into the syringe from the bowl. See table

below to determine the correct amount of mixture, based on the patient's weight. It is not necessary to draw up any undissolved white powder as this is inert (inactive) material. The plunger of the syringe must be pushed down to empty its entire contents into a second bowl and any unused mixture discarded.

Body weight	**Recommended dose**	**Required amount of CIPLA OSELTAMIVIR mixture for one dose**
Less than or equal to 15 kg	30 mg	2 mL
More than 15 kg and up to 23 kg	45 mg	3 mL
More than 23 kg and up to 40 kg	60 mg	4 mL

- The recommended dose is 30 mg, 45 mg or 60 mg twice daily for 5 days for treatment, and once daily for prevention for 10 days.
- In the second bowl, a suitable amount [1 teaspoon (5 mL) maximum] of sweetened food product must be added to the mixture (to mask the bitter taste) and well mixed.
- This mixture must be stirred and the entire contents of the second bowl given to the patient. This mixture must be swallowed immediately after its preparation. If there is some mixture left inside the bowl, the bowl must be rinsed with a small amount of water and the patient must drink the remaining water.

For patients requiring 75 mg dose, follow these instructions:

- One 75 mg capsule must be held over a small bowl, the capsule must be carefully pulled

open and the powder poured into the bowl.

- A suitable, small amount [1 teaspoon (5 mL) maximum] of sweetened food product must be added to the mixture (to mask the bitter taste) and well mixed.
- The mixture must be stirred and the entire contents of the bowl given to the patient. This mixture must be swallowed immediately after its preparation. If there is some mixture left inside the bowl, it must be rinsed with a small amount of water and the patient must drink this remaining mixture.

Repeat this procedure every time this medicine is taken.

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

If you take more CIPLA OSELTAMIVIR than you should

Symptoms of overdosage may present as side effects associated with CIPLA OSELTAMIVIR (see section **4**). Treatment is supportive and symptomatic.
In the event of overdosage, consult your pharmacist or doctor. If neither is available, contact the nearest hospital or poison control center.

If you forget to take CIPLA OSELTAMIVIR

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

4. Possible Side Effects

CIPLA OSELTAMIVIR can have side effects.

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

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

- Hypersensitivity (allergic reaction, which includes swelling of the hands, feet, ankles, face, lips and mouth or throat which may cause difficulty in swallowing and breathing), anaphylactic/anaphylactoid reaction (body going into shock).
- Stevens-Johnson syndrome (severe skin reaction causing painful rash that spreads and blisters).
- Toxic epidermal necrolysis (life threatening skin condition which causes blistering and peeling of the skin).
- Erythema multiforme (skin disorder characterized by bull's-eye shaped lesions).

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

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

- Hepatic (liver) failure (symptoms may include yellowing of the skin and eyes along with stomach pain and swelling).
- Pneumonia (inflammation of the air sacs in the lung causing the lung to fill up with fluid).

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 (chest infection), upper respiratory tract infections.
- Herpes simplex (virus causing contagious sores, most often around the mouth or genitals).
- Nasopharyngitis (common cold).
- Sinusitis (swelling of the sinuses causing runny nose, headache, nasal congestion etc.).
- Otitis media (ear infection).
- Headache.
- Insomnia (difficulty sleeping or inability to sleep).
- Earache.
- Cough.
- Sore throat.
- Runny nose.
- Nasal congestion.
- Diarrhoea.
- Nausea.
- Vomiting.
- Abdominal (stomach) pain (including upper abdominal pain).
- Dyspepsia (indigestion).

Less frequent side effects:

- Thrombocytopenia (decreased number of blood cells called platelets which are required for blood clotting).
- Agitation.
- Abnormal behaviour.

- Anxiety.
- Confusion.
- Delusions.
- Delirium (confused thinking and lack of awareness).
- Hallucinations (seeing or hearing things that are not real).
- Nightmares.
- Self-injury.
- Altered level of consciousness.
- Convulsions (seizures).
- Conjunctivitis (pink eye).
- Visual disturbance (blurred vision).
- Ear disorder.
- Tympanic membrane disorder (inflamed eardrum).
- Cardiac arrhythmia (irregular heartbeat).
- Epistaxis (nose bleeds).
- Gastrointestinal bleeding.
- Hemorrhagic colitis (bloody stools).
- Elevated liver enzymes.
- Hepatitis (inflammation of the liver).
- Eczema (dry itchy skin).
- Dermatitis (skin irritation).
- Rash.
- Urticaria (hives).
- Swelling under the skin.

Side effects with unknown frequency:

- Lymphadenopathy (swelling of the lymph nodes).
- Asthma.

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 **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free) . By reporting side effects, you can help provide more information on the safety of CIPLA OSELTAMIVIR.

5. How to store CIPLA OSELTAMIVIR

- Store at or below 25 °C.
- Store all medicines out of reach of children.
- 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 CIPLA OSELTAMIVIR contains

The active substance is oseltamivir phosphate equivalent to oseltamivir 75 mg.

The other ingredients are croscarmellose sodium, pregelatinised starch, sodium stearyl fumarate and talc.

Capsule cap: gelatin, sodium lauryl sulphate, titanium dioxide (C.I. No. 77891), water and yellow iron oxide.

Capsule body: gelatin, sodium lauryl sulphate, titanium dioxide (C.I. No. 77891) and water.

What CIPLA OSELTAMIVIR looks like and contents of the pack

White to off white coloured free flowing powder filled in size ‘2’ capsule having white body spin printed with ’75 mg’ in black and yellow coloured cap.

CIPLA OSELTAMIVIR: is packed in an Alu-PVC/PE/PVDC blister containing 10 capsules which is packed into an outer cardboard carton.

Pack size: 10’s.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

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