Arbidol®

INTERNATIONAL NON-PROPRIETARY NAME (INN):
Umifenovir

DOSAGE FORM AND STRUCTURE:
Active ingredient: Umifenovir hydrochloride monohydrate (in terms of Umifenovir hydrochloride) - 100 mg.
Excipients: core: potato starch - 30.14 mg, microcrystalline cellulose - 55.76 mg, colloidal silicon dioxide (aerosil) - 2.0 mg, povidone K 25 (collidone 25) - 10.1 mg, calcium stearate - 2.0 mg.
Hard gelatin capsules No. 1:
Capsule case: titanium dioxide (E 171) - 2.0000%, gelatin - up to 100%.
Capsule cap: titanium dioxide (E 171) - 1.3333%, sunset yellow dye (E 110) - 0.0044%, quinoline yellow (E 104) - 0.9197%, gelatin - up to 100%.

DESCRIPTION:
Hard gelatin capsules No. 1. The case of the capsule is white, the cap is yellow. The content of the capsule is a mixture containing granules and powder of the colour ranging from white to white with a greenish and yellowish or creamy hue.

PHARMACOLOGICAL CLASSIFICATION: Antiviral agent.

ATC CODE: J05AX13 Umifenovir.

PHARMACODYNAMICS:
Arbidol® is an antiviral agent. It specifically inhibits influenza A and B viruses in vitro, including the highly pathogenic subtypes A(H1N1)pdm09 and A(H5N1), as well as other viruses that cause acute respiratory viral infections (ARVI) (coronavirus associated with a severe acute respiratory syndrome (SARS), rhinovirus, adenovirus, respiratory syncytial virus (pneumovirus) and paramyxovirus). Based on its antiviral mechanism of action, the drug belongs to the group of fusion inhibitors. It interacts with the hemagglutinin of the virus and prevents the fusion of the lipid membrane of the virus and the cell membranes. Arbidol® has a moderate immunomodulatory effect and it increases the body's resistance to viral infections. The drug exhibits an 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 the administration. The drug stimulates cellular and humoral immune responses: increases the number of lymphocytes in the blood, especially T-cells (CD3), increases the number of T-helpers (CD4) without affecting the level of T-suppressors (CD8), normalizes the immunoregulatory index, stimulates the phagocytic function of macrophages and increases the number of natural killer cells (NK cells).
The therapeutic efficacy against 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 complications associated with the viral infection and exacerbations of chronic bacterial diseases.
In the treatment of influenza or ARVI in adult patients, a clinical study have shown that the effect of Arbidol® in adult patients is most pronounced in the acute period of the disease and is manifested in a reduction of the treatment period of the disease symptoms, in a decrease in the severity of the disease manifestations, and in a reduction of the virus elimination period.

Arbidol® therapy leads to a higher frequency of symptoms reversal on the third day of the therapy compared to placebo. 60 hours after the start of the therapy, the relief of all symptoms of the laboratory-confirmed influenza is more than 5 times higher than that in the placebo group.
A significant effect of Arbidol® on the rate of the influenza virus elimination was determined in particular by a decrease in the frequency of detection of RNA virus on the 4th day of treatment.
Arbidol® is a low-toxic drug (LD50> 4 g/kg). It does not have any negative effects on the human body when administered orally in the recommended doses.

PHARMACOKINETICS:

Arbidol® is rapidly absorbed and distributed to organs and tissues. The maximum plasma concentration is reached after 1.5 hours. It is metabolized in the liver. The half-life is 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.

INTENDED USES:

- Prevention and treatment in adults and children: influenza A and B, and other ARVI;
- Complex therapy of recurrent herpetic infection;
- Prevention of postoperative infectious complications;
- Combined therapy of acute intestinal infections of rotavirus etiology in children older than 6 years old.

CONTRAINDICATIONS:

- Hypersensitivity to umifenovir or any component of the drug;
- Children under 6 years old;
- The first trimester of pregnancy;
- Breastfeeding period.

Administer with caution during the second and third trimesters of pregnancy.

PREGNANCY AND LACTATION:

Animal studies have not revealed harmful effects on pregnancy, the development of the embryo and fetus, and labor and postnatal development.
The use of Arbidol® in the first trimester of pregnancy is contraindicated.
In the second and third trimesters 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.
There is no data on whether Arbidol® penetrates into the breast milk in women during lactation or not. If the use of Arbidol® is necessary, breastfeeding should be stopped.

DOSAGE AND ADMINISTRATION:

Per os, before meals.

A single dose of the drug (depending on the age of the patient):

Age	*Single dose*
Children from 6 to 12 years old	100 mg (1 capsule)
Children over 12 years old and adults	200 mg (2 capsules)

Dosage regimen (depending on the age of the patient):

Indications	***Medication regimen***
In children from 6 years old and in adults:	
Nonspecific prevention during the epidemic of influenza and other ARVIs	single dose 2 times a week for 3 weeks
Nonspecific prevention in case of direct contact with patients suffering from influenza and other ARVIs	single dose once a day for 10-14 days
Treatment of influenza and other ARVIs	single dose 4 times a day (every 6 hours) for 5 days
Complex therapy of recurrent herpetic infection	single dose 4 times a day (every 6 hours) for 5-7 days then a single dose 2 times a week for 4 weeks
Prevention of postoperative infectious complications	single dose 2 days before the surgery, then on the 2nd and 5th day after the surgery
In children from 6 years old:	
Comprehensive therapy of acute intestinal infections of rotavirus etiology	single dose 4 times a day (every 6 hours) for 5 days

Use the drug only in accordance with the intended uses, method of application and at the doses indicated in the instructions.
The drug administration begins with the onset of the first symptoms of influenza and other ARVIs, preferably no later than 3 days from the onset of the disease.
If after using Arbidol® for three days during the treatment of influenza and other ARVIs, the severity of the symptoms of the disease, including high temperature (38°C (100.4°F) or higher), persists, you must consult a doctor to assess the feasibility of taking the drug.
In the treatment of influenza and ARVI, concomitant symptomatic therapy is applicable, including the administration of antipyretic drugs, mucolytic and local vasoconstrictors.

PRECAUTION:

It is necessary to follow the recommended scheme and duration of the drug administration. If you miss one dose of the drug, it should be taken as soon as possible, and then you should continue the drug course according to the original scheme.

SIDE EFFECTS:

Arbidol® is a low-toxic drug and is usually well tolerated.
Side effects are rare; they are usually mild or moderate, and 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), frequency unknown (frequency cannot be established according to available data).
Disorders in the immune system: rarely - allergic reactions.
If any of the above stated side effects are aggravated or if you notice any other side effects not listed in the instructions, notify your doctor.

OVERDOSE:
There are no records of the drug overdose.

INTERACTION WITH OTHER DRUGS:
When Arbidol® was prescribed with other drugs, no negative effects have been noted.
Special clinical studies of Arbidol® interactions with other drugs have not been conducted.
Information about the existence of undesirable interactions with antipyretic, mucolytic and local vasoconstrictor agents has not been recorded in clinical trials.

INFLUENCE ON THE ABILITY TO DRIVE VEHICLES AND OPERATE MECHANISMS:
Arbidol® does not exhibit central neurotropic activity and can be used in medical practice by people of various professions, including the ones requiring increased attention and coordination of movements (drivers, operators, etc.).

STORAGE CONDITIONS:
Store in a dry place, at a temperature not exceeding 25°C (77°F). Keep out of the reach of children.

SHELF LIFE:
3 years. Do not use beyond the expiration date.

MANUFACTURER:
OTCPharm JSC, Russia. www.otcpharm.ru, www.arbidol.ru