Package Leaflet: Patient Information

TRIAZAVIRIN®, 250 mg, capsules

Active ingredient: riamilovir

Read this leaflet carefully before using this medicine as it contains important information for you.

This medicine is an over-the-counter product.

Always take this medicine exactly as specified in this leaflet or as recommended by your doctor or pharmacist.

Keep this leaflet. You may need to read it again.

If you need more information or recommendations, talk to your pharmacist.

If you have any adverse reactions, please contact your doctor or pharmacist. This recommendation applies to all possible adverse reactions, including those not listed in section 4 of the package leaflet.

If there is no improvement or if you feel worse after 5 days, consult your doctor.

What is in this leaflet

1. What TRIAZAVIRIN® is and what it is used for

TRIAZAVIRIN® is an antiviral agent that contains the active ingredient: riamilovir.

Riamilovir is a synthetic analogue of purine nucleoside bases (guanine) with pronounced antiviral action. It has a broad-spectrum antiviral activity against RNA-containing viruses.

When used in patients with mild COVID-19, the medicinal product demonstrated a statistically significant acceleration in the sustained improvement in clinical symptoms of the disease. In terms of safety, the medicine did not differ from placebo.

When using TRIAZAVIRIN® to prevent COVID-19 infection in adults living together with a person exhibiting symptomatic manifestations of confirmed COVID-19 infection, its efficacy and safety were confirmed. The relative risk of disease in the group of subjects taking TRIAZAVIRIN® was 88.96% lower than that in the placebo group. In terms of safety, the medicine did not differ from placebo.

Therapeutic indications

TRIAZAVIRIN® is indicated for use in adults aged 18 and older:

- as part of combination therapy for influenza and other acute respiratory viral infections in adults;

- for the prevention of COVID-19 infection in adults living together with a person exhibiting symptomatic manifestations of confirmed COVID-19 infection.

How TRIAZAVIRIN® works

TRIAZAVIRIN® inhibits the synthesis of viral RNA and the replication of genomic fragments.

If there is no improvement or you feel worse after 5 days, consult your doctor.

2. What you need to know before taking TRIAZAVIRIN®

Contraindications

Do not take TRIAZAVIRIN®:

- if you are allergic to riamilovir or any other components of this medicine (listed in section 6 of this leaflet);
- if you are pregnant;
- if you are breastfeeding;
- if you have renal or hepatic failure (efficacy and safety have not been established).

Special warnings and precautions

Before using TRIAZAVIRIN®, consult your doctor or pharmacist.

Pediatric population

Do not give the medicine to children below 18 years of age, since the efficacy and safety of TRIAZAVIRIN® in this age group have not been established.

Other medicines and TRIAZAVIRIN®

Inform your doctor or pharmacist if you are taking, have recently taken or may start taking any other medicines.

No special studies of TRIAZAVIRIN® interaction with other medicines have been conducted.

Pregnancy and breastfeeding

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 using this medicinal product.

Pregnancy

Do not take TRIAZAVIRIN® if you are pregnant, as there are no studies available.

Breastfeeding

Do not take TRIAZAVIRIN® if you are breastfeeding, as the use of the medicinal product during breastfeeding has not been studied.

If it is necessary to use the medicinal product during lactation, you should stop breastfeeding.

Driving and using machines

No studies on the impact of TRIAZAVIRIN® on the ability to drive and use machines have been performed. However, with regard to the range of adverse reactions, if dizziness occurs, you should refrain from driving and using machines.

TRIAZAVIRIN® contains sunset yellow and azorubine

TRIAZAVIRIN® contains sunset yellow (E110) and azorubine (E122), which can cause allergic reactions.

3. How to use TRIAZAVIRIN®

Always take this medicine exactly as specified in this leaflet or as your doctor or pharmacist has told you.

If you have any doubts, consult your doctor or pharmacist.

Recommended dose

For influenza and other acute respiratory viral infections in adults: 1 capsule (250 mg) 3 times a day for 5 consecutive days.

Maximum single dose: 1 capsule (250 mg). Maximum daily dose: 3 capsules (750 mg).

