Trudhesa™
(dihydroergotamine mesylate) nasal spray
0.725 mg per spray

PROVEN DHE EFFICACY

POWERED BY PRECISION OLFACTORY DELIVERY (POD®) TECHNOLOGY[1,2]

DHE=dihydroergotamine mesylate.

Important Safety Information

Indication

Trudhesa is an ergotamine derivative indicated for the acute treatment of migraine with or without aura in adults.

WARNING: PERIPHERAL ISCHEMIA FOLLOWING COADMINISTRATION WITH POTENT CYP3A4 INHIBITORS

Serious and/or life-threatening peripheral ischemia has been associated with the coadministration of dihydroergotamine with strong CYP3A4 inhibitors. Because CYP3A4 inhibition elevates the serum levels of dihydroergotamine, the risk for vasospasm leading to cerebral ischemia and/or ischemia of the extremities is increased. Hence, concomitant use of Trudhesa with strong CYP3A4 inhibitors is contraindicated.

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YEARS OF DHE RESULTS DON'T LIE[3]

NOW THEY DON'T LIE IN WAIT

The safety and efficacy of Trudhesa were established in the bioavailability study, which demonstrated that Trudhesa was statistically biocomparable to established DHE treatments for migraine.[4]

Important Safety Information (cont'd)

Limitations of Use

Trudhesa is not indicated for the preventive treatment of migraine or for the management of hemiplegic or basilar migraine.

Contraindications

Trudhesa is not recommended in patients with:

- Concomitant use of strong CYP3A4 inhibitors such as protease inhibitors (eg, ritonavir, nelfinavir, or indinavir) and macrolide antibiotics (eg, erythromycin or clarithromycin)
- Ischemic heart disease or coronary artery vasospasm

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Efficacy of traditional DHE nasal spray[3]

Efficacy was evaluated in 4 randomized, double-blind studies vs placebo.[1]

More patients achieved mild or no pain at 2 and 4 hours[1*]

In studies 1 and 2, doses of 2- or 3-mg DHE treatment were assessed.

- The higher dose showed no advantage over the lower dose
- A 4-point pain intensity scale was used to evaluate responses

In studies 3 and 4, a total dose of 2 mg was compared with placebo.

- A 5-point scale was used to record pain response

*Headache response was defined as a reduction in headache severity to mild or no pain. Headache response was based on pain intensity as interpreted by the patient using a 4-point pain intensity scale. Patients treated a moderate to severe migraine headache with a single dose of study medication and assessed pain severity over the 24 hours following treatment. Headache response was determined 0.5, 1, 2, 3, and 4 hours after dosing. Although rescue medication was allowed in all 4 studies, patients were instructed not to use it during the 4-hour observation period.

†*p* value <0.001.

‡*p* value <0.01.

STUDY 1	2 HOURS	4 HOURS
DHE N=105	61%†	70%†
PLACEBO N=98	23%	28%
STUDY 2	**2 HOURS**	**4 HOURS**
DHE N=103	47%	56%‡
PLACEBO N=102	33%	35%
STUDY 3	**2 HOURS**	**4 HOURS**
DHE N=50	32%	48%‡
PLACEBO N=50	20%	22%
STUDY 4	**2 HOURS**	**4 HOURS**
DHE N=47	30%	47%
PLACEBO N=50	20%	30%

Important Safety Information (cont'd)

Contraindications (cont'd)

- Uncontrolled hypertension, known peripheral arterial diseases, sepsis, following vascular surgery, or severe hepatic or renal impairment
- Hypersensitivity to ergot alkaloids
- Concomitant use of other 5-HT_1 agonists (eg, sumatriptan) or ergotamine-containing or ergot-type medications within 24 hours
- Concomitant use of peripheral and central vasoconstrictors

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Safety and tolerability of DHE and Trudhesa

Traditional DHE nasal spray safety data[1]

Of the 1796 patients and subjects treated with DHE nasal spray doses ≤2 mg, 26 (1.4%) discontinued because of adverse events.

Adverse reactions reported by ≥1% of patients and more frequently than in the placebo group

ADVERSE REACTION	DHE Nasal Spray (N=597)	PLACEBO (N=631)
Rhinitis	26%	7%
Nausea	10%	4%
Altered Sense of Taste	8%	1%
Application Site Reaction	6%	2%
Vomiting	4%	1%
Dizziness	4%	2%
Pharyngitis	3%	1%
Diarrhea	2%	<1%
Somnolence	3%	2%
Hot Flashes	1%	<1%
Asthenia	1%	0%
Stiffness	1%	<1%

Important Safety Information (cont'd)

Warnings and Precautions

Trudhesa may cause:

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- **Cerebrovascular events:** Cerebrovascular events (eg, cerebral hemorrhage, subarachnoid hemorrhage, and stroke) have been reported, particularly with dihydroergotamine mesylate injection
- **Vasospasm/elevated blood pressure:** Dihydroergotamine may cause vasospasm or elevation in blood pressure

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The Trudhesa safety study was the largest longitudinal study ever conducted with DHE using nasal spray delivery[1,4,5]

