

MEDICATION GUIDE
TRUDHESA™ (true - deh - sa)
(dihydroergotamine mesylate)
nasal spray

What is the most important information I should know about TRUDHESA?

TRUDHESA can cause serious side effects, including:

- Serious problems with blood circulation to your legs and feet (peripheral ischemia). TRUDHESA can cause peripheral ischemia when you take it with certain medicines known as CYP3A4 inhibitors. Peripheral ischemia may lead to a stroke and death. Stop taking TRUDHESA and get emergency medical help right away if you have any of the following symptoms:
 - 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
 - slurred speech
 - sudden weakness

Do not take medicines known as strong CYP3A4 inhibitors, such as:

- | | | |
|--------------|------------------|----------------|
| ○ ritonavir | ○ erythromycin | ○ ketoconazole |
| ○ nelfinavir | ○ clarithromycin | ○ itraconazole |

These are not all of the medicines that could affect how TRUDHESA works. Your healthcare provider can tell you if it is safe to take TRUDHESA with other medicines.

What is TRUDHESA?

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

- TRUDHESA is not used to prevent migraine.
- TRUDHESA 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.

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

Do not take TRUDHESA if you:

- are taking medicines known as strong CYP3A4 inhibitors.
- have heart problems or a history of heart problems.
- have uncontrolled high blood pressure.
- have narrowing of blood vessels in your legs, arms, stomach, or kidneys (peripheral vascular disease).
- have sepsis.
- have had vascular surgery.
- have severe liver problems.
- have severe kidney problems.
- are allergic to dihydroergotamine mesylate, ergot alkaloids, or any ingredients in TRUDHESA. See the end of this Medication Guide for a complete list of ingredients.
- have taken any of the following medicines in the last 24 hours:
 - sumatriptan
 - almotriptan
 - eletriptan
 - frovatriptan
 - naratriptan
 - rizatriptan
 - ergotamine or ergotamine-type medicines
- have taken any medicines that constrict your blood vessels or raise your blood pressure.

Ask your healthcare provider if you are not sure if you are taking any of these medicines. Your healthcare provider can tell you if it is safe to take TRUDHESA with other medicines.

Before you take TRUDHESA, tell your healthcare provider about all of your medical conditions, including if you:

- have high blood pressure.
- have liver problems.
- have kidney problems.
- smoke.
- are pregnant or plan to become pregnant. TRUDHESA may cause preterm labor. TRUDHESA should be avoided during pregnancy. Talk to your healthcare provider right away if you are pregnant or want to become pregnant.
- are breastfeeding or plan to breastfeed. TRUDHESA may reduce breast milk supply and pass into your breast milk. TRUDHESA may be harmful to your baby. Do not breastfeed your baby while taking TRUDHESA and for

3 days after you use TRUDHESA. Talk with your healthcare provider about the best way to feed your baby if you take TRUDHESA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider will decide if you can take TRUDHESA with your other medicines.

Especially tell your healthcare provider if you take:

- sumatriptan
- ergot-type medicine
- saquinavir
- nefazodone
- fluconazole
- grapefruit juice
- zileuton
- nicotine
- propranolol or other medicines that can lower your heart rate
- any medicines that can increase your blood pressure
- selective serotonin reuptake inhibitors

These are not all of the medicines that could affect how TRUDHESA works. Your healthcare provider can tell you if it is safe to take TRUDHESA with other medicines.

How should I take TRUDHESA?

- Certain people should take their first dose of TRUDHESA in their doctor's office or in another medical setting. Ask your doctor if you should take your first dose in a medical setting.
- Use TRUDHESA exactly as your healthcare provider tells you to use it. Read and follow the instructions in the **Instructions for Use** which is provided with the TRUDHESA package before using.
- You should use TRUDHESA as soon as the symptoms of your headache start, but it may be given at any time during a migraine.
- After putting TRUDHESA together and priming the device, spray 1 time in each nostril (a complete dose).
- If your headache comes back after the first complete dose or you only get some relief from your headache, you can use a second dose 1 hour after the first complete dose. Use a new TRUDHESA nasal spray device for the second dose.
- Do not use more than 2 doses of TRUDHESA within a 24-hour period or 3 doses within a 7-day period.
- If you use too much TRUDHESA, call your healthcare provider or go to the nearest hospital emergency room right away.
- Taking TRUDHESA for 10 or more days in 1 month may make your headaches worse. You should write down when you have headaches and when you take TRUDHESA so that you can talk with your healthcare provider about how TRUDHESA is working for you.

What are the possible side effects of TRUDHESA?

TRUDHESA can cause serious side effects, including:

See "**What is the most important information I should know about TRUDHESA?**"

- **Heart attack and other heart problems.** Heart problems may lead to death. Stop taking TRUDHESA 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

TRUDHESA 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
- smoke
- have diabetes
- have high cholesterol levels
- are overweight
- have a family history of heart disease
- **Stroke.** Stop taking TRUDHESA and get emergency medical help right away if you have any of the following symptoms of a stroke:
 - face drooping
 - slurred speech
 - unusual weakness or numbness
- **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
 - constipation or diarrhea
 - bloody diarrhea

- weight loss
- nausea or vomiting
- fever

- **Increase blood pressure.**
- **Medicine overuse headache.** Some people who use too much TRUDHESA may make their headaches worse (medicine overuse headache). If your headaches get worse, your healthcare provider may decide to stop your treatment with TRUDHESA.
- **Preterm labor.**
- **Tissue changes (fibrotic complications).** Inflammation and fiber-like tissue that is not normal (fibrosis) can occur around the lungs and stomach.
- **Burning feelings in your nose, mouth and throat and abnormal taste.**

The most common side effects of TRUDHESA include:

- runny nose
- application site reactions
- sleepiness
- nausea
- dizziness
- sore throat
- abnormal taste
- vomiting
- diarrhea

These are not all the possible side effects TRUDHESA.

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 TRUDHESA?

Keep TRUDHESA away from heat and light.

- Store TRUDHESA at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not refrigerate or freeze.
- After a TRUDHESA vial has been opened, it must be thrown away after 8 hours.

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

Do not throw TRUDHESA into fire or incinerators as the canister inside the device may explode.

General information about the safe and effective use of TRUDHESA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TRUDHESA for a condition for which it was not prescribed. Do not give TRUDHESA 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 TRUDHESA that is written for health professionals.

What are the ingredients in TRUDHESA?

Active ingredient: Dihydroergotamine mesylate

Inactive ingredients: Caffeine, carbon dioxide, dextrose, and water. The nasal spray device canister contains hydrofluoroalkane-134a (HFA) propellant. The vial stopper is not made with natural rubber latex.

TRUDHESA is a trademark of Impel NeuroPharma Inc.

Marketed by: Impel NeuroPharma, Seattle, WA 98119, USA

www.impelnp.com

Manufactured by: Mipharm, S.p.A. Milano, Italy

Manufactured for: Impel NeuroPharma Inc. 201 Elliott Ave West, Suite 260 Seattle, WA 98119 USA

For more information, go to www.trudhesa.com or call 1-833-878-3437.

This Medication Guide has been approved by the U.S. Food and Drug Administration

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