For the prevention of COVID-19 infection in adults living together with a person exhibiting symptomatic manifestations of confirmed COVID-19 infection: 1 capsule (250 mg) once daily for 10 days.

Route and method of administration

The medicine should be taken orally, regardless of food intake, with a sufficient amount of fresh water. Swallow the capsule whole; do not chew or crush the capsule.

Duration of therapy

For influenza and other acute respiratory viral infections in adults, the medicine should be taken no later than the 2nd day from the onset of disease (appearance of symptoms of influenza and other acute respiratory viral infections).

If there is no improvement after 5 days of treatment, or symptoms aggravate, or new symptoms appear, please consult your doctor.

For the prevention of COVID-19 infection in adults living together with a person exhibiting symptomatic manifestations of confirmed COVID-19 infection, the medicine should be taken no later than 4 days after confirmation of COVID-19 infection in the first sick patient in the household outbreak.

If you experience COVID-19 symptoms or if laboratory tests confirm the infection, you should consult your doctor.

If you took more TRIAZAVIRIN® than you should

If you took far too much TRIAZAVIRIN®, you may experience nausea, vomiting, dyspepsia, and stomach pain. In this case, stop taking the medicinal product and consult your doctor.

If you forgot to take TRIAZAVIRIN®

If you forget to take the medicine at the proper time, you should take the next capsule and follow the usual dosing schedule with the usual time intervals between the doses.

Do not take a double dose to make up for a missed capsule.

If you stop taking TRIAZAVIRIN®

Do not stop taking this medicine until the end of the treatment course (5 consecutive days) or preventive use (10 days) without consulting your doctor due to the possible lack of the expected effect.

If you have any questions regarding the use of the medicinal product, consult your doctor or pharmacist.

4. Possible adverse reactions

Like all medicines, TRIAZAVIRIN® may cause adverse reactions, however, not everybody gets them.

Stop using TRIAZAVIRIN® and seek immediate medical attention if any of the following symptoms of serious adverse reactions occur:

Not known (frequency cannot be estimated from the available data):

- severe edema of the lips, eyelids, cheeks, and oral mucosa may spread to the laryngeal mucosa, which may cause difficulty breathing, hoarseness, and barking cough (angioedema) (*reactions were observed only in adult patients using TRIAZAVIRIN®, 250 mg, capsules).*

Other possible adverse reactions that may be observed when using TRIAZAVIRIN®:

Reactions were observed in children aged 12 to 17 years during clinical studies of TRIAZAVIRIN®, 100 mg, capsules:

Common (may affect up to 1 in 10 people):

- decreased heart rate;

Uncommon (may affect not more than 1 in 100 people):

- increased blood eosinophil counts.

Reactions were observed in children aged 6 to 11 years during clinical studies of TRIAZAVIRIN®, 100 mg, capsules:

Uncommon (may affect not more than 1 in 100 people):

- low systolic blood pressure;
- increase of segmented neutrophils in the leukocyte blood formula.

Reactions were observed in adult patients during clinical studies of TRIAZAVIRIN®, 100 mg, capsules

Uncommon (may affect not more than 1 in 100 people):

- increased blood eosinophil counts;
- mushy stools and bloating;

- abdominal pain;
- rash;
- high levels of erythrocytes, leukocytes, and squamous epithelium in urine;
- presence of bacteria in urine.

Reactions were observed in adult patients during clinical studies and during post-marketing use of TRIAZAVIRIN®, 250 mg, capsules:

Not known (frequency cannot be estimated from the available data):

- increased blood monocyte counts;
- rash;
- itching;
- itching, skin redness with blisters and welts (urticaria);
- abdominal discomfort, may be accompanied by vomiting, mushy stools, flatulence, abdominal pain, dry mouth, bitter taste in the mouth, heartburn, nausea, belching, bloating, diarrhea (dyspeptic symptoms);
- headache;
- dizziness;
- high levels of erythrocytes, leukocytes, and squamous epithelium in urine;
- presence of bacteria in urine;
- increased levels of liver enzymes in the blood (alanine aminotransferase (ALT), aspartate aminotransferase (AST));
- increased blood glucose levels;
- increased blood creatinine levels;
- weakness.

