Zaveg

Antimigraine
Nasal Spray

Zavegepant Hydrochloride INN

COMPOSITION
Zaveg Antimigraine Nasal Spray: Each metered dose spray contains Zavegepant Hydrochloride INN equivalent to Zavegepant 10 mg.

PHARMACOLOGY
Zavegepant is a calcitonin gene-related peptide (CGRP) receptor antagonist. In acute migraine, the release of CGRP increases vasodilation and modulates neuronal excitability, which facilitates pain responses in structures for migraine pain transmission, such as the trigeminal system. Therefore, CGRP receptor antagonists such as Zavegepant inhibit vasodilation mechanisms and desensitize neuronal circuits.

INDICATIONS
Zaveg is indicated for the acute treatment of migraine with or without aura in adults.

DOSAGE & ADMINISTRATION
The recommended dose of Zavegepant is 10 mg given as a single spray in one nostril, as needed. The maximum dose that may be given in a 24-hour period is 10 mg (one spray). The safety of treating more than 8 migraines in a 30-day period has not been established.

CONTRAINDICATIONS
Zavegepant is contraindicated in patients with known hypersensitivity to Zavegepant or any of its components.

WARNING & PRECAUTIONS
Hypersensitivity reactions, including facial swelling and urticaria, have occurred in patients treated with Zavegepant in clinical studies. If a hypersensitivity reaction occurs, discontinue Zavegepant and initiate appropriate therapy

SIDE EFFECTS
Taste disorders, allergic reactions, nausea, nasal discomfort and vomiting may occur.

DRUG INTERACTIONS
Co-administration of Zavegepant with inhibitors of the organic anion transporting polypeptide 1B3 (OATP1B3) or sodium taurocholate co-transporting polypeptide (NTCP) transporters may result in a significant increase in Zavegepant exposure and co-administration with inducers of OATP1B3 or NTCP transporters may result in a decrease in Zavegepant exposure. Avoid co-administration of Zavegepant with drugs that inhibit OATP1B3 or NTCP transporters and with drugs that induce OATP1B3 or NTCP transporters. Concomitant administration of Zavegepant with intranasal decongestants may decrease the absorption of Zavegepant. Avoid concomitant administration of intranasal decongestants with Zavegepant. When concomitant use is unavoidable, intranasal decongestants should be administered at least 1 hour after Zavegepant administration.

USE IN SPECIAL GROUP
Use in pregnancy: There are no adequate and well-controlled studies with Zavegepant in pregnant women to inform a drug-associated risk. Therefore, it should be used during pregnancy where there are no alternatives and benefits outweigh risks.
Use in lactation: There are no data available clinical data on the excretion of Zavegepant into human milk. A decision should be made to discontinue nursing or discontinue the drug, considering the importance of the drug to the mother.
Use in children & adolescents: The safety and effectiveness of Zavegepant have not been established in patients under the age of 18 years.
Use in hepatic impairment: No dosage adjustment of Zaveg is necessary in patients with mild hepatic impairment (Child-Pugh Class A) or moderate hepatic impairment (Child-Pugh Class B). Zavegepant has not been studied in patients with severe hepatic impairment (Child-Pugh Class C). Avoid use of Zaveg in patients with severe hepatic impairment
Use in renal impairment: No dosage adjustment of Zaveg is necessary in patients with estimated creatinine clearance (CLcr) 30 mL/min or greater. Avoid use of Zaveg in patients with CLcr less than 30 mL/min.

STORAGE
- Store below 25°C, keep in dry place and protect from light.
- Do not refrigerate or freeze
- Keep out of the reach of the children.

PACKING
Zaveg Antimigraine Nasal Spray: Each bottle contains aqueous solution of Zavegepant Hydrochloride for 10 metered sprays.

Special instruction:
Patients should be instructed that the device must be prepared properly:
- before first use, and
- if the cap is left off
- if the device does not seem to be working
- if the nasal spray has not been used for 30 days or more

How to prepare and use the Nasal Spray

1. Shake the bottle vigorously for about 10 seconds and remove the dust cover.

2. Put your forefinger and middle finger on either side of the nozzle and your thumb underneath the bottle. If using for the first time or if you have not used it for a week or more, press the nasal applicator approximately 3 times until a fine mist comes out from the container.

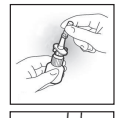
3. Blow the nose gently to clear the nostrils.

4. Close one nostril with the finger. Lean head slightly forward and keeping the spray upright carefully insert the nasal applicator into the open nostril. Breathe in through your nose and while breathing in, press the white collar of nasal applicator firmly down once to release a spray.

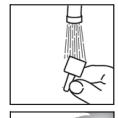
5. Breathe out through your mouth.

6. For consecutive doses, repeat above steps in the same/other nostril.

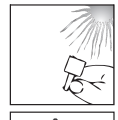
Cleaning
The nasal spray should be cleaned at least once a week or when the spray is blocked. Don't try to clean the nozzle with any needle. The cleaning procedures are as follows –



- Remove the dust cover and gently pull off the nasal applicator.



- Wash the applicator and dust cover in warm water.



- Shake off excess water and leave to dry in a normal place. Avoid applying additional heat.

- Gently push the applicator back on the top of the bottle and re-fix the dust cover.

Manufactured by:
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