



(Updated 2/15/22)

TRUDHESA (dihydroergotamine mesylate)

Trudhesa, also known as dihydroergotamine mesylate, is a prescription medication by Impel NeuroPharma for the acute treatment of migraine with or without aura in adults. Trudhesa was FDA approved on September 3, 2021, and is now available by prescription through Phil, a third-party provider offering an end-to-end process that will automatically enroll eligible, commercially insured patients in a savings program to obtain and ship the medication straight to your home at no additional cost OR through Carepoint. Trudhesa is not indicated for the preventive treatment of migraine and is not indicated for the management of hemiplegic or basilar migraine. This page is designed to answer some of the frequently asked questions about Trudhesa, as well as provide some helpful resources. Trudhesa is a nasal spray (POD - Precision Olfactory Delivery).

IMPORTANT NUMBERS & WEBSITES (USA)

- Trudhesa Customer Service Telephone: 833-878-3437
- Trudhesa Access Programs: <https://www.trudhesa.com/getting-trudhesa>
- Trudhesa Pharmacy Partners: 855-588-0387 Option 1 (Phil) or 855-237-9112 (Carepoint)
- Impel NeuroPharma Patient Assistance Program: 833-878-3437, option 2
- Website: www.trudhesa.com
- Report Side Effects To: www.fda.gov/medwatch or call: 800-FDA-1088

MEDICATION INFORMATION

1. **What format does the medication come in?**

A: Trudhesa comes in a vial that is inserted into a “POD” for use as a nasal spray.

2. **How do I store/handle Trudhesa?**

A: Trudhesa should be stored 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 eight (8) hours.

3. **How often may I take Trudhesa?**

A: After putting the Trudhesa vial into the pod and priming the device, spray one (1) time in each nostril (complete dose). It may be repeated, if needed, a minimum of one (1) hour after the first dose. Do not use more than two (2) doses within a 24-hour period or three (3) doses within a seven-day (7) period. Taking Trudhesa for 10 or more days in one (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.

4. **How long does it take for Trudhesa to start working?**

A: Many patients report getting freedom from migraine symptoms within two (2) hours, while some reported getting relief in as soon as 15 minutes.

5. **What is the half-life of Trudhesa?**

A: The half-life of Trudhesa is approximately 12 hours in healthy patients.

6. Will Trudhesa help my other migraine symptoms besides pain?

A: In clinical trials Trudhesa was found to help relieve patients' "most bothersome symptoms" besides pain.

7. Do I have to get this from a specialty pharmacy or do the mainstream ones also carry it?

A: Trudhesa is available exclusively through a partnership with Phil, a third-party provider offering an end-to-end process that will automatically enroll eligible, commercially insured patients in a savings program to obtain and ship the medication straight to your home at no additional cost.

8. Is Trudhesa a controlled substance?

A: Trudhesa is not a scheduled or controlled substance.

9. What about my teenage son/daughter? Can they take this medication?

A: Trudhesa is currently only approved in the USA for adults 18 years and older. If a doctor prescribes it to a teenager or other minor that would be off-label and a personal decision you make with that doctor.

SAFETY, SIDE EFFECTS & CONTRAINDICATIONS

10. What are the known side effects?

A: The most common side effects of Trudhesa as seen in the clinical trials are: runny nose, nausea, abnormal taste, application site reactions, dizziness, vomiting, sleepiness, sore throat, and diarrhea.

11. What do I do if I think I'm getting a serious side effect, or a side effect not listed?

A: If you are concerned about a side effect, please contact your doctor immediately. For urgent situations please go to urgent care or the ER. We also strongly recommend that any side effects needing medical care, a new medication, or cessation of Trudhesa be reported directly to Impel NeuroPharma as well as the FDA at: <https://www.fda.gov/safety/medwatch/>. Please also let us know about side effects in our [Facebook support group](#)!

12. Can I take this with cardiovascular or other vascular problems?

A: Trudhesa is not for people with risk factors for heart disease unless a heart exam is done and shows no problem. However, please talk to your doctor about your specific condition and safety. We are unable to offer medical advice here.

13. Can I take Trudhesa if I have renal or hepatic impairment?

A: Trudhesa is contraindicated in patients with severe renal or hepatic impairment.

14. Can I take this if I am pregnant, nursing, or planning to get pregnant or nurse?

A: Trudhesa should be avoided if you are pregnant or plan to become pregnant.

15. Can I take this if I am unable to take triptans due to their side effects?

A: Please consult with your doctor for medical advice about the safety of Trudhesa in your specific situation. Trudhesa is part of the dihydroergotamine class of medication which can cause vasoconstriction in some patients. Triptans and Trudhesa should not be taken within 24 hours of each other.

16. Are there any medications or substances which are contraindicated with Trudhesa?

A: Trudhesa should not be used with strong CYP3A4 inhibitors, such as protease inhibitors (e.g., ritonavir, nelfinavir, or indinavir), macrolide antibiotics (e.g., erythromycin or clarithromycin), and antifungals (ketoconazole or itraconazole). Some CBD and THC products are also strong CYP3A4 inhibitors, so make sure to tell your healthcare provider about use of these. Especially tell your healthcare provider if you take: sumatriptan, ergot-type medicine, saquinavir, nefazodone, fluconazole, grapefruit juice, zileuton, nicotine, propranolol or other medications that can lower your heart rate, selective serotonin reuptake inhibitors, or any medications that can increase your blood pressure.