Reporting adverse reactions

If you experience any adverse reactions, consult your doctor or pharmacist. This recommendation applies to any possible adverse reactions, including those which are not listed in the package leaflet. You can also report adverse reactions directly (see below). By reporting adverse reaction, you help to gather more data on product safety.

Russian Federation

Federal Service for Surveillance in Healthcare (Roszdravnadzor)

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Tel.: +7 800 550 99 03

E-mail: pharm@roszdravnadzor.gov.ru

Internet website:
https://www.roszdravnadzor.gov.ru

5. How to store TRIAZAVIRIN®

Keep the medicine out of the reach and sight of children.

Do not use the medicine after the expiration date (shelf life) indicated on the package after the words “UNTIL” (on the blister) or “EXP” (on the carton).

The expiration date is the last day of the month.

Store the medicine in the original package (carton) at a temperature not exceeding 25 °C to protect from light.

The medicinal product may be stored and transported in a place protected from light at a temperature from minus 50 to 50 °C for no more than 30 days.

Do not throw the product into the sewage system. Ask a pharmacist how to dispose of (destroy) the medicinal product you no longer need. These measures will help to protect the environment.

6. Contents of the package and other information

TRIAZAVIRIN® contains

The active ingredient is riamilovir.

Each capsule contains 250 mg riamilovir (equivalent to riamilovir dihydrate).

The excipients include: calcium stearate, capsule (body) No. 1 (titanium dioxide (E171), quinoline yellow (E104), sunset yellow (E110), medical gelatin), capsule (cap) No. 1 (titanium dioxide (E171), azorubine (E122), medical gelatin).

TRIAZAVIRIN® contains sunset yellow (E110) and azorubine (E122).

Appearance of TRIAZAVIRIN® and package contents

Capsules.

Size No. 1 hard gelatin capsules: a yellow body and a red cap. The contents of the capsules include finely crystalline powder or yellow or yellow-green granules.

Ten capsules in a blister made of polyvinylchloride film and printed lacquered aluminum foil. One or two blisters with the package leaflet in a carton.

Dispensing category of the medicinal product

The medicinal product is categorized as over-the-counter.

Marketing Authorization Holder

Russian Federation

Limited Liability Company "Zavod Medsintez" (LLC " Zavod Medsintez")

Bldg. 28B/2, Kirova street, premises 1, office 205, Yekaterinburg, Yekaterinburg City Urban District, Sverdlovsk region, 620028

Tel.: (34370) 2-50-61, tel.: 8-800-200-8434.

E-mail: medsintez@mail.ru

Manufacturer

Russian Federation

Limited Liability Company "Zavod Medsintez" (LLC "Zavod Medsintez")

9 Podgornaya St., Novouralsk, Sverdlovsk region, 624130

For any information about the medicinal product, contact the local representative of the marketing authorization holder:

Russian Federation

Limited Liability Company "Zavod Medsintez" (LLC "Zavod Medsintez")

9 Podgornaya St., Novouralsk, Sverdlovsk region, 624130

Tel.: (34370) 2-50-61, tel.: 8-800-200-8434

E-mail: medsintez@mail.ru

Other sources of information

Detailed information about this medicinal product is contained in the Unified Register of Registered Medicinal Products. The package leaflet is available in the Unified Register of Registered Medicinal Products and on the official website of the competent authority (expert organization) of the Eurasian Economic Union https://grls.rosminzdrav.ru.

Package Leaflet: Patient Information

TRIAZAVIRIN®, 100 mg, capsules

Active ingredient: riamilovir **Read this leaflet carefully before taking this medicine as it contains important information for you.**

Keep this leaflet. You may need to read it again.

If you have any further questions, please ask your doctor.

This medicine has been prescribed for you only. Do not give it to others. It may harm them, even if their signs of illness are the same as yours.

If you develop any adverse reactions, consult your doctor. This recommendation applies to all possible adverse reactions, including those not listed in section 4 of the package leaflet.

What is in this leaflet

1. What TRIAZAVIRIN® is and what it is used for

TRIAZAVIRIN® is an antiviral agent that contains the active ingredient: riamilovir.

