Sonata® Adamed

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Name in Cyrillic: Соната® Адамед

Active substance: Zaleplon

Pharmachologic effect: hypnotic, sleeping pill.

Pharmacodynamics:
Zaleplon is a hypnotic of the pyrazole-pyrimidine series, its chemical structure differs from benzodiazepines and other hypnotics. Zaleplon selectively binds to type 1 (omega-1) benzodiazepine receptors. Significantly reduces the latency of falling asleep, prolongs sleep time (in the first half of the night), does not cause changes in the ratio of different sleep phases. The use of the drug in a dose of 10 mg does not cause pharmacological tolerance when taken 2-4 weeks. In addition, it has a sedative, slightly pronounced anxiolytic, anticonvulsant and central muscle relaxant effect.

Zaleplon excites benzodiazepine receptors (omega) of gamma-aminobutyric acid receptor complexes of type A. Interaction with omega receptors leads to the opening of neuronal ionomorphic channels for chlorine ions, the development of hyperpolarization and increased inhibition processes in the central nervous system (CNS).

Pharmacokinetics:
After oral administration, zaleplon is rapidly and almost completely absorbed (~ 71%), reaching a maximum concentration in the blood after 1 hour. As a result of presystemic metabolism, the absolute bioavailability is ~ 30%. Plasma concentration is directly proportional to the dose.

Taking the drug immediately after a meal can delay the time to reach the maximum concentration by 2 hours, without affecting the absorption of zaleplon.

Zaleplon is a fat-soluble compound. The volume of distribution after intravenous administration is ~ 1.4 ± 0.3 l / kg. The likelihood of interaction with other drugs is very small due to ~ 60% binding to plasma proteins. Zaleplon penetrates into breast milk.

Aldehyde oxidase is involved in the primary metabolism, which leads to the formation of 5-oxosaleplone. The isoenzyme CYP3A4 is also involved in the metabolism of zaleplon with the formation of desethylzaleplon, which, in turn, is converted to 5-oxo-desethylzaleplon with the help of aldehyde oxidase. Subsequently, the oxidation products are conjugated with glucuronic acid. All zaleplon metabolites are devoid of activity. At daily doses up to 30 mg, cumulation is not observed. The half-life of the zaleplon is ~ 1 hour.

Excretion of Zaleplon exists in the form of inactive metabolites, mainly in the urine (71%) and feces (17%). 57% of the dose taken is found in urine in the form of 5-oxosaleplon or its metabolites, 9% of the dose - in the form of 5-oxo-desethylzaleplon or its metabolites, the rest of the dose - in the form of less significant metabolites. Among the metabolites found in feces, 5-oxosaleplone predominates. It is quickly excreted from the body.

Pharmacokinetics in the elderly, incl. in patients over 75 years of age, does not differ significantly from that in young patients.

The pharmacokinetics of zaleplon in patients with renal insufficiency does not differ significantly from that in healthy people, although the concentration of inactive metabolites is higher in them.

Indications:
Short-term treatment of severe sleep disorders (difficulty falling asleep) that lead to excessive fatigue, impair daily activities and reduce performance.

Contraindications:

Hypersensitivity to zaleplon or any of the components of the drug;
Hepatic failure of moderate severity (for this dosage form of the drug);
Severe liver failure;
Severe renal failure;
Sleep apnea syndrome;
Severe pulmonary insufficiency;
Myasthenia gravis;
Acute respiratory failure;
Pregnancy;
Breastfeeding period;
Lactase deficiency, lactose intolerance, glucose-galactose malabsorption;
Children under the age of 18.
Elderly age (for this dosage form of the drug)

Use with caution:
Renal failure of mild and moderate severity, hepatic failure of mild severity, alcohol or drug dependence (including a history), depression.

Side effects:
The most common adverse effects of zaleplon are amnesia, paresthesia, drowsiness, and dysmenorrhea.

Interaction:
Drinking alcohol enhances the sedative effect of zaleplon.

Simultaneous use of antipsychotic (neuroleptic), other hypnotics, anxiolytic, sedative, antidepressant, antiepileptic drugs, general anesthetics, H1-histamine receptor blockers with a sedative effect, narcotic analgesics leads to an increase in the sedative effect of zaleplon.

With simultaneous use of narcotic analgesics, the euphoric effect of the latter may appear, leading to the development of drug dependence.

As an inhibitor of the isoenzyme CYP3A4 and aldehyde oxidase, cimetidine increases the plasma concentration of zaleplon by 85%.

Powerful inhibitors of the CYP3A4 isoenzyme (ketoconazole, erythromycin) increase the plasma concentration of zaleplon and enhance its sedative effect; sometimes it may be necessary to adjust the dose of zaleplon.

Powerful inducers of liver microsomal enzymes (including rifampicin, carbamazepine, phenobarbital) can reduce the effectiveness of zaleplon by 25%.

Zaleplon does not affect the pharmacodynamics and pharmacokinetics of digoxin and warfarin; dose adjustment of these drugs is not required due to their low therapeutic index.

Interaction of ibuprofen with zaleplon has not been identified.

No pharmacokinetic interaction (sustained release) between zaleplone and venlafaxine has been identified.

Dosing and Administration:
The duration of treatment should not exceed 2 weeks.

Take orally just before going to bed, 2 hours after eating or after the patient feels that he cannot sleep.

