

MINISTRY OF HEALTH OF THE RUSSIAN FEDERATION

INSTRUCTIONS FOR MEDICAL USE

ARBIDOL ®

Registration number:

Trade name of the drug: Arbidol ®

International Nonproprietary Name: Umifenovir

Chemical name: ethyl 6-bromo-4-[(dimethylamino)methyl]-5-hydroxy-1-methyl-2-[(phenylsulfanyl)methyl]-1H-indole-3-carboxylate monohydrate hydrochloride.

Dosage form: film-coated tablets

Composition per tablet

One tablet contains:

Active substance: Umifenovira hydrochloride monohydrate – 51,75 mg (per Umifenovir hydrochloride – 50,00 mg).

Excipients:

Core: potato starch – 31.86 mg, microcrystalline cellulose - 57.926 mg, povidone (povidone K30) - 8.137 mg, calcium stearate - 0.535 mg, crosscarmellose (crosscarmellose sodium) - 1.542 mg;

Coat: Opadry 10F280003 White – 6,000 mg, Hypromellose (hydroxypropyl methylcellulose 2910) - 3.54 mg, macrogol (polyethylene glycol) - 0.48 mg, polysorbate-80 (twin-80) - 0.06 mg, titanium dioxide - 1.92 mg.

Description

Film-coated tablets from white or white with a creamy tint, round, double radius. On a fracture from white to white with a greenish-yellow or creamy tint.

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 (H1N1) pdm 09* and *A (H5N1)*, 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 Arbidol® 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 Arbidol® 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 Arbidol® 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 ($LD_{50} > 4 \text{ g / kg}$). 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 50 mg is reached after 1.2 hours, at a dose of 100 mg - after 1.5 hours. It is metabolized in the liver. The elimination half-life is on average 17-21 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: influenza A and B, other acute respiratory viral infections.

Combined therapy of acute intestinal infections of rotavirus etiology in children over 3 years old.

Complex therapy of chronic bronchitis, pneumonia and recurrent herpetic infection.

Prevention of postoperative infectious complications.

Contraindications

Hypersensitivity to umifenovir or any component of the drug; children under 3 years old. The first trimester of pregnancy. The period of breastfeeding.

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.

A single dose (depending on age):

<i>Age</i>	<i>A single dose</i>
<i>From 3 to 6 years old</i>	<i>50 mg (1 pill)</i>
<i>From 6 to 12 years old</i>	<i>100 mg (2 pills)</i>
<i>Over 12 years old and adults</i>	<i>200 mg (4 pills)</i>

<i>Indication</i>	<i>Reception scheme the drug</i>
<i>In adults and children over 3 years of old and adults:</i>	
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.
<i>In adults and children over 3 years of old</i>	
Complex therapy of acute intestinal infections of rotavirus etiology	in a single dose 4 times a day (every 6 hours) for 5 days.

<i>In adults and children over 3 years of old and adults:</i>	
Combined therapy of recurrent herpes infection	in a single dose 4 times a day (every 6 hours) for 5-7 days, then in a single dose 2 times a week for 4 weeks.
Prevention of postoperative infectious complications	in a single dose 2 days before surgery, then on 2 and 5 days after surgery.

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 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.

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

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.

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

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.

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 coordination of movements (transport drivers, operators, etc.).

Release form

During production at JSC "Pharmstandard-Tomskkhimpharm", Russia:

Film-coated tablets, 50 mg

On 10 tablets in a blister strip packaging from a film of polyvinyl chloride and foil aluminum printed varnished.

1, 2, 3 or 4 outlined packs with instructions for use are placed in a cardboard pack.

Storage

Store at temperatures not above 25 °C. Keep out of reach of children.

Shelf life

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

Terms of sale

Release without a prescription.

Registration Certificate Holder / Consumer Complaints Organization

Otisifarm JSC, Russia

123112, Moscow, st. Testovskaya, 10

floor 12, room II, com. 29th

Tel .: +7 (800) 775-98-19

Fax: +7 (495) 221-18-02

www.otcpharm.ru

Manufacturer

Pharmstandard-Leksredstva OJSC

305022, Russia, Kursk, st. 2nd Aggregate, 1a / 18, tel / fax: (4712) 34-03-13,

www.pharmstd.ru

www.arbidol.ru