Riamilovir is a synthetic analogue of purine nucleoside bases (guanine) with pronounced antiviral action. It has a broad-spectrum antiviral activity against RNA-containing viruses.

Therapeutic indications

TRIAZAVIRIN® is used in children aged 6 to 17 years as part of combination therapy for acute respiratory viral infections.

How TRIAZAVIRIN® works

TRIAZAVIRIN® inhibits the synthesis of viral RNA and the replication of genomic fragments.

If there is no improvement or you feel worse after 5 days, consult your doctor.

2. What you need to know before taking TRIAZAVIRIN®

Contraindications

Do not take TRIAZAVIRIN®:

- if you are allergic to riamilovir or any other components of this medicine (listed in section 6 of this leaflet);

- if you are pregnant;
- if you are breastfeeding;
- if you have renal or hepatic failure (efficacy and safety have not been established).

Special warnings and precautions

Before taking TRIAZAVIRIN®, consult your doctor.

Pediatric population

Do not give TRIAZAVIRIN® to children under 6 years of age, as its efficacy and safety in this age group have not been established.

Other medicines and TRIAZAVIRIN®

Inform your doctor about any other medicines you are taking, planning to take or have recently taken.

No special studies of TRIAZAVIRIN® interaction with other medicines have been conducted.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, consult your doctor before taking this medicinal product.

Pregnancy

Do not take TRIAZAVIRIN® if you are pregnant, as there are no studies available.

Breastfeeding

Do not take TRIAZAVIRIN® if you are breastfeeding, as the use of the medicinal product during breastfeeding has not been studied.

If it is necessary to use the medicinal product during lactation, you should stop breastfeeding.

Driving and using machines

No studies on the impact of TRIAZAVIRIN® on the ability to drive and use machines have been performed. However, with regard to the range of adverse reactions, if dizziness occurs, you should refrain from driving and using machines.

3. How to use TRIAZAVIRIN®

When taking this medicine, always follow the recommendations of your doctor. If you have any doubts, consult your doctor.

Recommended dose

Children 12 to 17 years old: 1 capsule (100 mg) 3 times a day (at intervals of 4–5 hours) and 2 capsules (200 mg) at bedtime for 5 consecutive days. Maximum single dose: 2 capsules (200 mg). Maximum daily dose: 5 capsules (500 mg).

Children 6 to 11 years old: 1 capsule (100 mg) 2 times a day, morning and evening, for 5 consecutive days. Maximum single dose: 1 capsule (100 mg). Maximum daily dose: 2 capsules (200 mg).

Route and method of administration

The medicine should be taken orally, regardless of food intake, with a sufficient amount of fresh water. Swallow the capsule whole; do not chew or crush the capsule.

Duration of therapy

Start taking the medicine no later than the 2nd day from the disease onset (appearance of symptoms of acute respiratory viral infections).

If there is no improvement after 5 days of treatment, or symptoms aggravate, or new symptoms appear, please consult your doctor.

If you took more TRIAZAVIRIN® than you should

If too much TRIAZAVIRIN® was taken, nausea, vomiting, dyspeptic disorders, and stomach pain may occur. In this case, you should stop taking the medicinal product and consult your doctor.

If you forgot to take TRIAZAVIRIN®

If you forget to take the medicine at the proper time, take the next capsule and follow the usual dosing schedule with the usual intervals between the doses.

Do not take a double dose to make up for a missed one.

If you stop taking TRIAZAVIRIN®

You must not stop taking the medicine until the end of the treatment course (5 consecutive days). If you stop taking the medicine too early, the infection may not be completely cured and its symptoms may return or worsen.

If you have any questions regarding the use of the medicinal product, consult your doctor.

4. Possible adverse reactions

Like all medicines, TRIAZAVIRIN® may cause adverse reactions, however, not everybody gets them.