The recommended dose for adults is 10 mg. The maximum daily dose is 10 mg (patients should be warned against taking a repeated dose of the drug within one night!).

With renal failure of mild to moderate severity, dose adjustment is not required. There are no data on the safety of the drug in patients with severe renal failure; therefore, the use of the drug in this group of patients is contraindicated.

There is no data on the use of the drug in children under the age of 18, therefore the use of the drug in children under the age of 18 is contraindicated.

Overdose:
Like benzodiazepines and other benzodiazepine-like drugs, overdose does not cause life-threatening conditions if zaleplon is not taken in combination with other drugs that depress the central nervous system, including alcohol. In case of overdose, one should never forget about the possibility of combined poisoning.

Overdose symptoms:
Symptoms of CNS depression, manifested in depression of consciousness from drowsiness to coma. In the case of mild poisoning, drowsiness, confusion, lethargy are possible, in more severe cases - ataxia, muscle hypotension, decreased blood pressure, respiratory depression, urine staining blue-green (a sign of chromaturia development), less often coma, in very rare cases with fatal.

Treatment:
The antagonist of zaleplon is flumazenil, which can be used as an antidote for drug overdose. In the first hour after an overdose, a patient who is conscious should induce vomiting; an unconscious patient is washed with a stomach, and activated charcoal is prescribed. Cardiac and respiratory monitoring is performed in the intensive care unit.

Pregnancy and breast-feeding:
Due to the lack of data, the use of zaleplon during pregnancy is contraindicated. When prescribing the drug to women of childbearing age, before starting therapy, pregnancy should be excluded and a reliable contraceptive should be selected. The doctor should, in each individual case, warn patients about the need to immediately consult a doctor in case of conception or when planning a pregnancy.

If it is necessary to use large doses of zaleplon during childbirth, the newborn may develop hypothermia, muscle hypotension, moderate respiratory failure, as a result of the pharmacological action of the drug.

Due to the penetration of zaleplon into breast milk, the use of the drug during breastfeeding is contraindicated.

Special instructions:
Before starting treatment, the patient should be warned about the short duration of the course of treatment and about the possibility of a withdrawal syndrome after the end of treatment with Sonata® Adamed.

The duration of treatment should be as short as possible, in no case should it exceed 2 weeks. Treatment can be extended only after a thorough clinical examination of the patient.

Sleep disturbance can be the result of a physical or mental illness. If, after a short-term treatment with Sonata® Adamed, sleep does not normalize or sleep disturbance progresses, the diagnosis should be reconsidered.

If the patient wakes up shortly after midnight as a result of the short half-life of zaleplon, another drug with a longer half-life may be required.

Patients should be warned not to use more than one capsule in one night.

Taking benzodiazepines and short-acting benzodiazepine-like drugs for several weeks may be accompanied by a decrease in the hypnotic effect.

Taking benzodiazepines and benzodiazepine-like drugs can lead to the development of physical and mental dependence, the likelihood of which is associated with taking large doses of the drug, long-term treatment, alcohol and drug dependence.

With the formed physical dependence, abrupt withdrawal of the drug leads to the development of symptoms of the "withdrawal" syndrome: headache, muscle pain, a pronounced state of anxiety, increased tension and irritability, psychomotor agitation, confusion. In severe cases, autoaggression, depersonalization, hearing loss, paresthesia in the

extremities, an increased reaction to light, sound and physical stimuli, hallucinations and epileptic seizures are possible.

Upon termination of treatment with benzodiazepines and benzodiazepine-like drugs, a relapse or the appearance of transient and more pronounced than at the beginning of treatment symptoms of insomnia ("withdrawal" syndrome) is possible. In this case, the development of other related phenomena, such as mood changes, anxiety, sleep disturbances or anxiety, is possible.

Benzodiazepines and benzodiazepine-like drugs can cause anterograde amnesia and impairment of psychomotor functions.

In order to avoid the development of these symptoms, the drug should be taken only when patients have the possibility of uninterrupted sleep for at least 4 hours after taking the drug.

Patients taking sedatives and sleeping pills may experience combinations of activities such as "driving in their sleep," "eating in their sleep," or "sex in their dreams." Such effects have been reported in patients who did not quite wake up after taking sedatives or sleeping pills, and they usually did not remember these events. In these cases, it is recommended to stop taking Zaleplon.

Zaleplon treatment should be discontinued in the event of increased excitability, irritability, aggressiveness, extraversion, impaired perception and thinking, "nightmares", hallucinations, psychotic disorders, and especially behavioral disorders. Elderly patients are most likely to develop these symptoms.

Caution is necessary when prescribing zaleplon to patients with a history of allergic reactions in response to taking sedatives and hypnotics. Very rarely, when taking zaleplon, anaphylactic / anaphylactoid reactions may develop, requiring urgent medical attention. Re-use of zaleplon in such patients is contraindicated.

The use of the drug in patients with severe hepatic insufficiency due to the risk of encephalopathy development is contraindicated.

The use of the drug in patients with moderate hepatic impairment is contraindicated for the drug at a dose of 10 mg due to the impossibility of reducing the dose and the risk of encephalopathy developing.

The use of the drug in patients with severe renal failure is contraindicated.

Manufacturer:
Adamed Pharma, Poland

Reliable supplier with fast Worldwide shipping:
RussianMeds Online Store
https://russianmeds.com

Storage:
The temperature is not above 25 ° C.
Keep out of the reach of children.
Shelf-life of the drug is 4 years.