MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

INSTRUCTIONS FOR MEDICAL USE

ARBIDOL®

Registration number:
Trade name of the drug: Arbidol ®
International Nonproprietary Name: Umifenovir
Dosage form: powder for suspension preparation for ingestion
Composition for 5 ml:
Active substance : Umifenovir (Umifenovira hydrochloride monohydrate – 25,88 mg) (per Umifenovir hydrochloride – 25,00 mg) .

Excipients: sodium chloride - 26.85 mg, maltodextrin (Kleptosa Linecaps) - 750.00 mg, saccharose (sugar) - 840.42 mg, silicon dioxide colloidal (aerosil) – 24.60 mg, titanium dioxide - 25, 00 mg, pre-gelatinized starch (PA5PH type) - 129.50 mg, sodium benzoate - 9.25 mg, banana flavor - 12.40 mg, cherry flavor - 6.10 mg.

Description: white or nearly white granulated powder with a distinctive fruity smell.
Description of prepared suspension: a homogeneous suspension of white or white with a yellowish or creamy shade of color with a distinctive fruit smell.
Pharmacotherapeutic group: antiviral agent.
ATC Code: J 05 AX 13

Pharmacology

Pharmacodynamics

Antiviral agent. Specifically inhibits *in vitro* influenza A and B viruses (*Influenzavirus A , B*), including the highly pathogenic subtypes *A (H 1 N 1) pdm 09* and *A (H 5 N 1)* , as well as other acute respiratory viral infections (ARVI) viruses (coronavirus (*Coronavirus*) associated with severe acute respiratory syndrome (SARS), rhinovirus (*Rhinovirus*), adenovirus (*Adenovirus*), respiratory syncytial virus (*Pneumovirus*) and parainfluenza virus (*Paramyxovirus*)). According to the mechanism of antiviral action, it belongs to fusion (fusion) inhibitors, interacts with the hemagglutinin of the virus and prevents the fusion of the lipid membrane of the virus and cell membranes. It has a moderate immunomodulatory effect, increases the body's resistance to viral infections. It has interferon-inducing activity - in a study on mice, the induction of interferons was observed after 16 hours, and high titers of interferons remained in the blood until 48 hours after administration. Stimulates cellular and humoral immunity reactions: increases the number of lymphocytes in the blood, especially T-cells (CD3), increases the number of T-helpers (CD 4),

without affecting the level of T - suppressors (CD 8), normalizes the immunoregulatory index, stimulates phagocytic macrophage function and increases the number of natural killer cells (NK cells).

Therapeutic efficacy in viral infections is manifested in a decrease in the duration and severity of the course of the disease and its main symptoms, as well as in a decrease in the frequency of development of complications associated with a viral infection and exacerbations of chronic bacterial diseases.

In the treatment of influenza or SARS in adult patients, a clinical study showed that the effect of the drug in adult patients is most pronounced in the acute period of the disease and is manifested by a reduction in the resolution of symptoms of the disease, a decrease in the severity of the manifestations of the disease, and a reduction in the elimination of the virus.

Therapy with the drug leads to a higher frequency of relief of the symptoms of the disease on the third day of therapy compared with placebo - 60 hours after the start of therapy, the resolution of all symptoms of laboratory-confirmed influenza is more than 5 times higher than the similar indicator in the placebo group.

A significant effect of the drug on the rate of elimination of the influenza virus was established, which, in particular, was manifested by a decrease in the frequency of detection of virus RNA on the 4th day.

Refers to low-toxic drugs ($LD_{50} > 4$ g / kg). It does not have any negative effects on the human body when administered orally in recommended doses.

Pharmacokinetics It is rapidly absorbed and distributed to organs and tissues. The maximum concentration in blood plasma when taken at a dose of 200 mg of umifenovir is reached after 1 hour, volume of distribution (Vd) - 1432 L. It is metabolized in the liver. The elimination half-life is on average 11 hours. About 40 % is excreted unchanged, mainly with bile (38.9 %) and in a small amount by the kidneys (0.12 %). During the first day, 90 % of the administered dose is excreted .

Indications

- prevention and treatment in adults and children from 2 years: influenza A and B, other acute respiratory viral infections.
- combined therapy of acute intestinal infections of rotavirus etiology in children over 2 years old.

Contraindications

Hypersensitivity to umifenovir or any component of the drug. Children under 2 years old. The first trimester of pregnancy. The period of breastfeeding. Sugarase/isomaltaza deficiency, fructose intolerance, glucose-galactose malabsorption.

Carefully

The second and third trimesters of pregnancy.

Pregnancy & Lactation

Animal studies have not revealed harmful effects on pregnancy, the development of the embryo and fetus, labor and postnatal development.

The use of the drug Arbidol® in the first trimester of pregnancy is contraindicated.

In the second and third trimester of pregnancy, Arbidol® can only be used for the treatment and prevention of influenza, and if the intended benefit to the mother outweighs the potential risk to the fetus. The benefit / risk ratio is determined by the attending physician.

