

Patient Information
ONZETRA™ (On ze' trah) Xsail™ (Eks'-seil)
(sumatriptan nasal powder) 11 mg

Read this Patient Information before you start using ONZETRA Xsail and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is the most important information I should know about ONZETRA Xsail?

ONZETRA Xsail can cause serious side effects, including:

Heart attack and other heart problems. Heart problems may lead to death.

Stop taking ONZETRA Xsail and get emergency medical help right away if you have any of the following symptoms of a heart attack:

- discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw or stomach
- shortness of breath with or without chest discomfort
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded

ONZETRA Xsail is not for people with risk factors for heart disease unless a heart exam is done and shows no problem. You have a higher risk for heart disease if you:

- have high blood pressure
- have high cholesterol levels
- smoke
- are overweight
- have diabetes
- have a family history of heart disease

What is ONZETRA Xsail?

ONZETRA Xsail is a prescription medicine used to treat acute migraine headaches with or without aura in adults.

ONZETRA Xsail is not used to treat other types of headaches such as hemiplegic migraines (that make you unable to move on one side of your body) or basilar migraines (rare form of migraine with aura).

ONZETRA Xsail is not used to prevent or decrease the number of migraine headaches you have.

It is not known if ONZETRA Xsail is safe and effective to treat cluster headaches.

It is not known if ONZETRA Xsail is safe and effective in children under 18 years of age.

Who should not use ONZETRA Xsail?

Do not use ONZETRA Xsail if you have:

- an allergy to sumatriptan
- heart problems or history of heart problems
- narrowing of blood vessels to your legs, arms, stomach or kidney (peripheral vascular disease)
- uncontrolled high blood pressure
- severe liver problems
- hemiplegic migraines or basilar migraines. If you are not sure if you have these types of migraines, ask your healthcare provider.
- had a stroke, transient ischemic attacks (TIAs) or problems with your blood circulation

- taken any of the following medicines in the last 24 hours:
 - almotriptan (AXERT[®])
 - eletriptan (RELPAX[®])
 - frovatriptan (FROVA[®])
 - naratriptan (AMERGE[®])
 - rizatriptan (MAXALT[®], MAXALT-MLT[®])
 - zolmitriptan (ZOMIG[®], ZOMIG-ZMT[®], ZOMIG[®] NASAL SPRAY)
 - sumatriptan (IMITREX[®], IMITREX[®] NASAL SPRAY, IMITREX[®] INJECTION)
 - sumatriptan and naproxen (TREXIMET[®])
 - sumatriptan (SUMAVEL[®] DOSE PRO[®] INJECTION)
 - sumatriptan (ALSUMA[®])
 - sumatriptan (ZECUITY[®] TRANSDERMAL PATCH)
 - ergotamines (CAFERGOT[®], ERGOMAR[®], MIGERGOT[®])
 - dihydroergotamine (D.H.E. 45[®], MIGRANAL[®])

Ask your healthcare provider if you are not sure if your medicine is listed above.

What should I tell my healthcare provider before taking ONZETRA Xsail?

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

- have high blood pressure
- have high cholesterol
- have diabetes
- smoke
- are overweight
- have heart problems or a family history of heart problems or stroke
- have kidney problems
- have liver problems
- have had epilepsy or seizures
- are not using effective birth control
- become pregnant while taking ONZETRA Xsail
- are breastfeeding or plan to breastfeed. ONZETRA Xsail passes into your breast milk and may harm your baby. Talk with your healthcare provider about the best way to feed your baby if you use ONZETRA Xsail.

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

ONZETRA Xsail and certain other medicines can affect each other, causing serious side effects.

Especially tell your healthcare provider if you take anti-depressant medicines called:

- selective serotonin reuptake inhibitors (SSRIs)
- serotonin norepinephrine reuptake inhibitors (SNRIs)
- tricyclic antidepressants (TCAs)
- monoamine oxidase inhibitors (MAOIs)

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure.

