PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

OSELTAMIVIR ADCO 30 mg, hard gelatine capsules

OSELTAMIVIR ADCO 45 mg, hard gelatine capsules

OSELTAMIVIR ADCO 75 mg, hard gelatine capsules

Oseltamivir

Sugar free

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

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

1. What OSELTAMIVIR ADCO is and what it is used for

OSELTAMIVIR ADCO contains oseltamivir, which belongs to a group of medicines called neuraminidase inhibitors. These medicines prevent the flu virus from spreading inside the body.

Treatment

OSELTAMIVIR ADCO is used for the treatment of influenza in adults, adolescents and children above 1 year of age.

Prophylaxis

OSELTAMIVIR ADCO is also used for preventing flu in adults and children ≥ 1 year of age, on a case-by-case basis – for instance, if you have been in contact with someone who has flu.

Pandemic use

OSELTAMIVIR ADCO is used in children 6 – 12 months 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.

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

Do not take OSELTAMIVIR ADCO:

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

Warnings and precautions

Take special care with OSELTAMIVIR ADCO:

- if you are allergic to other medicines
- 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 OSELTAMIVIR ADCO, tell your 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.

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

Other medicines and OSELTAMIVIR ADCO

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:

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

OSELTAMIVIR ADCO with food and drink

OSELTAMIVIR ADCO may be taken with or without food.

Pregnancy and breastfeeding

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 health care provider for advice before taking OSELTAMIVIR ADCO.

Driving and using machines

OSELTAMIVIR ADCO may cause confusion or visual disturbances, which may have an effect on your ability to drive a vehicle or use machines. Take special care when using OSELTAMIVIR ADCO until you know how it will affect you.

3. How to take OSELTAMIVIR ADCO

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

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

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

The recommended doses

The usual dose for treating flu is one capsule taken twice 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 adult 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 daily for 10 days. It is best to take this in the mornings with breakfast.

You must use the amount of oral capsules or suspension prescribed by the doctor.

Swallow the capsules whole with water. Do not break or chew the capsules. OSELTAMIVIR ADCO 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 find it hard to take capsules you can use a liquid medicine, oseltamivir oral suspension. If you need oseltamivir oral suspension, but it is not available from your pharmacy, you can make a liquid form of OSELTAMIVIR ADCO from these capsules (see section 6.6 Special precautions for disposal and other handling of the professional information for OSELTAMIVIR ADCO).

If you take more OSELTAMIVIR ADCO than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Always take the labelled medicine package with you, whether there are any OSELTAMIVIR ADCO capsules left or not.

If you forget to take/give OSELTAMIVIR ADCO

If you forget to take/give a dose, take/give it as soon as you remember. Do not take/give a double dose to make up for forgotten individual doses.

If you stop taking OSELTAMIVIR ADCO

If OSELTAMIVIR ADCO is stopped earlier than your doctor told you, the symptoms of flu may come back. Always complete the course that your doctor prescribed.

If you have any further questions on the use of OSELTAMIVIR ADCO, ask your doctor or pharmacist.

4. Possible side effects

OSELTAMIVIR ADCO can have side effects.

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

If any of the following happens, stop taking OSELTAMIVIR ADCO 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 OSELTAMIVIR ADCO. 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:

Less frequent side effects:

- Liver disorders (fulminant hepatitis, liver function disorder and jaundice): yellowing of the skin and white of the eyes, change in stool colour, changes in behaviour, increased liver enzymes, liver failure.
- Angioneurotic oedema: sudden onset of severe swelling of the skin mainly around the head and neck area, including eyes and tongue, with difficulties in breathing.

- 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 unusual weakness or tiredness, 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 (blood in your stools) or spitting up blood.
- Neuropsychiatric disorders: convulsions (fits/seizures), disturbed state of mind, confusion, abnormal behaviour, delusions (false beliefs), hallucinations (hearing, seeing or feeling things that are not real), agitation, anxiety, nightmares or self-injury. Patients, especially children and adolescents, should be closely monitored for the behavioural changes described above.
- Heart disorders

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:

- headache
- nausea
- bronchitis
- viral cold sores
- cough
- dizziness
- fever
- pain
- pain in the limbs
- runny nose

- sleeping difficulties
- sore throat
- stomach ache (including pain in the upper stomach area)
- tiredness
- heartburn
- upper respiratory tract infections (inflammation of the nose, throat and sinuses)
- vomiting.

Less frequent side effects:

- thrombocytopenia (low platelet count)
- visual disturbances.

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 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 OSELTAMIVIR ADCO.

5. How to store OSELTAMIVIR ADCO

- Store at or below 30 °C.
- Keep blister strips in outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

The active ingredient is oseltamivir.

What OSELTAMIVIR ADCO contains:

OSELTAMIVIR ADCO 30 mg: Each hard gelatine capsule contains oseltamivir phosphate equivalent to 30 mg oseltamivir.

OSELTAMIVIR ADCO 45 mg: Each hard gelatine capsule contains oseltamivir phosphate equivalent to 45 mg oseltamivir.

OSELTAMIVIR ADCO 75 mg: Each hard gelatine capsule contains oseltamivir phosphate equivalent to 75 mg oseltamivir.

The other ingredients are:

Capsule core: croscarmellose sodium, povidone, pregelatinised starch, talc , sodium stearyl fumarate

Capsule shell for OSELTAMIVIR ADCO 30 mg: gelatine, iron oxide red (E172), iron oxide yellow (E172), titanium dioxide (E171)

Capsule shell for OSELTAMIVIR ADCO 45 mg: gelatine, iron oxide black (E172), titanium dioxide (E171)

Capsule shell for OSELTAMIVIR ADCO 75 mg: gelatine, iron oxide red (E172), iron oxide yellow (E172), iron oxide black (E172), titanium dioxide (E171)

Printing ink: ammonia solution (E527), iron oxide black (E172), potassium hydroxide (E525), propylene glycol (E1520), shellac (E904)

What OSELTAMIVIR ADCO looks like and contents of the pack

OSELTAMIVIR ADCO 30 mg: Size “4” hard gelatine capsules with light yellow opaque body with black band, imprinted with “M” and light yellow opaque cap, imprinted with “30 mg”.
OSELTAMIVIR ADCO 45 mg: Size “4” hard gelatine capsules with grey opaque body with black band, imprinted with “M” and grey opaque cap, imprinted with “45 mg”.
OSELTAMIVIR ADCO 75 mg: Size “2” hard gelatine capsules with grey opaque body with black band, imprinted with “M” and light yellow opaque cap, imprinted with “75 mg”.

PVC/PE/PVdC aluminium blister strip packed in an outer carton.

Pack sizes: 10 or 30 capsules.

Not all pack sizes will be marketed.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

South Africa

Customer Care: 0860 ADCOCK / 232625

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