It is not known whether Arbidol® passes into breast milk in women during lactation. If it is necessary to use Arbidol® breastfeeding should be stopped.

Dosage and administration

Inside, before eating.

Suspension preparation.

Add 30 ml (or approximately 2/3 of the bottle volume) of boiled water cooled to room temperature to the vial with powder. Close the vial with a lid, turn it over and shake thoroughly until a homogenous suspension is obtained. Add boiled and cooled water to 100 ml (to the mark on the vial) and shake again. Before each drug administration it is necessary to thoroughly shake the contents of the vial until a homogeneous suspension is obtained. Measure the single dose with the measuring spoon, which is accompanied.

A single dose (depending on age):

Age	*A single dose, suspension ml (mg umifenovir)*
From 2 to 6 years old	*10 ml (50 mg)*
From 6 to 12 years old	*20 ml (100 mg)*
Over 12 years old and adults	*40 ml (200 mg)*

Dosing regime (depending on age):

Indication	***Reception scheme the drug***
In children from 2 years old and adults	
Nonspecific prevention during the flu epidemic and other acute respiratory viral infections	in a single dose 2 times a week for 3 weeks.
Nonspecific prophylaxis in direct contact with patients with influenza and other acute respiratory viral infections	in a single dose 1 time per day for 10-14 days.
Treatment of influenza and other acute respiratory viral infections	in a single dose 4 times a day

	(every 6 hours) for 5 days.
In children from 2 years old:	
Complex therapy of acute intestinal infections of rotavirus etiology	in a single dose 4 times a day (every 6 hours) for 5 days.

Use the drug only according to the indications, the method of use and at the doses indicated in the instructions.

Taking the drug begins with the onset of the first symptoms of the disease with influenza and other acute respiratory viral infections, preferably no later than 3 days from the onset of the disease.

If after using the drug Arbidol ® for 3 days during the treatment of influenza and other acute respiratory viral infections, the severity of the symptoms of the disease, including high temperature (38 ° C or more), remains, then you must consult a doctor to assess the feasibility of taking the drug.

When the treatment of influenza and acute respiratory viral infections can be related symptomatic therapy, including receiving antipyretic drugs, mucolytic and local vasoconstrictor.

Adverse reactions

The drug Arbidol ® refers to low-toxic drugs and is usually well tolerated.

Side effects are rare, usually mild or moderate, and are transient.

The frequency of adverse drug reactions is determined in accordance with the WHO classification: very often (with a frequency of more than 1/10), often (with a frequency of at least 1/100, but less than 1/10), infrequently (with a frequency of at least 1/1000, but less than 1/100), rarely (with a frequency of at least 1/10000, but less than 1/1000), very rarely (with a frequency of less than 1/10000), the frequency is unknown (cannot be established according to available data).

Disorders from the immune system : rarely - *allergic reactions* - skin itching, rash, angioedema, hives; very rarely - anaphylactic reactions.

If any of the side effects indicated in the instructions are aggravated, or if you notice any other side effects not listed in the instructions, inform your doctor.

Overdose

Not marked.

Interaction with other drugs

When prescribed with other drugs, no negative effects were noted.

Special clinical studies on the interactions of the drug Arbidol ® with other drugs have not been conducted.

Information about the presence of undesirable interactions with antipyretic, mucolytic and local vasoconstrictor drugs in a clinical trial have not been identified.

Special instructions

In patients with diabetes mellitus, as well as on a low-calorie diet, it should be taken into account that the suspension contains saccharose (0.8g/ 5 ml or 0.06 XE/5 ml).

It is necessary to observe the recommended scheme and the duration of the drug. If you miss one dose of the drug, the missed dose should be taken as early as possible and continue the course of taking the drug according to the scheme begun.

If after using the drug Arbidol ® for three days during the treatment of influenza and other acute respiratory viral infections, the severity of the symptoms of the disease, including high temperature (38 °C or more), remains , then you must consult a doctor to assess the feasibility of taking the drug.

If calculating the amount of suspension required for the drug intake course, the storage time of the prepared suspension, which is 10 days, must be taken into account. In indication non-specific prophylaxis during the epidemic of influenza and other acute respiratory infections in children from 2 to 6 years it is required two vial of Arbidol ® on a drug administration course.

Influence on the ability to drive vehicles and mechanisms

It does not show central neurotropic activity and can be used in medical practice in people of various professions, including requiring attention and cordination of movements (transport drivers, operators, etc.).

Release form

Powder for suspension preparation for ingestion, 25 mg/5 ml

37 g in 125 ml volume vials (tagged to 100 ml) of dark (amber) glass.

One vial with instructions for medical use and measuring spoon are placed in a cardboard pack.

Storage

Store at temperatures not above 25 °C.

Store the prepared suspension at a temperature not exceeding 8 °C (in a fridge).

Keep out of reach of children.

Shelf life

Powder for suspension preparation for ingestion - 2 years.

Prepared suspension – no more than 10 days

Do not use beyond the expiration date printed on the pack.

Terms of sale

Release without a prescription.

Registration Certificate Holder / Consumer Complaints Organization

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