Know the medicines you take. Keep a list of them to show your healthcare provider or pharmacist when you get a new medicine.

How should I use ONZETRA Xsail?

Before using ONZETRA Xsail, read the Patient Instructions for Use.

- Certain people should use their first dose of ONZETRA Xsail in their healthcare provider's office or in another medical setting. Ask your healthcare provider if you should use your first dose in a medical setting.
- Use ONZETRA Xsail exactly as your healthcare provider tells you to use it.

- Use a full dose (2 nosepieces) to treat your headache.
- If you do not get any relief after your first full dose, do not use a second dose without first talking with your healthcare provider.
- If your headache comes back after the first full dose or you only get some relief from your headache, you can use a second full dose 2 hours after the first full dose.
- Do not take more than a total of 44 mg (two full doses) of ONZETRA Xsail in a 24-hour period.
- It is not known how using ONZETRA Xsail for a long time affects the nose and throat.
- If you use too much ONZETRA Xsail, call your healthcare provider or go to the nearest hospital emergency room right away.
- You should write down when you have headaches and when you take ONZETRA Xsail so you can talk with your healthcare provider about how ONZETRA Xsail is working for you.

What should I avoid while taking ONZETRA Xsail?

ONZETRA Xsail can cause dizziness, weakness, or drowsiness. If you have these symptoms, do not drive a car, use machinery or do anything where you need to be alert.

What are the possible side effects of ONZETRA Xsail?

ONZETRA Xsail may cause serious side effects. See “What is the most important information I should know about ONZETRA Xsail?”

These serious side effects include:

- changes in color or sensation in your fingers and toes (Raynaud’s syndrome)
- stomach and intestinal problems (gastrointestinal and colonic ischemic events). Symptoms of gastrointestinal and colonic ischemic events include:
 - sudden or severe stomach pain
 - stomach pain after meals
 - weight loss
 - nausea or vomiting
 - constipation or diarrhea
 - bloody diarrhea
 - fever
- problems with blood circulation to your legs and feet (peripheral vascular ischemia). Symptoms of peripheral vascular ischemia include:
 - cramping and pain in your legs or hips
 - feeling of heaviness or tightness in your leg muscles
 - burning or aching pain in your feet or toes while resting
 - numbness, tingling or weakness in your legs
 - cold feeling or color changes in 1 or both legs or feet
- hives (itchy bumps); swelling of your tongue, mouth or throat
- medication overuse headaches. Some people who use too much sumatriptan may have worse headaches (medication overuse headache). If your headaches get worse, your healthcare provider may decide to stop your treatment with ONZETRA Xsail.
- serotonin syndrome. Serotonin syndrome is a rare but serious problem that can happen in people using ONZETRA Xsail, especially if ONZETRA Xsail is used with anti-depressant medications called SSRIs or SNRIs. Call your healthcare provider right away if you have any of the following symptoms of serotonin syndrome:
 - Mental changes such as seeing things that are not there (hallucinations), agitation, or coma
 - Fast heartbeat
 - Changes in blood pressure
 - High body temperature
 - Tight muscles
 - Trouble walking
- seizures. Seizures have happened in people taking sumatriptan who have never had seizures before. Talk with your healthcare provider about your chance of having seizures while you take ONZETRA Xsail.

The most common side effects of ONZETRA Xsail include:

- unusual or bad taste in your mouth
- discomfort of your throat or nose
- runny nose, stuffy nose, and/or postnasal drip

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ONZETRA Xsail. For more information, ask your healthcare provider or pharmacist.

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 ONZETRA Xsail?

- Store at room temperature, between 68°F to 77°F (20°C to 25°C).
- Do not store in the refrigerator or freezer.

Keep ONZETRA Xsail and all medicines out of the reach of children.

General information about the safe and effective use of ONZETRA Xsail.

