

# Instructions for use

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Read this information carefully before using this medicine.  
Ask your doctor or pharmacist if you need further information.

## IMPAZA

Orodispersible tablets

Trade name: Impaza

Composition: Each orodispersible tablet contains:

Active ingredient: Affinity purified antibodies to endothelial NO-synthase 3 mg (water-ethanol mixture or the active substance dilutions).

\*Weight of lactose saturated with water-ethanol mixture of dilutions of the active substance with concentration not more than 10-15 ng/g.

Excipients: lactose, microcrystalline cellulose, magnesium stearate.

Pharmacotherapeutic group

Drugs used in erectile dysfunction.

Pharmacological properties

Pharmacodynamics: IMPAZA enhances the activity of endothelial nitric oxide (NO) synthase, restores production of NO by the endothelium under sexual stimulation, increases concentration of cyclic guanosine monophosphate (cGMP) in smooth muscles and facilitates their relaxation, which leads to increased blood inflow to the cavernous bodies. The abovementioned effects enable the beginning of erection which is sufficient in strength and duration.

Due to positive influence on central mechanisms of erection the medicine increases libido (sexual drive) and intercourse satisfaction.

Long-term use of the medicine contributes to an increase in total serum testosterone levels (in cases of partial androgen deficiency).

Pharmacokinetics: The sensitivity of contemporary physicochemical methods (gas-liquid chromatography, high performance liquid chromatography and mass spectrometry) does not allow assessing the content of ultralow doses of antibodies in biological fluids, organs and tissues; that makes technically impossible to investigate the pharmacokinetic properties of Impaza.

Therapeutic indications

Erectile disturbances (erectile dysfunction) of various origin. Vegetative disorders related to male climacterial period (weakness, rapid fatigue, decrease in physical activity, decrease in libido etc.)

Contraindications

Individual hypersensitivity to components of the medicine.

Posology and method of administration

Oral route.

One tablet per intake (the tablet should be held in the mouth until it is completely dissolved, not during the meal).

Therapeutic schedules:

Regular intake. To stabilize sexual potency (the ability for sexual intercourse) except cases of underlying organic causes, a 12 week treatment course is recommended. During the course the drug is taken with frequency from once on alternate days to 2 times per day, preferably in the evening hours.

If necessary, the therapeutic courses both for potency stabilization and treatment of symptoms of male climacterial period may be repeated at 3-6 months intervals.

On-demand use. In order to stimulate erection, 2 tablets should be taken 1-2 hours before intercourse.

There is no relevant indication for use of IMPAZA by children.

Undesirable effects

No side effects have been reported for the drug used in accordance with the specified indications in the recommended doses.

Individual hypersensitivity to components of the medicine is possible.

Inform doctors of any unwanted effects related to drug use.

Overdose

No cases of overdose have been reported.

Dyspepsia caused by excipients is possible in accidental overdose.

Effects on ability to drive and use machines

Impaza has no influence on the ability to drive and use machines.

Interaction with other medicinal products and other forms of interaction

IMPAZA can be used by patients suffering from coronary heart disease (angina pectoris of 1-2 functional class) and taking nitrates. IMPAZA can be co-administered with betaadrenergic blocking agents, diuretics, ACE inhibitors, calcium channel blockers.

Special warnings and precautions for use

Medicine contains lactose. Patients with rare hereditary problems of galactose intolerance, the lactase deficiency or glucose-galactose malabsorption should not take this medicine.

IMPAZA is not indicated for use by women.

No correction therapy for hepatic and renal failure.

Use in Pregnancy and lactation

There were no special clinical studies of IMPAZA on woman in period of pregnancy or lactation.

Pharmaceutical form

Orodispersible tablets.

Nature and contents of container

20 orodispersible tablets in PVC/Aluminum blister. 1 blister is inserted into a cardboard box with leaflet.

Storage conditions

Store in dry light-protected place at temperature below 30°C.

Store in the original package.

Keep out of reach of children.

Shelf life

3 years since the manufacturing date. Do not use after the expiry date indicated on the package.