RIAMILOVIR 250 PHARMACENTRIX®

FOR THE TREATMENT OF FLU AND UPPER RESPIRATORY VIRAL INFECTIONS.

ANTIVIRAL PRODUCT

DOSE PACK

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RIAMILOVIR 250 PHARMACENTRIX® HAS A DIRECT MODE OF ACTION

Inhibition of synthesis of viral RNA

Which results in

Stopping of virus replication in the cell

RIAMILOVIR 250 PHARMACENTRIX® is a universal drug

In the absence of a laboratory-confirmed diagnosis of Influenza A, Influenza B or other Upper Respiratory Viral Infections it is advisable to use universal direct-acting antiviral drugs.

RIAMILOVIR 250 PHARMACENTRIX® is effective[5]:

- Reduces the duration of major clinical syndromes.
- Prevents the risk of developing complications.
- Accelerates the elimination of pathogens from the body.
- Reduces the number of sick days.

RIAMILOVIR 250 PHARMACENTRIX® is safe[6,7]

Results of multi-center clinical trials have demonstrated that Riamilovir 250 Pharmacentrix® has a very good safety profile. No significant adverse events were detected throughout the observation period.

RIAMILOVIR 250 PHARMACENTRIX® administration regimen

TREATMENT **3** TIMES PER DAY ONE CAPSULE **5** FOR DAYS

1. Instruction for medical use of pharmaceutical: Riamilovir 250 Pharmacentrix® 250 mg capsules, RU LP-002604.
2. K.V. Kasyanenko et al. Efficacy and safety of administration of Riamilovir for treatment of patients with COVID-19. Antibiotics and chemotherapy, 2021, 66:1–2
3. https://cr.minzdrav.gov.ru/schema/724_1
4. https://cr.minzdrav.gov.ru/recomend/749_1
5. I.I. Tokin et al. Experience of etiotropic therapy of acute respiratory viral infections with a domestically-produced antiviral. Infectious diseases. 2019; 17 (4): 13–17.
6. A.U. Sabitov et al. Meta-analysis of randomized controlled clinical trials of efficacy of Riamilovir in etiotropic therapy of acute respiratory viral infection. Antibiotics and chemotherapy, 2021, Volume 66, No.5–6: 48–57.
7. A.U. Sabitov et al. Meta-analysis of randomized clinical trials of efficacy of Riamilovir in etiotropic therapy of influenza. Antibiotics and Chemotherapy, 2021, Volume 66, No.5–6: 58–71

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CLINICAL EFFICACY, SAFETY AND TOLERANCE

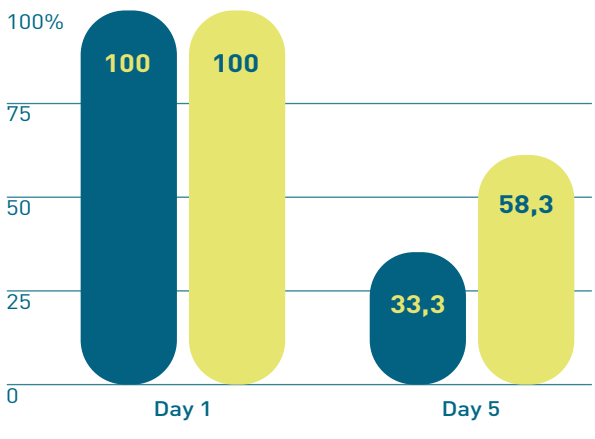
of RIAMILOVIR 250 PHARMACENTRIX® for treatment of FLU

A comparative study was conducted to analyze the efficacy and safety of RIAMILOVIR 250 PHARMACENTRIX®

Patients diagnosed with FLU

Main Group	**RIAMILOVIR 250 PHARMACENTRIX® 1 CAPSULE 3X PER DAY**
Comparison Group	**OSELTAMIVIR 1 CAPSULE 2X PER DAY**

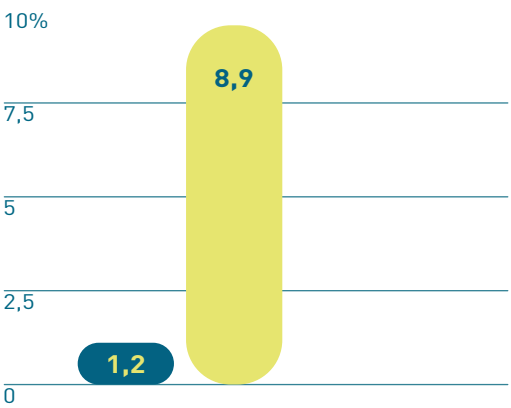
Rate of repeat detection of RNA viruses (1 and 5 days after disease onset), %



