PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ANVIATIR 30 hard capsules

ANVIATIR 45 hard capsules

ANVIATIR 75 hard capsules

Oseltamivir phosphate

Sugar free.

Read all of this leaflet carefully before you start taking ANVIATIR.

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

1. What ANVIATIR is and what it is used for

ANVIATIR 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.

ANVIATIR is used for adults, adolescents, children and infants (including full-term newborn babies) 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.

ANVIATIR can also be prescribed for adults, adolescents, children and infants 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.

ANVIATIR may be prescribed for adults, adolescents, children and infants (including full-term newborn babies) as **preventive treatment** in exceptional circumstances – for example, if there is a global epidemic of flu (an influenza pandemic) and the seasonal flu vaccine may not provide sufficient protection.

Influenza, usually called flu, is an infection caused by a virus. The signs of flu often include a sudden fever (higher 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.

2. What you need to know before you take ANVIATIR

Do not take or give ANVIATIR

If you or your child is hypersensitive (allergic) to oseltamivir or any of the other ingredients of ANVIATIR (see **What ANVIATIR contains**).

Warnings and precautions

Before you take or give ANVIATIR to your child, make sure the prescribing doctor knows:

- If you or your child has **problems with your kidneys**. If so, your dose may need adjustment.
- If you or your child has a **severe medical condition**, which may require immediate

hospitalisation.

- If you or your child's **immune system** is not working.
- If you or your child has a chronic **heart disease** or **respiratory disease**.

During treatment with ANVIATIR, 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.

ANVIATIR is not a flu vaccine

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

Other medicines and ANVIATIR

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

Tell your doctor or pharmacist if you or your child is currently using:

- 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).

ANVIATIR with food, drink and alcohol

See section 3.

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 health care provider for advice before taking ANVIATIR.

The safety of ANVIATIR during pregnancy and lactation has not been established.

Driving and using machines

ANVIATIR can cause side effects, such as dizziness, fatigue and severe confusion. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how ANVIATIR affects you.

ANVIATIR contains sodium

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

3. How to take ANVIATIR

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

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

For treating flu:

The usual dose is a 75 mg capsule twice daily. It is usually convenient to take one capsule 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:

The usual dose is one 75 mg dose daily for 10 days. It is best to take this in the mornings with breakfast.

The recommended dose is based on your body mass. Your doctor will decide which dose is best for you.

You can take ANVIATIR with or without food. However, taking it with food can reduce the chance of feeling or being sick (nausea or vomiting).

People who find it hard to take capsules can make a liquid form of ANVIATIR from the capsules – see **Making liquid ANVIATIR at home** below:

Making liquid ANVIATIR at home:

- **If you have the right capsule strength** for the dose needed (a 75 mg dose), 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.
- **If you need smaller doses,** making liquid ANVIATIR from capsules involves extra steps. This is suitable for younger children and babies: they usually need a ANVIATIR dose of less than 30 mg.

To make a* 75 mg *dose, you need:

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

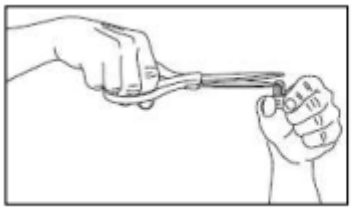
Examples are chocolate or cherry syrup and dessert toppings such as caramel or fudge sauce. Or you can make sugar water: mix a teaspoon of water with three-quarters (3/4) of a teaspoon of sugar.

Step 1: Pour all the powder into a bowl

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 2: 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 ANVIATIR powder. Stir the mixture well.





Give the whole contents of the bowl to your child straight away.

If there is some mixture left in the bowl, rinse the bowl with a small amount of water and get your child to drink it all.

Repeat this procedure every time you need to give ANVIATIR.

***To make a* 30 – 60 mg *dose (children weighing less than* 40 kg):**

To make a smaller single dose, you need:

- **One 75 mg ANVIATIR capsule.**
- **Sharp scissors.**
- **Two small bowls.**
- **One large oral dose dispenser to measure out water – a 5 mL or 10 mL dispenser.**
- **One small oral dose dispenser showing measurements of 0,1 mL, to give the dose.**
- **Teaspoon (5 mL spoon).**
- **Water.**
- **Sweet food** to hide the bitter taste of the ANVIATIR.

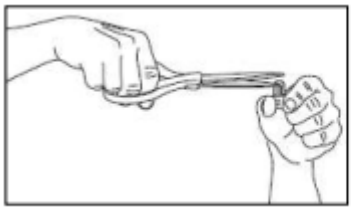
- Examples are: chocolate or cherry syrup and dessert toppings such as caramel or fudge sauce. Or you can make sugar water: mix a teaspoon of water with three-quarters (3/4) of a teaspoon of sugar.

Step 1: Pour all the powder into a bowl

Hold a **75 mg capsule** upright over one of the bowls and carefully snip off the rounded tip with scissors. Be careful with the powder, it may irritate your skin and eyes.

Pour all of the powder into the bowl, whatever the dose you are making.

The amount is the same whether you are treating or preventing flu.





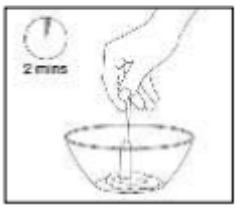
Step 2: Add water to dilute the medicine

Use the larger dispenser to draw up 5,0 mL water.

Add the water to the powder in the bowl.

