

PATIENT INFORMATION

Sumavel® DosePro® (SUE-muh-vell DOSE-pro) (sumatriptan injection) Needle-free Delivery System

Read this Patient Information before you start to take Sumavel DosePro. There may be new information. This information does not take the place of talking with your doctor about your medical condition or treatment. You and your doctor should talk about Sumavel DosePro when you start taking it and at regular checkups.

What is the most important information I should know about Sumavel DosePro?

In very rare cases, people taking triptans, such as Sumavel DosePro, may experience serious side effects, including heart attacks. Call your doctor right away if you have:

- severe chest pain
- shortness of breath

Sumavel DosePro 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
- are a female who has gone through menopause
- are a male over age 40

“Serotonin syndrome” is a serious and life-threatening problem that can happen with Sumavel DosePro, especially if used with anti-depressant medicines called selective serotonin reuptake inhibitors (SSRIs) or selective norepinephrine reuptake inhibitors (SNRIs).

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

Call your doctor if you have any of these symptoms of serotonin syndrome:

- mental changes (hallucinations, agitation, coma)
- fast heartbeat
- changes in blood pressure
- high body temperature
- tight muscles
- trouble walking
- nausea, vomiting, diarrhea

What is Sumavel DosePro?

Sumavel DosePro is a prescription medicine given with a needle-free delivery system to treat people who have been diagnosed with migraine or cluster headaches.

Sumavel DosePro is not used to prevent or lessen the number of migraine or cluster headache attacks you have.

Sumavel DosePro is not used to treat other types of headaches.

It is not known if Sumavel DosePro is safe or effective in people younger than 18 years of age.

Who should not take Sumavel DosePro?

Do not take Sumavel DosePro if you have:

- narrowing of blood vessels to the legs, arms, stomach or kidney (peripheral vascular disease)
- heart disease or a history of heart disease
- uncontrolled high blood pressure
- migraines that cause temporary paralysis (unable to move) on one side of your body or basilar migraine. If you are not sure about this, ask your doctor.
- 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)
- sumatriptan and naproxen (Treximet)
- ergotamines like Bellerгал-S, Cafergot, Ergomar
- dihydroergotamine (D.H.E. 45) or (Migranal)
- an allergy to sumatriptan
- expired medication

What should I tell my doctor before taking Sumavel DosePro?

Before taking Sumavel DosePro, tell your doctor about all of your medical conditions, including if you:

- have high cholesterol
- have diabetes
- smoke
- are overweight
- have gone through menopause
- have heart disease or a family history of heart disease or stroke
- are pregnant or plan to become pregnant. It is not known if Sumavel DosePro will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breast feeding or plan to breast feed. Sumavel DosePro passes into your breast milk and may harm your baby. Talk to your doctor about the best way to feed your baby if you take Sumavel DosePro.
- are not using effective birth control
- have had epilepsy or seizures

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

Using Sumavel DosePro with certain other medicines can affect each other causing serious side effects.

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

- selective serotonin reuptake inhibitors (SSRIs)
- serotonin norepinephrine reuptake inhibitors (SNRIs)
- Monoamine Oxidase Inhibitors (MAO-A)

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

How should I take Sumavel DosePro?

- Use Sumavel DosePro exactly as your doctor tells you to
- Read the detailed Instructions for Use at the end of this leaflet
- Deliver Sumavel DosePro into your stomach area (abdomen), or thigh
- Do not deliver Sumavel DosePro into the arm or other body parts.
- Do not deliver Sumavel DosePro into a vein or a muscle
- Do not deliver Sumavel DosePro within 2 inches of your belly button (navel)
- You may deliver a second dose of Sumavel DosePro or 1 dose of another sumatriptan medicine separated by at least 1 hour
- Do not deliver more than two doses of Sumavel DosePro in a 24-hour period.

What should I avoid while taking Sumavel DosePro?

You may feel drowsy or dizzy because of your migraine or your treatment with Sumavel DosePro. If you have these symptoms, do not drive a car, use machinery, or do anything that needs you to be alert.

What are the possible side effects of Sumavel DosePro?

Sumavel DosePro can cause serious side effects including death. See “What is the most important information I should know about Sumavel DosePro?”

Serious side effects include:

- heart attack
- fast heartbeat
- increase in blood pressure
- stroke
- changes in mental status (agitation, hallucinations, coma)
- changes in color or sensation to your fingers and toes (Raynaud’s syndrome)
- gastrointestinal ischemic events
- peripheral vascular ischemia and colonic ischemia

Get medical help right away, if you have:

- severe tightness, pain, pressure or heaviness in your chest, throat, neck, or jaw
- shortness of breath or wheezing
- sudden or severe stomach pain
- hives (itchy bumps), swelling of your tongue, mouth, or throat
- problems seeing
- unusual weakness or numbness
- nausea or vomiting
- bloody diarrhea
- stomach pain
- high temperature
- unusual sweating

The most common side effects of Sumavel DosePro include:

- bleeding, swelling, redness, bruising and pain at the administration site
- tingling or numbness in your fingers or toes
- dizziness
- warm, hot, burning feeling to your face (flushing)
- feeling of heaviness or pressure
- discomfort or tightness in the chest, neck, throat, nose, or jaw
- feeling weak, drowsy, or tired
- feeling strange
- muscle pain

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Sumavel DosePro.