Riamilovir 250 Pharmacentrix®

Oseltamivir

Incidence of complications, %



% of patients taking Riamilovir 250 Pharmacentrix®

% of patients taking Oseltamivir

SUPERIORITY OF THERAPY IN THE MAIN GROUP (RIAMILOVIR 250 PHARMACENTRIX®):

- frequency of repeat detection of RNA of flu virus on the 5th day of treatment was significantly lower than in patients in the comparison group;
- duration of temperature normalization period was 2 times lower;
- lower duration of symptoms: headache, myalgia, sore eyes, coughing and sore throat;
- incidence of complications was almost 7 times lower;
- duration of symptomatic therapy was lower by 60%;
- no development of complications in the form of pneumonia was detected.

The efficacy of RIAMILOVIR 250 PHARMACENTRIX® (main group) surpassed that of the comparison group according to a number of indicators. Moreover, Riamilovir 250 Pharmacentrix® was found to be safe and well tolerated.

PROFESSIONAL INFORMATION

SCHEDULING STATUS [S4]

NAME OF THE MEDICINE:
Riamilovir 250 Pharmacentrix capsules

COMPOSITION Active substance:
Each gelatine capsule contains **riamilovir sodium dihydrate 250 mg.**

THERAPEUTIC INDICATIONS
Treatment of influenza and other acute respiratory viral infections in adults. If necessary, combine with the use of symptomatic medicines.

Posology
RIAMILOVIR 250 PHARMACENTRIX 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.

Special populations
Elderly population
RIAMILOVIR 250 PHARMACENTRIX is not recommended for elderly patients as safety and efficacy have not been established.
Renal impairment
RIAMILOVIR 250 PHARMACENTRIX is not recommended for patients with renal impairment as safety and efficacy have not been established.
Hepatic impairment
RIAMILOVIR 250 PHARMACENTRIX is not recommended for patients with hepatic impairment as safety and efficacy have not been established.
Paediatric population
RIAMILOVIR 250 PHARMACENTRIX is not recommended for children under 18 years of age.

Method of administration
Oral use.
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.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Pharmacological classification: A 20.2.8 Antiviral agents ATC Code: J05AX, Antiviral drug

Mechanism of action
Riamilovir is a synthetic analogue of purine nucleoside (guanine) bases, with a pronounced antiviral effect. It possesses broad-spectrum antiviral activity against RNA-containing viruses. The main mechanism of action of the molecule is the inhibition of synthesis of viral RNA and replication of viral fragments.

The obtained data suggests that the use of riamilovir in etiotropic treatment of influenza helps to reduce the length of the main symptoms: intoxication, fever, catarrhal symptoms and decrease the severity of the disease. Riamilovir reduced the level of post-treatment detection rate of influenza virus type A and B, with significantly reduced duration and amount of concomitant symptomatic treatment. Use of riamilovir reduced the incidence of complications.
Administration of riamilovir promotes normalisation of a number of blood counts, reflecting severity of the disease, severity of the process and the immune system status of patients.

Pharmacokinetic properties
Absorption
After oral administration, riamilovir is quickly absorbed in the gastrointestinal tract. The maximum concentration (Cmax) is achieved on average in 1-1,5 h regardless of the dose.

Distribution
Apparent volume of distribution at steady state, Vss, is about 4,7 L/kg.

Metabolism
Following oral administration riamilovir reached detectable levels in system blood after 30 min with time to reach maximum concentration of about 1,5-20 hrs (5,15-6,66 µg/mL). The concentration of riamilovir was then gradually decreased and 6 hours after dosing riamilovir was detected in blood in minimal quantities (0,62 ± 0,03 µg/mL). The spread in individual values was moderate: coefficient of variations CV was 12 - 30 %.

Elimination
Kidneys, in an unmodified form, excreted from 15 to 45 % of the riamilovir. Riamilovir elimination is non-linear.

Special precautions for storage: Store in a dry and dark place, at or below 25 °C.

Nature and contents of container: 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, 6 Ateljee Street, Randpark Ridge, Randburg, South Africa
REGISTRATION NUMBER: 550440
Please consult the Package Insert for full details:

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