PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

TAMYGEN Capsules

Oseltamivir

Sugar free

Read all of this leaflet carefully before you start taking TAMYGEN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **TAMYGEN** 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 **TAMYGEN** is and what it is used for
2. What you need to know before you take **TAMYGEN**
3. How to take **TAMYGEN**
4. Possible side effects
5. How to store **TAMYGEN**
6. Contents of the pack and other information

1. What TAMYGEN is and what it is used for

TAMYGEN 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.

TAMYGEN is used for adults, adolescents, infants and children 1 year old and older.

TAMYGEN is prescribed for treating flu (influenza). It can be used when you have flu symptoms and the flu virus is known to be circulating in your community. Other times it may be used as listed below.

TAMYGEN is prescribed for preventing flu. It can be used if you have been in contact with someone who has flu.

TAMYGEN is sometimes prescribed as preventive treatment. For example, it can be used when the seasonal flu vaccine may not provide sufficient protection and when there is a flu pandemic (global epidemic of flu).
During a flu pandemic, **TAMYGEN** can also be used to treat or prevent flu in babies below 1 year of age.

2. What you need to know before you take TAMYGEN

Do not take TAMYGEN:

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

Warnings and precautions

Take special care with TAMYGEN:

- 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.

During treatment with **TAMYGEN**, 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.

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

Other medicines and TAMYGEN

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

Especially tell your doctor if you are taking any of the following medicines:

- chlorpropamide (used to treat diabetes)
- methotrexate (used to treat e.g. rheumatoid arthritis)
- phenylbutazone (used to treat pain and inflammation)
- probenecid (used to treat gout)

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking **TAMYGEN**.

Your doctor will decide if you can take **TAMYGEN** while you are pregnant.

Mothers on treatment with **TAMYGEN** should not breastfeed their infants.

Driving and using machines

You may feel tired or dizzy after taking **TAMYGEN**. You should be careful if you are driving a car or operating heavy machinery until you know how TAMYGEN affects you.

3. How to take TAMYGEN

Do not share medicines prescribed for you with any other person.
Always take **TAMYGEN** exactly as your doctor has told you. Check with your doctor if you are not sure.

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

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 patients with a weak immune system, treatment will continue for 10 days.

For preventing flu or after being exposed to an infected person, take one dose (1 capsule) daily for 10 days. It is best to take this in the mornings with breakfast.
In special situations, such as widespread flu and for patients with a weak immune system, treatment may continue for up to 6 weeks.

The oral suspension can be used by people who find it hard to take capsules. You can make a liquid form of **TAMYGEN** from these capsules prescribed by the doctor. Your doctor will recommended a dose based on the patient's body weight.

If you have the impression that the effect of **TAMYGEN** is too strong or too weak, tell your doctor or pharmacist.

Method of administration

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

Adults, adolescents or children who are unable to swallow capsules may receive appropriate doses of **TAMYGEN** by opening capsules and pouring the contents of capsules into a suitable, small amount (1 teaspoon 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 given to the patient. The mixture must be swallowed immediately after its preparation.

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

If you take more TAMYGEN 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 TAMYGEN

It is important to take your **TAMYGEN** capsules regularly at the same time each day. If you forget to take a dose, take it as soon as you remember, unless it is time for your next dose.

In that case, just carry on with the next dose as normal. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with TAMYGEN is stopped:

There are no side effects when you stop **TAMYGEN**. But if **TAMYGEN** 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

TAMYGEN can have side effects.

Not all side effects reported for **TAMYGEN** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **TAMYGEN**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **TAMYGEN** 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.

These are all very serious side effects. If you have them, you may have had a serious reaction to **TAMYGEN**. 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,
- 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,

- gastrointestinal bleeding: prolonged bleeding from the large bowel or spitting up blood),
- neuropsychiatric disorders (behavioural changes),
- angioneurotic oedema: sudden onset of severe swelling of the skin mainly around the head and neck area, including eyes and tongue, with difficulties breathing.

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

Tell your doctor if you notice any of the following:

Frequent:

- headache,
- nausea,
- bronchitis,
- cold sore virus,
- cough,
- nasal congestion,
- dizziness,
- conjunctivitis (red eyes and discharge or pain in the eye),
- ear inflammation and other ear disorders,
- fever,
- pain,
- pain in limb,
- runny nose,
- sleeping difficulties,
- sore throat,

- stomach ache,
- tiredness,
- upper abdominal fullness,
- upper respiratory tract infections (inflammation of the nose, throat and sinuses),
- upset stomach,
- vomiting.

Less frequent:

- allergic reactions,
- altered level of consciousness,
- convulsion,
- heart rhythm abnormalities,
- mild to severe liver function disorders,
- skin reactions (inflammation of the skin, red and itchy rash, scaling skin),
- thrombocytopenia (low platelet count),
- visual disturbances,
- tympanic membrane (eardrum) disorder.

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.

By reporting side effects, you can help provide more information on the safety of

TAMYGEN.

5. How to store TAMYGEN

Store all medicines out of reach of children.

- Store at or below 30 ˚C.
- Keep blisters in outer carton until required for use.
- Keep in the original container until required for use.
- Do not use after the expiry date stated on the carton / label.

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 TAMYGEN contains:

The active substance is oseltamivir.

Each capsule contains oseltamivir phosphate equivalent to 75 mg oseltamivir base.

Sugar free.

The other ingredients are**:**

Capsule fill: Croscarmellose sodium, povidone, pregelatinised starch, sodium stearyl fumarate, talc.

Capsule shell: Gelatin, titanium dioxide (E171), D&C yellow 10, FD&C yellow # 6

Imprinting ink: Black iron oxide, butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide propylene glycol, shellac, strong ammonia solution.

What TAMYGEN looks like and contents of the pack

White to off-white powder filled in hard shell gelatin capsule with yellow opaque cap and white opaque body imprinted axially with 'MYLAN' over 'OS3' in black ink on cap and body.

Contents of the pack:

High density polyethylene (HDPE) bottle pack (30's and 100's) comprises of round wide mouth white High-Density Polyethylene bottle with white opaque polypropylene (PP) screw cap with induction sealing liner wad.

The HDPE bottle pack may be placed in an outer cardboard carton based on commercial requirement.

PVC/ PE / PVdC Blister pack (10's) comprises of clear transparent, PVC laminated with polyethylene which is further coated with PVDC. PVC blister pack (10's) comprises of clear transparent, non-toxic PVC film, sealed with aluminium foil.

Suitable number of blister strips will be placed in an outer cardboard carton. The number of capsules per strip and the number of strips in carton shall be based on commercial requirement.

7. Holder of Certificate of Registration and Manufacturer

MYLAN (PTY) LTD

4 Brewery Street

Isando

Johannesburg, 1609

Republic of South Africa

8. This leaflet was last revised in

9. Registration numbers

48/20.2.8/0963

Access to the corresponding Professional Information

To be confirmed