For more information, ask your doctor 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 Sumavel DosePro?

- Store Sumavel DosePro between 59°F to 86°F (15°C to 30°C).
- Do not freeze.

Keep Sumavel DosePro and all medicines out of the reach of children.

General information about Sumavel DosePro.

Medicines are sometimes prescribed for purposes other than those listed in patient information leaflets. Do not use Sumavel DosePro for a condition for which it was not prescribed. Do not give Sumavel DosePro to other people, even if they have the same symptoms that you have. It may harm them.

This patient information leaflet summarizes the most important information about Sumavel DosePro. If you would like more information about Sumavel DosePro, talk to your doctor. You can ask your doctor or pharmacist for information about Sumavel DosePro that is written for health professionals.

For more information, go to www.SumavelDosePro.com or call 1-866-ZOGENIX.

What are the Ingredients in Sumavel DosePro?

Active ingredient: sumatriptan

Inactive ingredient: sodium chloride

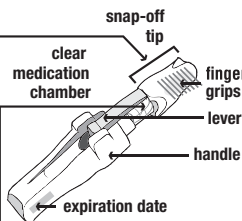
Instructions for Use

Read these Instructions for Use which come with Sumavel DosePro before you start using it and each time you get a refill. Follow these instructions each time you use Sumavel DosePro. Before you use Sumavel DosePro for the first time, make sure your doctor shows you the right way to use it.

A Check your device:

⚠ The snap-off tip should sit firmly on the end of the clear medication chamber. Do not use Sumavel DosePro if the snap-off tip is tilted or broken off.

⚠ The medicine inside Sumavel DosePro should be clear and colorless or pale yellow. Do not use Sumavel DosePro if the medicine looks dark-colored or cloudy.



⚠ The expiration date is printed on both the Sumavel DosePro label and carton. Do not use Sumavel DosePro if the medicine is expired.

B Choose a delivery site:

Select a delivery site such as your stomach area (abdomen) or your thigh.

Do not deliver Sumavel DosePro in the arm.

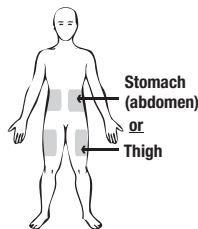
Your skin should be clean, dry, and free of clothing.

Do not deliver through your clothes.

Do not deliver into scars or moles, or within 2 inches of your belly button (navel).

Do not deliver into the same spot.

Change delivery sites with each use.

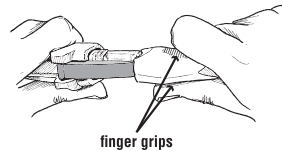


Shaded areas show all possible areas of delivery.

1 Snap: In this step, you will learn how to correctly remove the snap-off tip.

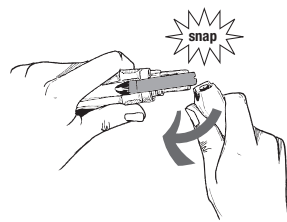
⚠ Do not begin these steps until you are ready to take your dose.

Firmly hold the handle of Sumavel DosePro in one hand. With the other hand, use your fingers to **grip the top and bottom of the snap-off tip**, where the finger grips are located.



To break off the snap-off tip, firmly snap it off in a downward motion. You may need to use some force.

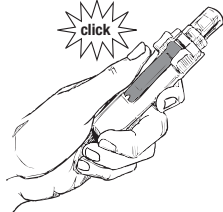
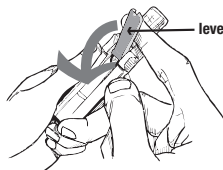
You do not need to twist or pull the snap-off tip; doing so will not work.



2 Flip: In this step, you will learn how to prepare Sumavel DosePro for delivery of the medicine.

Firmly press the green lever **all the way down** (away from the clear plastic end), until it **clicks and locks into the handle**. You may feel some resistance – this is normal.

⚠ Once you have flipped the lever, **do not touch the end of the clear medication chamber**. Keep the medication chamber pointed away from your face or eyes.



3 Press: In this step, you will learn how to deliver the medicine.

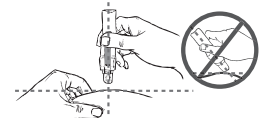
Deliver the dose exactly as shown to you by your healthcare provider.

Pinch about 2 inches of the skin of your stomach (abdomen) or thigh to create a firm section of skin.



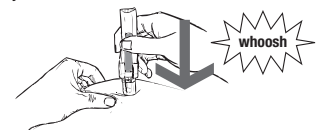
Place Sumavel DosePro straight out from the delivery site with the end of the **clear medication chamber against your skin**.

⚠ Do not hold Sumavel DosePro at an angle to your skin.



⚠ During the next step, **you will hear a loud burst of air**. Do not be alarmed – this indicates that the medicine has been delivered.

Steadily press Sumavel DosePro straight down against your skin until you hear and feel a burst of air. There is no button to push. After you hear the burst of air (whoosh), the medicine has been delivered and you can remove Sumavel DosePro from your skin.



Let go of your pinched skin after the medicine has been delivered.

After removing Sumavel DosePro from your skin, a small droplet of blood may be present. You can gently press a cotton ball or gauze over the injection site. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if needed.

Manufactured by Patheon UK, Limited
Swindon, United Kingdom

Manufactured for:
Zogenix, Inc.
San Diego, CA 92130

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