Spitomin® instructions

translated from original Russian instructions by Extrapharmacy Online Store
https://extrapharmacy.ru
Name in Cyrillic : СПИТОМИН

Active substance : Buspirone

Pharmachologic effect : antidepressive, anxiolytic.

Pharmacodynamics:
Spitomin is an anxiolytic, tranquilizer of non-benzodiazepine group, also has antidepressive effects. In contrast to classical anxiolytics Spitomin has no antiepileptic, sedative, hypnotic and muscle relaxant effects.
The mechanism of action of Spitomin is associated with the effect of buspirone on the serotonergic and dopaminergic systems. Buspirone selectively blocking presynaptic dopamine receptors and increases the rate of excitation of the midbrain dopamine neurons. In addition, buspirone is partial selective agonist of 5-HT1A serotonin receptors. Buspirone has no significant effect on the benzodiazepine receptors and does not affect the binding of GABA, has no adverse effects on psychomotor functions, it does not cause tolerance, dependence and drug withdrawal. It does not potentiate the effect of alcohol. By anxiolytic activity of buspirone is approximately equal to the benzodiazepines.
The therapeutic effect develops gradually and is manifested in 7-14 days from the beginning of treatment, the maximum effect is registered after 4 weeks.

Indications :
generalized anxiety disorder (GAD);
panic disorder;
autonomic dysfunction syndrome;
alcohol withdrawal syndrome (as adjuvant therapy);
depressive disorder - adjuvant therapy (Spitomin is not indicated for the monotherapy of depression).

Contraindications
hypersensitivity to any component of the drug;
severe renal insufficiency (glomerular filtration rate (GFR) - less than 10 mL / min);
severe hepatic impairment (PX - more than 18);
the simultaneous use of MAO inhibitors or the 14-day period after the abolition of irreversible MAO inhibitor, or 1 day after the cancellation of a reversible MAO inhibitor;
glaucoma;
myasthenia gravis;
lactation;
pregnancy or suspected pregnancy;
age of 18 years (the safety and effectiveness of buspirone in this age group have not been proved).

Precautions: liver cirrhosis, renal failure (see "Special Instructions".).

Side effects
Spitomin (Buspirone) is generally well tolerated. Side effects, if they occur, usually occur early in the treatment course and then disappear, in spite of continued drug administration. In some cases, dose reduction is necessary.

Interaction
Due to the pharmacokinetic properties of the drug (low bioavailability, intensive metabolism in the liver, high protein binding),Due to the pharmacokinetic properties of the drug (low bioavailability, intensive metabolism in the liver, high protein binding), there is a high probability of interaction of buspirone administered simultaneously with drugs; however, since buspirone has significant therapeutic breadth, pharmacokinetic interactions do not lead to clinically significant pharmacodynamic changes.

MAO inhibitors (MAOIs). Described increase in blood pressure and the occurrence of hypertensive crises after the simultaneous administration of buspirone and drugs acting on MAO (moclobemide, selegiline); in this regard, buspirone can not be combined with MAOIs. After the cancellation of an irreversible MAOI (eg selegiline) prior to administration of the drug Spitomin (and vice versa) should be at least 14 days. Similarly, there should be at least 14 days after discontinuation of the drug Spitomin prior to administration of moclobemide (a reversible MAOI). However Spitomin can be given 1 day after the cancellation of moclobemide.
Inhibitors and inducers of CYP3A4. Studies in vitro have shown that buspirone is metabolized mainly by CYP3A4 isozymes of cytochrome P450. Simultaneous administration of buspirone and CYP3A4 inhibitors (erythromycin, itraconazole, nefazodone, diltiazem, verapamil and grapefruit juice) may result the drug interactions, and the introduction of a potent inhibitor also increase concentration of buspirone in blood plasma; therefore must decrease the dose of buspirone (e.g. to 2.5 mg 2 times a day).
Strong inducers of CYP3A4 (eg rifampicin) can significantly decrease the levels of buspirone in the blood plasma, and reduce its pharmacodynamic effects. there is a high probability of interaction of buspirone administered simultaneously with drugs; however, since buspirone has significant therapeutic breadth, pharmacokinetic interactions do not lead to clinically significant pharmacodynamic changes.
Drugs that strongly binding proteins. Since buspirone binds strongly with proteins (95%), there is always the probability interactions with other proteine-active substances. Studies in vitro have shown that buspirone can not displace proteins from strongly bound drugs (warfarin, phenytoin, propranolol), but can replace loosely drugs such as digoxin.
When buspirone co-administered with cimetidine - buspirone Cmax increased by 40% and the AUC is not changed. Co-administration of these medications requires careful medical supervision.
When buspirone is co-administered with diazepam - nordiazepame level increases slightly, and there may be side effects: vertigo, headache, nausea.
Substances that suppress the central nervous system, and alcohol. Co-administration of buspirone with triazolam or flurazepam does not increase the length or strength of the effect of these benzodiazepines. After a single dose of 20 mg buspirone its effects on the CNS are not amplified. Experience of the joint use of buspirone and other anxiolytics, or other means of acting on the CNS (such as neuroleptics and antidepressants), is insufficient. Therefore, in such cases, careful medical supervision.