- A total of 5099 doses of Trudhesa were self-administered by 354 patients over the first 24 weeks of the study to treat 4257 migraine attacks[4]
- Nasal safety was the primary focus[5]
- CV effects (treatment-emergent adverse events [TEAEs], concomitant medication use, vital signs, and ECGs) were regularly collected and reviewed against preexisting conditions, concomitant medication use, and Trudhesa exposure[1]

Local irritative symptoms reported by ≥1% of patients during the 6- or 12-month study

LOCAL IRRITATIVE SYMPTOM	PERCENT OF PATIENTS TAKING ≥1 DOSE OF TRUDHESA
Nasopharyngitis	21%
Rhinitis	19%
Nasal discomfort	7%
Product taste abnormal/dysgeusia	6%
Sinusitis	5%
Sinus discomfort	4%
Olfactory test abnormal	4%
Epistaxis	3%
Pharyngitis	3%
Nasal mucosal disorder	2%
Change in smell	1%
Ear discomfort	1%
Rhinorrhea	1%

CV=cardiovascular; ECG=electrocardiogram.

Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

- **Fibrotic complications:** Rare cases have been reported following prolonged daily use of dihydroergotamine mesylate. Administration of Trudhesa should not exceed the dosing guidelines or be used for chronic daily administration
- **Medication overuse headache:** Detoxification may be necessary
- **Preterm labor:** Advise pregnant women of the risk
- **Local irritation:** Local irritation has been reported following administration of Trudhesa

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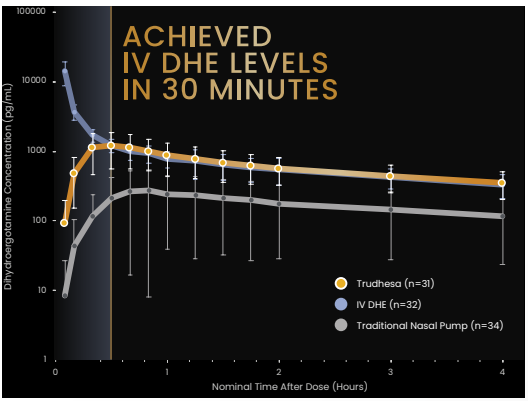
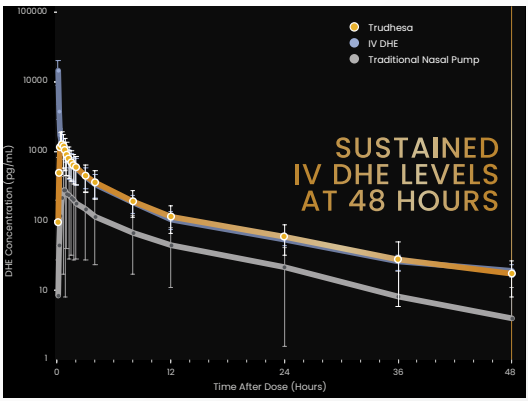
Trudhesa comparative bioavailability study

Trudhesa achieved plasma concentrations comparable to IV DHE (1.0 mg) and C_{max} within 30 minutes without the initial C_{max} spike of IV DHE, sustained through 48 hours[4,6]





IV=intravenous.

Important Safety Information (cont'd)

Most Common Adverse Reactions

Most common adverse reactions (incidence >1%) were rhinitis, nausea, altered sense of taste, application site reactions, dizziness, vomiting, somnolence, pharyngitis, and diarrhea.

Use in Special Populations

Pregnancy: Available data from published literature indicate an increased risk of preterm delivery with Trudhesa use during pregnancy.

Lactation: Patients should not breastfeed during treatment with Trudhesa and for 3 days after the last dose.

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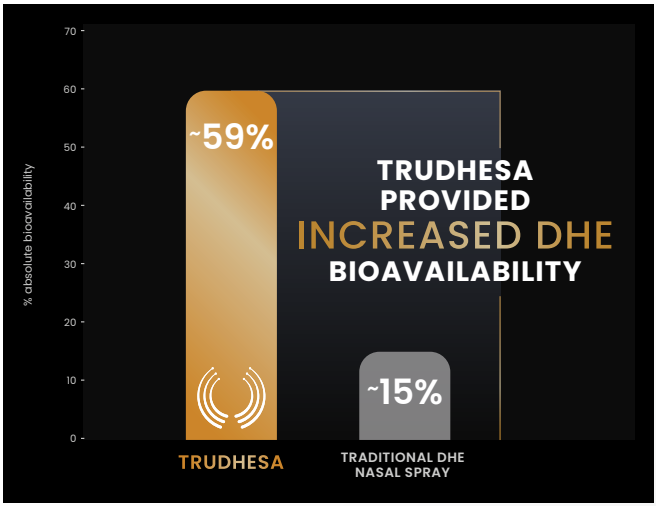
Trudhesa provided approximately 4 times the DHE bioavailability of a traditional DHE nasal spray product[4]

Increased bioavailability is a primary indicator for drug absorption.



