

## **Instructions for the Medical Use of Arbidol**

Manufactured 8 April 2005 by order of the Federal Supervisory  
Organization of Health and Welfare

Registration number: 003610/01

**Trade name of medication: Arbidol**

**Chemical composition:** ethyl 6 – bromo 5 – hydroxy 1 – methyl 4 – dimethyl 2 – phenylmethyl 3 – carboxylate hydrochloride monohydrate

**Drug form:** capsules

### **Ingredients:**

Active ingredient: arbidol (as an expression of dry weight) 50 mg or 100 mg.  
Auxiliary ingredients: potato starch, microcrystalline cellulose, silicon dioxide, povidone, calcium stearate.

### **Capsule markings for each strength:**

50 mg capsules: “No. 3” yellow capsules

100 mg capsules: “No. 1” capsules with white bottoms and yellow tops.

Each capsule contains a mixture of granules and powder in colors from white to greenish-yellow or cream-colored.

### **Pharmacological group:**

Antiviral and immunomodulating medications

ATX code: LOZAX

### **Pharmacological attributes:**

This medication is an antiviral preparation, having an immunomodulating and anti-influenza effect, specifically against influenza groups A and B, and SARS. It prevents contact and entry of the virus into cells by inhibiting the fusion of viral lipid membranes with cell membranes. It has an interferon-inducing action, stimulates humoral and cell-mediated immunity, helps the phagocytic action of macrophages, and heightens the body’s ability to fight infection. It decreases the frequency of complications associated with viral infections, and lessens the effects of chronic bacterial illnesses.

In viral infections, its therapeutic effectiveness is seen in a lowering of toxicity, lessening of clinical symptoms, and decrease in duration of the disease.

Arbidol is in the category of least toxic drugs (LD50 > 4 g/kg). It has no negative side effects on the human body when taken orally at the recommended dosages.

### **Pharmacokinetics:**

The drug is absorbed quickly and spreads to organs and tissues. The maximum blood level (concentration) after taking a 50 mg dose occurs 1.2 hours after

administration; for a 100 mg dose, 1.5 hours after administration. Arbidol is metabolized in the liver. The half-life of the drug in the body is 17-21 hours. About 40% is excreted in unchanged form, mostly through bile (38.9%) and an insignificant amount through the kidneys (0.12%). Within the first 24 hours after administration, 90% of the drug has left the body.

**Indications and Usage:**

- Prevention and treatment in adults and children:
- Influenza A and B, RSV, SARS (including exacerbation of bronchitis and pneumonia)
  - Secondary immunodeficiency
  - Overall therapy for chronic bronchitis, pneumonia and recurrent herpes infections
  - Prevention of post-operative infections and stabilization of immune status
  - Overall therapy of acute rotavirus-type intestinal infections in children over 2 years old.

**Contraindications:**

Children under 2 years have an increased sensitivity to the medication.

**Directions for Use:**

For internal use, to be taken on an empty stomach.

Single dose amount: Children 2 - 6 years, 50 mg; 6 - 12 years, 100 mg; 12 - adult, 200 mg (2 - 100 mg capsules, or 4 - 50 mg capsules).

***For non-specific prophylaxis:*** During direct contact with patients with influenza or RSV, children 2 - 6, 50 mg; children 6 - 12, 100 mg; 12 to adult, 200 mg, once a day for 10 to 14 days.

During influenza or other RSV epidemics, or in order to prevent exacerbation of chronic bronchitis, or recurrent herpes infection, the dosage is children 2 - 6, 50 mg; children 6 - 12, 100 mg; and over 12 to adult, 200 mg, twice a week for three weeks.

For SARS prophylaxis (during contact with SARS patients), the dosage for children over 12 - adult is 200 mg once a day; for children from 6 to 12, 100 mg, taken before food, once a day for 12 - 14 days.

For prophylaxis against postoperative complications: children 2 - 6, 50 mg; children 6 - 12, 100 mg; children over 12 - adult, 200 mg 48 hours before the procedure, then from 2 to 5 days after the procedure.

***For treatment of illness:*** For influenza, or other uncomplicated RSV, children 2 - 6, 50 mg; children 6 - 12, 100 mg, and children over 12 and adults, 200 mg, 4 times a day (every 6 hours) for 5 days.

For influenza with complications (bronchitis, pneumonia), children 2 – 6, 50 mg; children 6 – 12, 100 mg; children over 12 and adults, 200 mg, 4 times a day (every 6 hours) for 5 days, then one dose per week for the next four weeks.

For Severe Acute Respiratory Syndrome (SARS), in children over 12 and adults, 200 mg twice a day for 8 – 10 days.

For chronic bronchitis or herpes-type infections, in children 2 – 6 years, 50 mg; children 6 – 12, 100 mg; children over 12 and adults, 200 mg 4 times a day (every 6 hours) for 5 – 7 days; thereafter, one dose twice a week for the next 4 weeks.

For treatment of acute intestinal infections of the rotavirus-type, in children over 2 years old, give 50 mg; children 6 – 12, 100 mg; and children over 12, 200 mg, four times a day (every 6 hours) for 5 days.

**Side effects:**

Possible allergic reaction

**Overdose effects:**

None noted

**Reactions in combination with other drugs:**

No negative side effects have been observed when using this medication in combination with other drugs.

**Special instructions:**

Arbidol has not been shown to have negative effects on central nervous activity, and can be taken in a prophylactic capacity by otherwise healthy people engaged in any profession, including those demanding a high level of attention and physical coordination (for example, bus drivers, machine operators, etc.).

**Packaging form:**

Capsules are in 50 and 100 mg doses.

Packaging: either 5 or 10 capsules contained in blister packs, composed of plastic, polyvinylchloride and aluminum, or 10 or 20 capsules contained in a plastic bottle. Instructions for use come with each bottle and with each set of either one or two blister packs.

**Storage conditions:**

“Category B.” Store in a dry place, protected from light and out of the reach of children, at a temperature no higher than 25 degrees Celsius (76 F).

**Expiration limit:**

2 years. Do not use after the expiration date printed on packaging.

**Availability of dosages:**

100 mg capsules are available without prescription; 50 mg capsules require a doctor's prescription.

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