Dosing and Administration
Spitomin always taken in the same time of the day, before or after the meal (to avoid significant fluctuations in active agent concentration in the blood plasma during the day).
Spitomin should not be taken occasionally to treat anxiety, because the therapeutic effect of Spitomin develops only after multiple dose and appears no earlier than 7-14 days of treatment.
The dose should be titrated for each patient individually.
The recommended initial dose - 15 mg; it can be increased to 5 mg / day every 2 or 3 days.
The daily dose should be divided into 2-3 doses. The typical daily dose of 20-30 mg. The maximum single dose is 30 mg; the maximum daily dose should not exceed 60 mg.

Special patient groups
Elderly patients. Old age does not require the specification of the dose, as the pharmacokinetics of buspirone does not undergo age-related changes.
Impaired renal function. If the kidney function of the drug should be used with caution and in reduced dosages.
Abnormal liver function. If abnormal liver function the drug should be used with caution and in reduced dosages, which reduce individual doses or increase the interval between doses.

Overdose
Symptoms: gastrointestinal disturbances, nausea, vomiting, dizziness and drowsiness; depression of consciousness of varying severity (in severe forms).
Treatment: gastric lavage and symptomatic therapy. Dialysis is ineffective.
The experience has shown that even very high doses (a single oral 375 mg) is not necessarily cause severe symptoms.

Pregnancy and breast-feeding

Due the lack of properly controlled clinical trial data, the use of Spitomin during pregnancy is possible only when the benefits of the drug justifies the potential risk. Women of childbearing age during treatment buspirone should use adequate contraception as buspirone safety has not been proven in pregnancy.

Buspirone is released in breast milk. Sufficient data from clinical trials of buspirone during breast-feeding are not available, so nursing mothers should not take this drug.

Special instructions

Liver failure. Buspirone is extensively metabolized in the liver.

The drug is contraindicated in patients with severe hepatic insufficiency. Patients with cirrhosis should be prescribed at lower doses or in the same doses with longer intervals.

Renal insufficiency. In moderate or severe renal insufficiency buspirone clearance can be reduced by 50%. The drug is contraindicated in patients with severe renal insufficiency (GFR less than 10 mL / min). When light (GFR 30 mL / min) and moderate (GFR 10-30 ml / min) renal insufficiency buspirone can be used, but it must be careful to assign a reduced dose.

Elderly patients. Advanced age in itself does not require specification of doses, but caution is recommended compliance (eg due to a possible decrease in renal function and / or liver function and increased the likelihood of side effects). Patients should be given the lowest possible effective dose and for an increase in dose should be installed close observation of the patient.

Use of Spitomin requires special caution in patients with glaucoma and myasthenia rectangular.

In the case of lactose intolerance in the preparation of the diet should take into account the content of lactose in tablets (55.7 mg in tablets of 5 mg, and 111.4 mg in tablets of 10 mg).

Patients should be advised not to eat grapefruit in the food or drink grapefruit juice in large quantities, as these foods can increase the buspirone blood plasma and lead to an increase in frequency or severity of side effects.

The transference of patients from benzodiazepines to buspirone Buspirone can not eliminate withdrawal symptoms ofbenzodiazepines. If a patient is transferred to buspirone therapy after prolonged benzodiazepine, buspirone should be administered only after a period of gradual reduction of the dose of benzodiazepines.

Buspirone does not cause addiction to the drug, but its administration to patients with established or suspected susceptibility to drug dependence requires careful medical supervision.

Since the anxiolytic effect is manifested after 7-14 days of taking the drug, and the full therapeutic effect occurs in about 4 weeks, with severe anxiety patients need careful medical supervision during the initial period of therapy. consumption of alcoholic beverages should be avoided throughout the entire course of treatment buspirone.

Effects on ability to drive vehicles and management mechanisms:

Clinical studies have shown that monotherapy with buspirone does not affect the performance of psychomotor activity patients. Despite this, at the beginning of treatment may be transient adverse effects, and therefore patients should be warned that driving the vehicles and management mechanisms is possible only with the full confidence of the patient in their psychomotor functions. The ability of the patient to drive vehicles and mechanisms should be determined individually, depending on the patient's response to treatment and the use of concomitant therapy.

Manufacturer

EGIS, Hungary

Reliable supplier with fast Worldwide shipping

Extrapharmacy Online Store

http://extrapharmacy.ru

Storage

The temperature is not above 30 ° C

Shelf-life of the drug is 5 years.