Stop using TRIAZAVIRIN® and seek immediate medical attention if any of the following symptoms of serious adverse reactions occur:

Not known (frequency cannot be estimated from the available data):

- severe edema of the lips, eyelids, cheeks, and oral mucosa may spread to the laryngeal mucosa, which may cause difficulty breathing, hoarseness, and barking cough (angioedema) (*reactions were observed only in adult patients using TRIAZAVIRIN®, 250 mg, capsules).*

Other possible adverse reactions that may be observed when using TRIAZAVIRIN®:

Reactions were observed in children aged 12 to 17 years during clinical studies of TRIAZAVIRIN®, 100 mg, capsules:

Common (may affect up to 1 in 10 people):

- decreased heart rate;

Uncommon (may affect not more than 1 in 100 people):

- increased blood eosinophil counts.

Reactions were observed in children aged 6 to 11 years during clinical studies of TRIAZAVIRIN®, 100 mg, capsules:

Uncommon (may affect not more than 1 in 100 people):

- low systolic blood pressure;
- increase of segmented neutrophils in the leukocyte blood formula.

Reactions were observed in adult patients during clinical studies of TRIAZAVIRIN®, 100 mg, capsules

Uncommon (may affect not more than 1 in 100 people):

- increased blood eosinophil counts;
- mushy stools and bloating;
- abdominal pain;
- rash;
- high levels of erythrocytes, leukocytes, and squamous epithelium in urine;
- presence of bacteria in urine.

Reactions were observed in adult patients during clinical studies and during post-marketing use of TRIAZAVIRIN®, 250 mg, capsules:

Not known (frequency cannot be estimated from the available data):

- increased blood monocyte counts;
- rash;
- itching;
- itching, skin redness with blisters and welts (urticaria);
- abdominal discomfort, may be accompanied by vomiting, mushy stools, flatulence, abdominal pain, dry mouth, bitter taste in the mouth, heartburn, nausea, belching, bloating, diarrhea (dyspeptic symptoms);
- headache;
- dizziness;
- high levels of erythrocytes, leukocytes, and squamous epithelium in urine;
- presence of bacteria in urine;
- increased levels of liver enzymes in the blood (alanine aminotransferase (ALT), aspartate aminotransferase (AST));
- increased blood glucose levels;
- increased blood creatinine levels;
- weakness.

Reporting adverse reactions

If any adverse reactions occur, consult your doctor. This recommendation applies to any possible adverse reactions, including those which are not listed in the package leaflet. You can also report adverse reactions directly (see below). By reporting adverse reaction, you help to gather more data on product safety.

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5. How to store TRIAZAVIRIN®

Keep the medicine out of the reach and sight of children.

Do not use the medicine after the expiration date (shelf life) indicated on the package after the words “UNTIL” (on the blister) or “EXP” (on the carton).

The expiration date is the last day of the month.

Store the medicine in the original package (carton) at a temperature not exceeding 25 °C to protect from light.

The medicinal product may be stored and transported in a place protected from light at a temperature from minus 50 to 50 °C for no more than 30 days.

Do not throw the product into the sewage system. Ask a pharmacist how to dispose of (destroy) the medicinal product you no longer need. These measures will help to protect the environment.

6. Contents of the package and other information

TRIAZAVIRIN® contains

The active ingredient is riamilovir.

Each capsule contains 100 mg riamilovir (equivalent to riamilovir dihydrate).

The excipients include: calcium stearate, capsule (body) No. 1 (titanium dioxide (E171), quinoline yellow (E104), allura red (E129), medical gelatin), capsule (cap) No. 1 (titanium dioxide (E171), allura red (E129), medical gelatin).

Appearance of TRIAZAVIRIN® and package contents

Capsules.

TRIAZAVIRIN® is a hard gelatin capsule (size No. 1) with a yellow body and a red cap. The contents of the capsules include finely crystalline powder or yellow or yellow-green granules.

Ten capsules in a blister made of polyvinylchloride film and printed lacquered aluminum foil. One or two blisters with the package leaflet in a carton.

Dispensing category of the medicinal product

This medicinal product is available only by prescription.

Marketing Authorization Holder

Russian Federation

Limited Liability Company "Zavod Medsintez" (LLC "Zavod Medsintez")

Bldg. 28B/2, Kirova street, premises 1, office 205, Yekaterinburg, Yekaterinburg City Urban District, Sverdlovsk region, 620028

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Manufacturer

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