Stir the mixture with the teaspoon for about 2 minutes.





Don’t worry if not all of the powder dissolves. The undissolved powder is just inactive ingredients.

Step 3: Choose the correct amount for your child’s weight

Look up your 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 (nearest)	**How much mixture to draw up**
Less than or equal to 15 kg (30 mg dose)	2,0 mL
More than 15 kg and up to 23 kg (45 mg dose)	3 mL
More than 23 kg and up to 40 kg (60 mg dose)	4 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 your 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 ANVIATIR.

Mix the sweet food and ANVIATIR liquid well.





Give the whole contents of the second bowl (ANVIATIR liquid mixture with sweet food added) to your child straight away.

If there is anything left in the second bowl, rinse the bowl with a small amount of water and get your child to drink it all.

Spoon-feed or use a bottle to feed your child the remaining liquid.

Throw away any unused liquid left in the first bowl.

Repeat this procedure every time you need to give ANVIATIR to your child.

Always take or give ANVIATIR exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

If you take more ANVIATIR than you should

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

Take this leaflet and the remaining ANVIATIR with you so the doctor will know what you have taken. In most cases of overdose, people have not reported any side effects. When side effects were reported, they were similar to those from normal doses, as listed in section 4.

If you forget to take ANVIATIR

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

4. Possible side effects

ANVIATIR can have side effects.

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

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

- swelling of your hands, feet, ankles, face, lips, 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 allergic reaction to ANVIATIR. 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:

- bleeding or bruising more easily than normal;
- fits (seizures);
- changes in the way your heart beats (faster, slower or irregular);
- gastrointestinal bleeding (bleeding from your large bowel [bloody diarrhoea] or spitting up blood);
- yellowing of your skin and eyes, dark urine and tiredness, which may be symptoms of liver problems;
- painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome or toxic epidermal necrolysis.

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

Adults and adolescents 13 years and over

Tell your doctor if you notice any of the following

Frequent side effects

- bronchitis (inflammation of the air passages of your lungs);
- infections of your sinuses (runny nose, nasal congestion), cough, fever;
- cold sore virus infection;
- upper respiratory tract infection (sneezing, runny nose, scratchy or sore throat);
- headaches or dizziness;

- difficulty falling and staying asleep;
- nausea (feeling sick), vomiting (being sick), abdominal pain, indigestion;
- pain, pain in limb, tiredness.

Less frequent side effects

- feeling agitated, anxious or confused;
- abnormal behaviour;
- mental confusion and emotional disruption (delirium), believing in something that is not true or based on reality (delusions)
- hallucinations (seeing or hearing things that do not exist);
- having nightmares;
- accidental self-injury;
- altered level of consciousness;
- visual problems;
- skin reactions (inflammation of your skin, red and itchy rash, scaling skin).

Children 1 to 12 years

Tell your doctor if you notice any of the following

Frequent side effects

- bronchitis (inflammation of the air passages of your lungs);
- earache, middle ear infection;
- infections of your sinuses (runny nose, nasal congestion), cough, fever;
- headaches;
- red, itchy, burning eyes with a white or green discharge or thick yellow discharge (conjunctivitis);
- asthma;
- vomiting (being sick), abdominal pain, indigestion, nausea (feeling sick), diarrhoea;
- inflammation of your skin.

Less frequent side effects

- 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 or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8

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

5. How to store ANVIATIR

- Store at or below 25 °C.
- Keep the blister strip in the outer carton until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the blister or 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

What ANVIATIR contains

ANVIATIR 30: Each capsule contains 30 mg oseltamivir (as phosphate).

ANVIATIR 45: Each capsule contains 45 mg oseltamivir (as phosphate).

ANVIATIR 75: Each capsule contains 75 mg oseltamivir (as phosphate).

The other ingredients are the *capsule core*: croscarmellose sodium, povidone (E1201), pregelatinised starch, sodium stearyl fumarate, talc (E553b), the *capsule shell*: gelatine, sodium

laurilsulfate (SLS) and titanium dioxide (E171) and *black ink*: black iron oxide (E172), potassium hydroxide (E525) and shellac (E904).

The capsule shell of ANVIATIR 45 and ANVIATIR 75 also contains D&C Red 28, FD&C Blue 1 (E133) and FD&C Red 40 (E129).

What ANVIATIR looks like and contents of the pack

ANVIATIR 30: Off-white powder filled in size “4” hard gelatine capsules with white opaque cap imprinted with “1008” in black ink and white opaque body imprinted with “N” in black ink.
ANVIATIR 45: Off white powder filled in size “4” hard gelatine capsules having light blue grey opaque cap imprinted with “1009” in black ink and light blue grey opaque body imprinted with “N” in black ink.
ANVIATIR 75: Off white powder filled in size “2” hard gelatine capsules having light blue grey opaque cap imprinted with “1010” in black ink and white opaque body imprinted with “N” in black ink.

PVC/PE/PVDC/aluminium blister strips containing 10 capsules, packed in an outer carton.

Holder of certificate of registration

Zydus Healthcare SA (Pty) Ltd
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22 Karee Street
Centurion, Pretoria
0157
Tel: 012 748 6400

This leaflet was last revised on

Date of registration: 26 March 2024

Registration numbers

ANVIATIR 30: 55/20.2.8/0686

ANVIATIR 45: 55/20.2.8/0687

ANVIATIR 75: 55/20.2.8/0688