

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S4****RIAMILOVIR 250 PHARMACENTRIX capsules****Riamilovir sodium dihydrate****Sugar free**

Read all of this leaflet carefully before you start taking RIAMILOVIR 250 PHARMACENTRIX

- 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.
- RIAMILOVIR 250 PHARMACENTRIX 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

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2. What you need to know before you take RIAMILOVIR 250 PHARMACENTRIX
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1. What RIAMILOVIR 250 PHARMACENTRIX is and what it is used for

RIAMILOVIR 250 PHARMACENTRIX is an antiviral medicine.

RIAMILOVIR 250 PHARMACENTRIX is used for the treatment of flu (influenza) in adults.

2. What you need to know before you take RIAMILOVIR 250 PHARMACENTRIX

Do not take RIAMILOVIR 250 PHARMACENTRIX:

- If you are hypersensitive to the riamilovir sodium dihydrate or to any of the excipients of RIAMILOVIR 250 PHARMACENTRIX.

Warnings and precautions

Take special care with RIAMILOVIR 250 PHARMACENTRIX if you:

- have kidney or liver problems,
- are an elderly person,

RIAMILOVIR 250 PHARMACENTRIX is not recommended for children under 18 years of age.

Other medicines and RIAMILOVIR 250 PHARMACENTRIX

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

If RIAMILOVIR 250 PHARMACENTRIX is used together with ribavirin, the dose of ribavirin should be reduced.

Interaction with purine analogues, e.g. azathioprine, mercaptopurine, thioguanine and pyrimidine bases, e.g., 5-fluorouracil, cytarabine and gemcitabine used for different types of cancer can lead to an increased drug toxicity.

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 this medicine.

Do not take RIAMILOVIR 250 PHARMACENTRIX during pregnancy or if you are breastfeeding.

Driving and using machines

It is not always possible to predict to what extent RIAMILOVIR 250 PHARMACENTRIX 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 RIAMILOVIR 250 PHARMACENTRIX affects them.

RIAMILOVIR 250 PHARMACENTRIX is not likely to impair your ability to drive vehicles or operate machinery.

3. How to take RIAMILOVIR 250 PHARMACENTRIX

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

Always take RIAMILOVIR 250 PHARMACENTRIX as your doctor or pharmacist had told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with RIAMILOVIR 250 PHARMACENTRIX will last. If you are under the impression that the effect of RIAMILOVIR 250 PHARMACENTRIX is too strong or too weak, tell your doctor or pharmacist.

The usual dose should be started no later than the 2nd day after the onset of the disease (the onset of clinical symptoms of influenza and other acute respiratory viral infections), at a dose of 1 capsule (250 mg) three times a day (maximum daily dose of 750 mg) for 5 consecutive days.

RIAMILOVIR 250 PHARMACENTRIX is taken orally, with or without food with sufficient drinking water. The capsule should be swallowed whole, it is not recommended to chew or crush the capsule.

If you take more RIAMILOVIR 250 PHARMACENTRIX than you should

Treatment for overdose should be symptomatic and supportive.

Symptoms: nausea, vomiting, dyspepsia, stomach pain.

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

If you forget to take RIAMILOVIR 250 PHARMACENTRIX

If you forget to take RIAMILOVIR 250 PHARMACENTRIX, take the missed dose as soon as you remember, provided this does not result in taking a double dose.

Then continue to take RIAMILOVIR 250 PHARMACENTRIX at the usual time.

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

Possible side effects

RIAMILOVIR 250 PHARMACENTRIX can have side effects.

If any of the following happens, stop taking RIAMILOVIR 250 PHARMACENTRIX and tell your doctor immediately or go to the casualty department at your nearest hospital:

- a feeling of heaviness, tension, sore throat, hoarseness, swallowing disorders, as well as the rapid development of dense, asymmetrical, painless swellings, accompanied by urticaria and itching on the face (lips, eyelids) and in the mouth.

These are all very serious side effects. If you have them, you may have had a serious reaction to RIAMILOVIR 250 PHARMACENTRIX. You may need urgent medical attention or hospitalisation.

Very rare:

- Increased eosinophils (white blood cells).
- Allergic reactions
- Flatulence, diarrhoea, nausea, vomiting, bloating with pasty stools, heartburn, abdominal pain.
- Increased erythrocytes, leukocytes, squamous epithelial cells and presence of bacteria in the urine.
- Increase in plasma levels of alanine transferase (ALT) and aspartate transferase (AST) and bilirubin.

Frequency unknown:

- Helminthosis (worm infection), respiratory syncytial infection (RS-infection) (a common respiratory virus infection that usually causes mild, cold-like symptoms).
- Parotid atheroma (a fatty substance that builds up in your parotid gland over time).
- Headache.
- Catarrhal symptoms, such as a buildup of mucus in the back of the nose, throat or sinuses.
- Skin irritation.
- Angioedema (swelling of the face, mouth, tongue, vocal cords, stomach or arms and legs, with urticaria and itching.)

Should your general health worsen or if you experience any untoward effects while taking RIAMILOVIR 250 PHARMACENTRIX, please consult your doctor, pharmacist or other health care professional for advice.

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 RIAMILOVIR 250 PHARMACENTRIX.

4. How to store RIAMILOVIR 250 PHARMACENTRIX

Store in a dry and dark place, at or below 25 °C.

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

Do not take RIAMILOVIR 250 PHARMACENTRIX after the expiry date which is stated on the carton and PVC/Aluminium foil blisters after EXP.

The expiry date refers to the last day of the month.

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

5. Contents of the pack and other information

What RIAMILOVIR 250 PHARMACENTRIX tablets contain

- The active substance is riamilovir sodium dihydrate.

Each gelatine capsule contains riamilovir sodium dihydrate 250 mg.

- The other ingredients are calcium stearate and hard gelatine capsule size #1, consisting of: Capsule body (titanium dioxide (E171), quinoline yellow (E104), sunset yellow (E110), medical gelatine) and Capsule cap (titanium dioxide (E171), azorubine (E122), medical gelatine).

What RIAMILOVIR 250 PHARMACENTRIX looks like and contents of the pack

Hard gelatin capsules, size #1 with a yellow body and red cap. The content of the capsules is a yellow to yellow-green fine crystalline powder or granules.

RIAMILOVIR 250 PHARMACENTRIX capsules are packed into PVC/Aluminium blister strips, 10 capsules per strip.

Pack sizes: 20 or 50 capsules in an outer carton.

Holder of Certificate of Registration

Pharmacentrix (Pty) Ltd

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South Africa

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Riamilovir 250-PI/A<FINAL>

Agreement of the parties	Full name, position	(signature)	(date)
From the customer:	Elize Grobler Responsible Pharmacist		18/03/2025
From the developer:			