



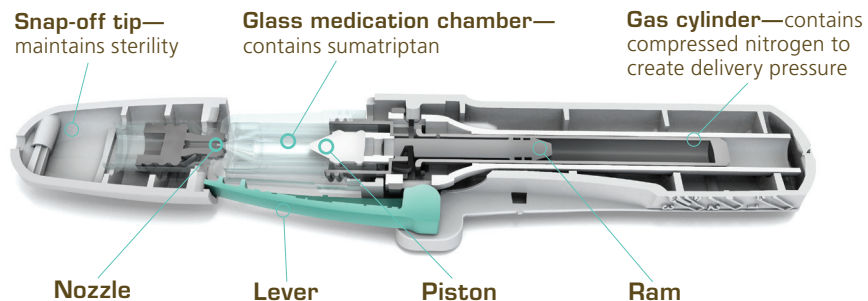
Sumavel® DosePro®
(sumatriptan injection)
Needle-free delivery system 6 mg

Instructions for Use

SUMAVEL[®] DosePro[®]

A Unique Needle-Free Delivery System

Sumavel[®] DosePro[®]
(sumatriptan injection)
Needle-free delivery system 6 mg



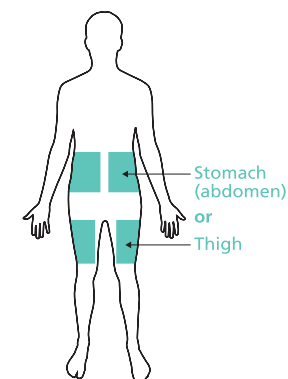
- **SNAP:** The nozzle at the end of the medication chamber is exposed when patients snap off the tip.
- **FLIP:** Flipping the lever prepares the system for delivery.
- **PINCH & PRESS:** When patients pinch their stomach or thigh and press the exposed nozzle against the skin, the compressed nitrogen gas is released. This drives the ram into the piston, pushing the medication through the glass chamber and out through the nozzle. The resulting stream of medication is propelled through the skin, into the subcutaneous tissue within 1/10th of a second.

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.

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.



IMPORTANT SAFETY INFORMATION about SUMAVEL[®] DosePro[®]

What is SUMAVEL[®] DosePro[®] used for?

SUMAVEL[®] DosePro[®] is a prescription medicine used to treat acute migraine headaches with or without aura and acute cluster headaches in adults who have been diagnosed with migraine or cluster headaches.

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Please see additional Important Safety Information on pages 6-7.

Please [click here](#) for full Prescribing Information, including Patient Information and Instructions for Use.

IMPORTANT SAFETY INFORMATION about SUMAVEL[®] DosePro[®] (cont)

What should I tell my healthcare provider before taking SUMAVEL[®] DosePro[®]?

Before you take SUMAVEL[®] DosePro[®], tell your healthcare provider about all of your medical conditions, and about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Using SUMAVEL[®] DosePro[®] with certain other medicines can affect each other, causing serious side effects.

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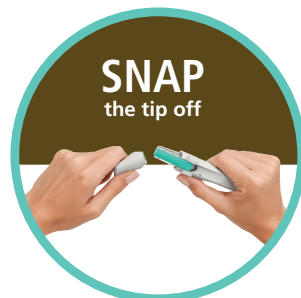
Snap: In this step, you will learn how to correctly remove the snap-off tip.

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.



This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

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Pinch and 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 click and feel a burst of air**. Do not be alarmed – this means that the medicine has been delivered.

Steadily press SUMAVEL® DosePro® straight down against your skin until you hear a click and feel a burst of air. You will feel the dose being delivered. There is no button to push. After you hear the click and feel the burst of air, 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.



IMPORTANT SAFETY INFORMATION about SUMAVEL® DosePro® (cont)

The most common side effects of SUMAVEL® DosePro® include:

- pain or redness at your injection site
- tingling or numbness in your fingers or toes
- dizziness
- warm, hot, burning feeling to your face (flushing)
- discomfort or stiffness in your neck
- feeling weak, drowsy, or tired

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 SUMAVEL® DosePro®. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects.

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IMPORTANT SAFETY INFORMATION about SUMAVEL® DosePro®

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(sumatriptan injection)
Needle-free delivery system 6 mg

What is SUMAVEL® DosePro® used for?

SUMAVEL® DosePro® is a prescription medicine used to treat acute migraine headaches with or without aura and acute cluster headaches in adults who have been diagnosed with migraine or cluster headaches.

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

SUMAVEL® DosePro® is not used to prevent or decrease the number of migraine or cluster headaches you have.

It is not known if SUMAVEL® DosePro® is safe and effective in children under 18 years of age.

Who should not take SUMAVEL® DosePro®?

Do not take SUMAVEL® DosePro® if you have:

- heart problems or a history of heart problems
- narrowing of blood vessels to your legs, arms, stomach, or kidney (peripheral vascular disease)
- uncontrolled high blood pressure
- 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 other prescription migraine medications in the last 24 hours, including other triptans, ergotamines or ergotamine-type medicines. Ask your healthcare provider if you are not sure if your medicine is listed above.
- are allergic to sumatriptan or any of the ingredients in SUMAVEL® DosePro®.

What should I tell my healthcare provider before taking SUMAVEL® DosePro®?

Before you take SUMAVEL® DosePro®, tell your healthcare provider about all of your medical conditions, and about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Using SUMAVEL® DosePro® with certain other medicines can affect each other, causing serious side effects.

What should I avoid while taking SUMAVEL® DosePro®?

SUMAVEL® DosePro® 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 is the most important information I should know about SUMAVEL® DosePro®?

SUMAVEL® DosePro® can cause serious side effects, including:

Heart attack and other heart problems.

Heart problems may lead to death. Stop taking SUMAVEL® DosePro® 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

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

What are the possible side effects of SUMAVEL® DosePro®? SUMAVEL® DosePro® may cause serious side effects, including:

- **stroke**
- **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

- **medication overuse headaches.** Some people who use too many SUMAVEL® DosePro® injections may have worse headaches (medication overuse headache). If your headaches get worse, your healthcare provider may decide to stop your treatment with SUMAVEL® DosePro®.

- **serotonin syndrome.** Serotonin syndrome is a rare but serious problem that can happen in people using SUMAVEL® DosePro®, especially if SUMAVEL® DosePro® is used with anti-depressant medicines 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 SUMAVEL® DosePro® who have never had seizures before. Talk with your healthcare provider about your chance of having seizures while you take SUMAVEL® DosePro®.

The most common side effects of SUMAVEL® DosePro® include:

- pain or redness at your injection site
- tingling or numbness in your fingers or toes
- dizziness
- warm, hot, burning feeling to your face (flushing)
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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 SUMAVEL® DosePro®. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects.

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