INSURANCE – USA ONLY

17. What happens if my insurance requires a prior authorization (PA)?

A: Your doctor should be able to submit a prior authorization easily together with any documentation asked for.

18. I saw my doctor last week, two weeks ago, etc., and have not heard back. Now what?

A: You are your own best advocate. It's important to follow up with your doctor's office regularly to track the progress of the medication request and ensure they submitted the information needed to get it approved. You can also call your insurance company directly to help expedite the process.

19. What happens if my insurance denies Trudhesa?

A: Your doctor should be working with your insurance to appeal any denial. Your insurance may require a Prior Authorization, letter of medical necessity, information about your medical history and more. It is possible to appeal multiple times when insurance denies coverage. Some doctors' offices are reluctant to file appeals because it is time consuming; sometimes you can help this process by being a "squeaky wheel," but other times you may need to submit the appeal(s) yourself. We have a document in our Files giving information on how to file an appeal yourself when necessary.

<https://www.facebook.com/download/preview/437511106724266>

20. How long will it take for my insurance to cover Trudhesa?

A: There is no set time for this. We expect some insurance companies to cover it quickly, while others may take a little while, and still others will fight it as long as they can! Many will require a prior authorization and/or a letter of medical necessity and some will need several appeals. We suggest staying on top of the approval process, so your "paperwork" doesn't get lost in the mix. Often it is the "squeaky wheel" that gets the oil!

TRUDHESA ACCESSIBILITY – USA ONLY

21. Is there a copay card or savings program for Trudhesa?

A: There is a copay program that provides Trudhesa for as low as \$10 per prescription with commercial insurance. Contact Phil (855-588-0387 Option 1) or Carepoint (855-237-9112). Eligibility includes: valid in the USA only; with a valid prescription; commercially insured and is 18 years or older. Offer is not valid for patients who use any state or federal government-funded healthcare program to cover a portion of medication costs, such as Medicare (including Medicare Part D), Medicaid, Medigap, TRICARE, Department of Defense (DOD), Veterans Administration (VA), patients who are cash-paying or where prohibited by law.

22. I have government-funded insurance; am I eligible for any programs to access Trudhesa?

A: Due to FDA rules copay programs are not available to patients with government-funded health insurance such as Medicare, Medicaid and TriCare. However, Impel NeuroPharma has a Patient Assistance Program (PAP) for which you may be eligible. Learn more by calling 833-878-3437, option 2.

23. What is the Patient Assistance Program (PAP)?

The Impel NeuroPharma PAP is designed to help make Trudhesa available to those patients who otherwise may not be able to access it – especially for those who do not have commercial insurance and who can't use the Copay Card. Eligibility includes:

- Have a gross adjusted income at or below 165% of the Federal Poverty Level (FPL)
- Provide proof of income
- Are a resident of the U.S. or U.S. territories and Pacific Jurisdictions
- Have an "on-label" diagnosis for which Trudhesa was FDA approved
- Medicare Part D enrollees must have applied for and been denied (proof of denial required)
- Patient is uninsured or otherwise meets the criteria for being considered underinsured
- Signed patient authorization

24. What is the Partnership for Prescription Assistance?

Patients who aren't eligible for the savings program can reach out to the Partnership for Prescription Assistance (PPARx)[®]. This is an independent organization that provides a single point of access to numerous patient assistance programs and healthcare resources. The program assists patients with meeting their healthcare needs for free or at a reduced cost. Resources include locating free and low-cost clinics in your area, identification of disease advocacy support programs and organizations dedicated to aiding with health insurance and access problems. PPARx does NOT provide free medicine, but rather connects individuals to healthcare support resources that may be able to assist them. Contact Information: <https://www.pparx.org/> Or 1-888-4PPA-Now (1-888-477-2669). You can also contact the Patient Advocate Foundation Migraine Matters for free case management assistance at: www.patientadvocate.org/MigraineMatters .

25. Is there a free trial for Trudhesa?

A: There is no official free trial for Trudhesa, but you may be able to obtain a sample from your doctor's office.

26. Are there any USA doctors close to me who are prescribing Trudhesa?

A: We do not have information about specific doctor's prescribing practices, however if you are able to see a certified headache specialist it may be easier to access the medication. You can **CLICK HERE to see a list of every certified headache doctor** in the USA as well as some that are recommended by patients. If you are not able to see a certified headache specialist, which is true for most migraine patients, then we suggest finding a neurologist who is open to learning about these new medications.

HOPE FOR MIGRAINE GROUP INFORMATION

If you are not already a member you are welcome to join the **Hope for Migraine** group as well as our partner group, **Migraine Meanderings**, for all things migraine.

RESOURCES

<https://www.trudhesa.com>

CLICK HERE to download a medication guide for Trudhesa