PATIENT INFORMATION

ZAVZPRET™ (zav-spret) (zavegepant) nasal spray

What is ZAVZPRET?

ZAVZPRET is a prescription medicine used in adults for the acute treatment of migraine attacks with or without aura.

ZAVZPRET is not used to prevent migraine attacks.

It is not known if ZAVZPRET is safe and effective in children.

Do not use ZAVZPRET if you are:

allergic to zavegepant, or any of the ingredients in ZAVZPRET.

See the end of this leaflet for a complete list of ingredients in ZAVZPRET.

Before you use ZAVZPRET, tell your healthcare provider about all of your medical conditions, including if you:

- have high blood pressure.
- have circulation problems in your fingers and toes.
- have kidney problems.
- have liver problems.
- are pregnant or plan to become pregnant. It is not known if ZAVZPRET will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known whether ZAVZPRET passes into your breast milk. Talk with your healthcare provider about the best way to feed your baby if you use ZAVZPRET.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I use ZAVZPRET?

- Use ZAVZPRET exactly how your healthcare provider tells you to use it.
- See the Instructions for Use for complete information on how to use ZAVZPRET nasal spray.
- ZAVZPRET is given in the nose (nasal) only.
- Each ZAVZPRET only sprays 1 time and cannot be reused. Do not test or prime the nasal spray
 before use.
- Each dose of ZAVZPRET is provided in an individual pack. Use all of the medicine in 1 pack for a complete dose.
- The recommended dose is 10 mg given as a single spray in one nostril.
- Do not use more than 1 spray (10 mg) of ZAVZPRET nasal spray in a 24-hour period.
- It is not known if it is safe to use more than 8 sprays (doses) of ZAVZPRET in 30 days.
- Avoid using intranasal decongestants with ZAVZPRET. If you have to use an intranasal decongestant, use it at least 1 hour after using ZAVZPRET.

What are the possible side effects of ZAVZPRET?

ZAVZPRET may cause serious side effects including:

- Allergic reactions. Allergic reactions, including trouble breathing, hives, and swelling of the face, can happen after you use ZAVZPRET. Call your healthcare provider or get emergency help right away if you have any of the following symptoms, which may be part of an allergic reaction:
 - o swelling of the face, mouth, tongue, or throat
 - trouble breathing
 - o rash
 - hives
- **High blood pressure**. High blood pressure or worsening of high blood pressure can happen after you use ZAVZPRET. Contact your healthcare provider if you have an increase in blood pressure.
- Raynaud's phenomenon. A type of circulation problem can worsen or happen after you use ZAVZPRET. Raynaud's phenomenon can lead to your fingers or toes feeling numb, cool, or painful, or changing color from pale, to blue, to red. Contact your healthcare provider if these symptoms occur.

The most common side effects of ZAVZPRET are:

- unusual taste
- nausea
- nasal discomfort
- vomiting

These are not the only possible side effects of ZAVZPRET.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ZAVZPRET?

- Store ZAVZPRET in the blister package that it comes in.
- Store ZAVZPRET at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not freeze.

Keep ZAVZPRET and all medicines out of the reach of children.

General information about the safe and effective use of ZAVZPRET:

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ZAVZPRET for a condition for which it was not prescribed. Do not give ZAVZPRET to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ZAVZPRET that is written for health professionals.

What are the ingredients in ZAVZPRET?

Active ingredients in ZAVZPRET: zavegepant

Inactive ingredients in ZAVZPRET: dextrose, hydrochloric acid, sodium hydroxide, and succinic acid in water for injection.



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For more information, go to www.zavzpret.com or call 1-800-438-1985.

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This Patient Information has been approved by the US. Food and Drug Administration

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