

Nazopam™ Nasal Spray

Diazepam 5 mg/0.1 ml spray

Presentation

Nazopam™ nasal spray: Each actuation delivers Diazepam BP 5 mg.

Description

Diazepam is a benzodiazepine derivative and is a safe tranquilizer with anxiolytic, anticonvulsant, and central muscle relaxant actions. Diazepam attaches to the specific site on the GABA receptor and potentiates the effect of GABA, which acts by opening chloride ion channels into cells.

Indications

Diazepam nasal spray is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 6 years of age and older.

Dosage and Administration

Nasal spray: The recommended dose of Diazepam nasal spray is 0.2 mg/kg or 0.3 mg/kg, depending on the patient's age and weight.

Table 1: Recommended Dosage for Adults and Pediatric Patients 6 Years of Age and Older

Dose Based on Age and Weight			No. of sprays and ways of administration	
6 to 11 Years of Age (0.3 mg/kg)	12 Years of Age and Older (0.2 mg/kg)	Dose (mg)	No. of sprays	Ways of administration
Weight (Kg)	Weight (Kg)			
10 - 18	14 - 27	5	1 spray	1 spray in 1 nostril
19 - 37	28 - 50	10	2 sprays	1 spray in each nostril
38 - 55	51 - 75	15	3 sprays	2 sprays in 1 nostril & 1 spray in the other nostril
56 - 74	≥ 76	20	4 sprays	2 sprays in each nostril

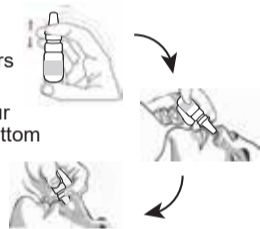
A second dose, when required, may be administered after at least 4 hours after the initial dose. Do not use more than 2 doses to treat a single episode. It is recommended that Diazepam nasal spray be used to treat no more than one episode every five days and no more than five episodes per month.

Instructions for using Nazopam (Diazepam) nasal spray:

- Family members, care partners, and others can promptly administer nasal spray when need it most.
- If a person appears to be having a seizure, lay them either on their side or back.
- Ways of administering various doses: If giving the 5 mg-One spray in one nostril; If giving the 10 mg-One spray in one nostril & one spray in the other nostril; If giving the 15 mg dose-Two sprays in one nostril & one spray in the other nostril; If giving the 20 mg dose-Two sprays in one nostril & two sprays in the other nostril.

Steps for using Nazopam (Diazepam) nasal spray:

- Hold:** Hold the nasal spray device with your thumb on the bottom of the bottle and your first and middle fingers on either side of the nozzle.
- Insert:** Insert the tip of the nozzle into 1 nostril until your fingers, on either side of the nozzle, are against the bottom of the nose.
- Press:** Press the bottom of the bottle firmly with your thumb to give spray. The person does not need to breathe deeply when spray is given.



Side-effects

The common side-effects of Diazepam Nasal spray include: somnolence, headache, nasal discomfort etc.

Precautions

May cause an increased CNS-depressant effect when used with alcohol or other CNS depressants. Antiepileptic drugs increase the risk of suicidal ideation and behavior.

Contraindications

Diazepam is contraindicated in patients with known hypersensitivity to Diazepam, acute narrow-angle glaucoma, acute pulmonary insufficiency, severe hepatic impairment etc.

Drug Interactions

Diazepam should be used with caution in combination with Inhibitors of CYP2C19 and CYP3A4 (e.g. Cimetidine, quinidine, tranylcypromine etc. and ketoconazole, troleandomycin, clotrimazole etc.), Inducers of CYP2C19 and CYP3A4 (e.g. rifampin etc. and carbamazepine, phenytoin, dexamethasone, phenobarbital etc.).

Pregnancy and Lactation

Pregnancy: Diazepam may cause fetal harm when administered to a pregnant woman and it should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: Diazepam is excreted in human milk. The known benefits of breastfeeding should be weighed against the unknown risks of infant exposure to Diazepam.

Use in special population

Pediatric use: Safety and effectiveness of Diazepam nasal spray has not been established in pediatrics below 6 years.

Geriatric use: Start at the low end of the dosing range.

Compromised respiratory function: Diazepam should be used with caution in patients with compromised respiratory function related to a concurrent disease process (e.g., asthma, pneumonia).

Overdose

In the event of overdose, Diazepam should be discontinued and general supportive treatment given until clinical toxicity has been diminished or resolved. Flumazenil may be used for the complete or partial reversal of the sedative effects.


Storage

Do not store above 30°C. Keep away from light and out of the reach of children.

Commercial Pack

Nazopam™ nasal spray: Each bottle contains Diazepam solution for 50 metered spray.

Manufactured by

 **Incepta Pharmaceuticals Ltd**

Savar, Dhaka, Bangladesh

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