- ONZETRA Xsail is to be used only with the Xsail breath powered device.
- Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets.
- Do not use ONZETRA Xsail for a condition for which it was not prescribed.
- Do not give ONZETRA Xsail to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about ONZETRA Xsail. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about ONZETRA Xsail that is written for healthcare professionals.

For more information, go to www.ONZETRA.com or call 1-844-ONZETRA (669-3872).

What are the ingredients in ONZETRA Xsail?

- Active ingredient: sumatriptan succinate
- Inactive ingredient: hypromellose (capsule)

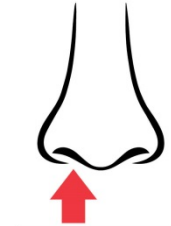
This Patient Information has been approved by the U.S. Food and Drug Administration.

Instructions for Use

Read these Instructions for Use which come with ONZETRA™ Xsail™ before you start using it and each time you get a refill. Follow these instructions each time you use ONZETRA Xsail.

HOW TO USE ONZETRA™ Xsail™

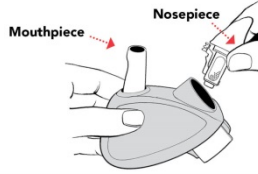
PART 1



1ST NOSEPIECE
in 1st nostril

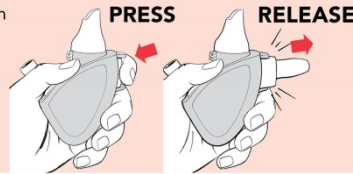
- 1** **OPEN** the pouch and remove the **first nosepiece**.

Remove device cover. **INSERT** the first nosepiece into the device until you hear it click into place.

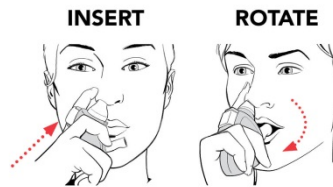


- 2** Fully **PRESS** and **RELEASE** white button to pierce the medication capsule.

! If you skip this step, you will not get any medication



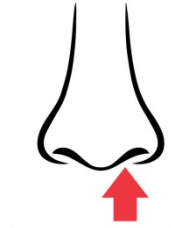
- 3** **INSERT** the nosepiece deeply into your nose. Keep the nosepiece in your nose while you rotate the device to place the mouthpiece into your mouth.



- 4** **BLOW WITH YOUR MOUTH** into the device for **2-3 seconds**, like you're blowing up a balloon, to deliver medication into your nose. (You may hear a rattling sound or feel a vibration.)

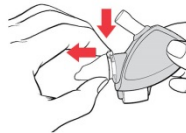


PART 2



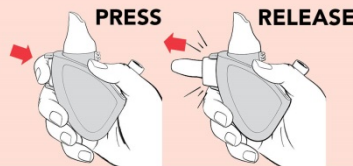
2ND NOSEPIECE
in 2nd nostril

- 5** Press the clear tab to remove the first nosepiece. **CHECK** the capsule to see if the medication is gone. **DISCARD** the used nosepiece in the trash. Insert **second nosepiece** into device.



- 6** **DON'T FORGET TO PIERCE THE CAPSULE IN SECOND NOSEPIECE.**

! If you skip this step, you will not get any medication



- 7** Lastly, repeat steps 3-4 with **second nosepiece** in **second nostril**.



DID I DO IT RIGHT?

- Checked the nosepieces.** It is normal to see a thin white residue after use. If one or both of the capsules appear unused, repeat steps 2-4 with the same nosepiece
- Used both nosepieces—**one in each nostril**
- Pierced **both capsules** before blowing
- DID NOT** hold down white button while blowing



These Instructions for Use have been approved by the U.S. Food and Drug Administration.

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U.S. Patent Nos, 6,715,485; 7,975,690; 8,047,202; 8,327,844; 8,550,073; 8,555,877; 8,590,530; 8,875,704; 8,899,229; 8,978,647; 9,108,015; 9,119,932

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