Arbidol® (umifenovir) capsules

Registration number:
P N003610/01

Trade name:
Arbidol®

International non-proprietary name (INN):
Umifenovir

Dosage form:
Capsules

Composition per capsule:
Active ingredient: Umifenovir hydrochloride monohydrate – 103.5 mg (equivalent to 100 mg Umifenovir hydrochloride).

Excipients: Potato starch – 30.14 mg, Microcrystalline cellulose 101 – 52.26 mg, Colloidal silicon dioxide – 2.0 mg, Povidone K-25 – 10.1 mg, Calcium stearate – 2.0 mg.

Capsule composition
Shell: Titanium dioxide (E 171) – 2.0000%, Gelatin – up to 100%.

Cap: Titanium dioxide (E 171) – 1.3333%, Sunset yellow dye (E 110) – 0.0044%, Quinoline yellow dye (E 104) – 0.9197%, Gelatin – up to 100%.

Description:
Hard gelatin capsules No. 1, with a white body and yellow cap. The capsule contents are a mixture of granules and powder ranging from white to white with a yellowish or greenish-yellow tint.

Pharmacological group:
Antiviral Agent

ATC code:
J05AX13

Pharmacological properties:

Pharmacodynamics:
Arbidol® is an antiviral drug that inhibits in vitro influenza A and B viruses, including high-pathogenic subtypes A(H1N1)pdm09 and A(H5N1), as well as other acute respiratory viruses (coronavirus, rhinovirus, adenovirus, respiratory syncytial virus, and parainfluenza virus). Its antiviral mechanism involves hemagglutinin interaction, preventing viral lipid envelope fusion with cell membranes. It has moderate immunomodulatory effects and enhances resistance to viral infections.

Arbidol® induces interferons, with production observed 16 hours post-administration and elevated titers persisting for 48 hours. It stimulates cellular and humoral immunity, increasing blood lymphocytes (particularly T-cells), normalizing the immunoregulatory index, and boosting phagocytic macrophage function and natural killer (NK) cell count.

Therapeutic efficacy is demonstrated by reduced illness duration and severity, diminished complications, and mitigated exacerbations of chronic bacterial diseases. Clinical studies show significant reduction in influenza symptoms and viral RNA detection by Day 4. The drug is low-toxicity (LD50 > 4 g/kg) and well-tolerated at recommended doses.

Pharmacokinetics:
Arbidol® is rapidly absorbed and distributed in organs and tissues. Maximum plasma concentration is reached within 1.5 hours. It is metabolized in the liver, with a half-life of 17-21 hours. About 40% is

excreted unchanged, mainly in bile (38.9%) and minimally by the kidneys (0.12%). Within 24 hours, 90% of the dose is eliminated.

Indications:

- Prevention and treatment of influenza A and B, other acute respiratory viral infections (ARVI).
- Combination therapy for recurrent herpes infections.
- Prevention of postoperative infectious complications.
- Combination therapy for acute rotavirus infections in children over 6 years.

Contraindications:

- Hypersensitivity to Umifenovir or any excipients.
- Children under 6 years.
- First trimester of pregnancy.
- Breastfeeding period.

Use with caution:

Second and third trimesters of pregnancy.

Pregnancy and lactation:

Animal studies show no harmful effects on pregnancy or fetal development. Use is contraindicated in the first trimester. In the second and third trimesters, it may be used for influenza treatment and prevention if the potential benefit outweighs the risk. Consult a physician for benefit-risk assessment. Unknown if it is excreted in human breast milk; discontinue breastfeeding if use is necessary.

Dosage and administration:

Oral administration before meals.
Single dose based on age

- Children 6-12 years: 100 mg (1 capsule).
- Children >12 years and adults: 200 mg (2 capsules).

Dosing schedule:

Indication	Dosage Schedule
Non-specific prevention during epidemics	Single dose 2 times/week for 3 weeks.
Post-exposure prevention	Single dose daily for 10-14 days.
Treatment of influenza and ARVI	Single dose 4 times/day (every 6 hours) for 5 days.
Combination therapy for recurrent herpes	Single dose 4 times/day (every 6 hours) for 5-7 days, then 2 times/week for 4 weeks.
Prevention of postoperative infections	Single dose 2 days pre-surgery, then on Day 2 and Day 5 post-surgery.
Acute rotavirus infections (children >6 years)	Single dose 4 times/day (every 6 hours) for 5 days.

Side effects:

Generally well-tolerated. Rare side effects include allergic reactions.

Frequency classification (WHO): Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000), unknown (not determinable from data).

Overdose:

No cases reported.

Drug interactions:
No adverse interactions noted with antipyretics, mucolytics, or local vasoconstrictors. Specific clinical studies on interactions are unavailable.

Special instructions:
Adhere to the prescribed regimen and duration. If a dose is missed, take it as soon as possible and continue as prescribed. Consult a physician if symptoms persist beyond 3 days.

Effects on driving and machinery:
Does not impair ability to drive or operate machinery.

Form of release:
Capsules, 100 mg.
5 or 10 capsules in PVC/aluminum blister packs.
1, 2, or 4 blister packs with instructions in a cardboard box.

Storage conditions:
Store at temperatures not exceeding 25°C. Keep out of reach of children.

Shelf life:
3 years. Do not use beyond the expiration date.

Dispensing conditions:
Over-the-counter.

Manufacturer
OTCPharm JSC, Russia.

These instructions translated from official manufacturer instructions in Russian by Extrapharma online pharmacy