Trudhesa bioavailability study design[6]

This was a phase 1, open-label, randomized, single-dose, 3-period, 3-way crossover study. Subjects were screened for up to 21 days before randomization into 1 of 6 sequences, dictating the order of the 3 treatments to produce a balanced crossover, with a 7-day washout period between each treatment.*

Subjects[6]:

A total of 38 healthy volunteers aged 18 to 55 years, with no significant medical history were enrolled in the study.

End points[6]:

The safety, tolerability, and bioavailability of DHE following a single-dose administration of Trudhesa 1.45 mg was compared with IV DHE 1.0 mg and a traditional DHE nasal spray (2.0 mg).

*Pretreatment with an antiemetic (metoclopramide 10 mg, delivered by slow IV push over 1 to 2 minutes, 5 to 10 minutes prior to DHE dosing) was given in all 3 treatment arms.

Important Safety Information (cont'd)

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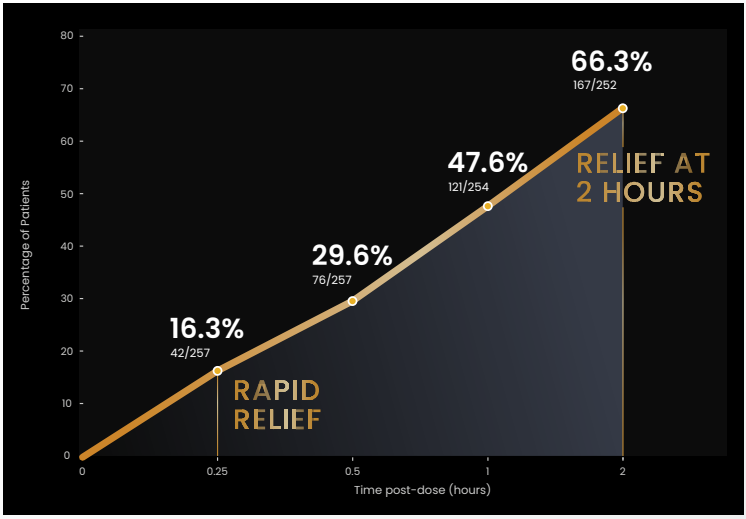
Trudhesa delivered rapid, sustained, consistent relief, with no dosing window[4,7]

The Trudhesa safety study was a phase 3, open-label study with exploratory efficacy end points and their post hoc analysis.[4]

Rapid pain relief[4,8]

38% of patients who took Trudhesa reported pain freedom at 2 hours (126/332).[8]

52% of patients had freedom from their most bothersome symptoms at 2 hours (173/332).[4]



Important Safety Information (cont'd)

Limitations of Use

Trudhesa is not indicated for the preventive treatment of migraine or for the management of hemiplegic or basilar migraine.

Contraindications

Trudhesa is not recommended in patients with:

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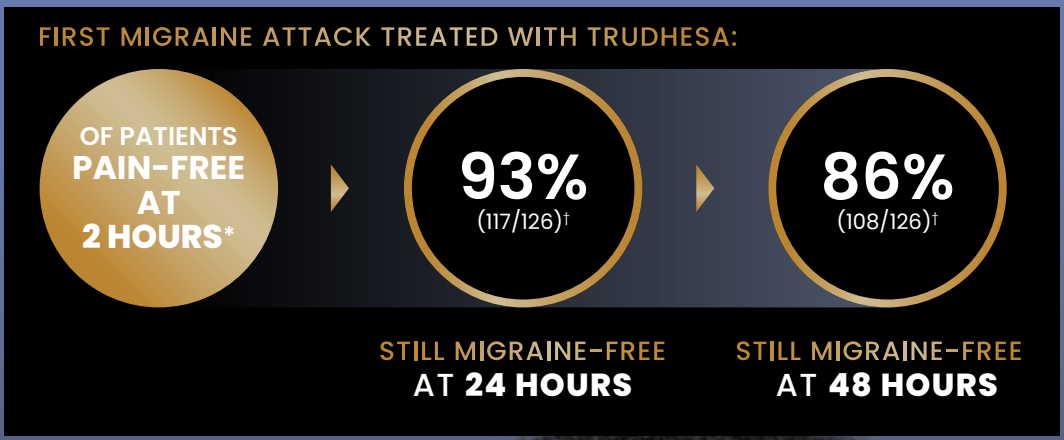
Sustained pain relief [4]



Of the 4257 migraine attacks treated during the 24-week study, where Trudhesa was used first, 85% did not require rescue medication.[7]

*Of patients who reported pain freedom at 2 hours for their first treated migraine attack with Trudhesa, **93%** were still pain-free at 24 hours and **86%** were still pain-free at 48 hours.[4]

†These analyses were exploratory in nature and no statistics were done.

Actor portrayal.

Important Safety Information (cont'd)

Contraindications (cont'd)

- Uncontrolled hypertension, known peripheral arterial diseases, sepsis, following vascular surgery, or severe hepatic or renal impairment
- Hypersensitivity to ergot alkaloids
- Concomitant use of other 5-HT_1 agonists (eg, sumatriptan) or ergotamine-containing or ergot-type medications within 24 hours
- Concomitant use of peripheral and central vasoconstrictors

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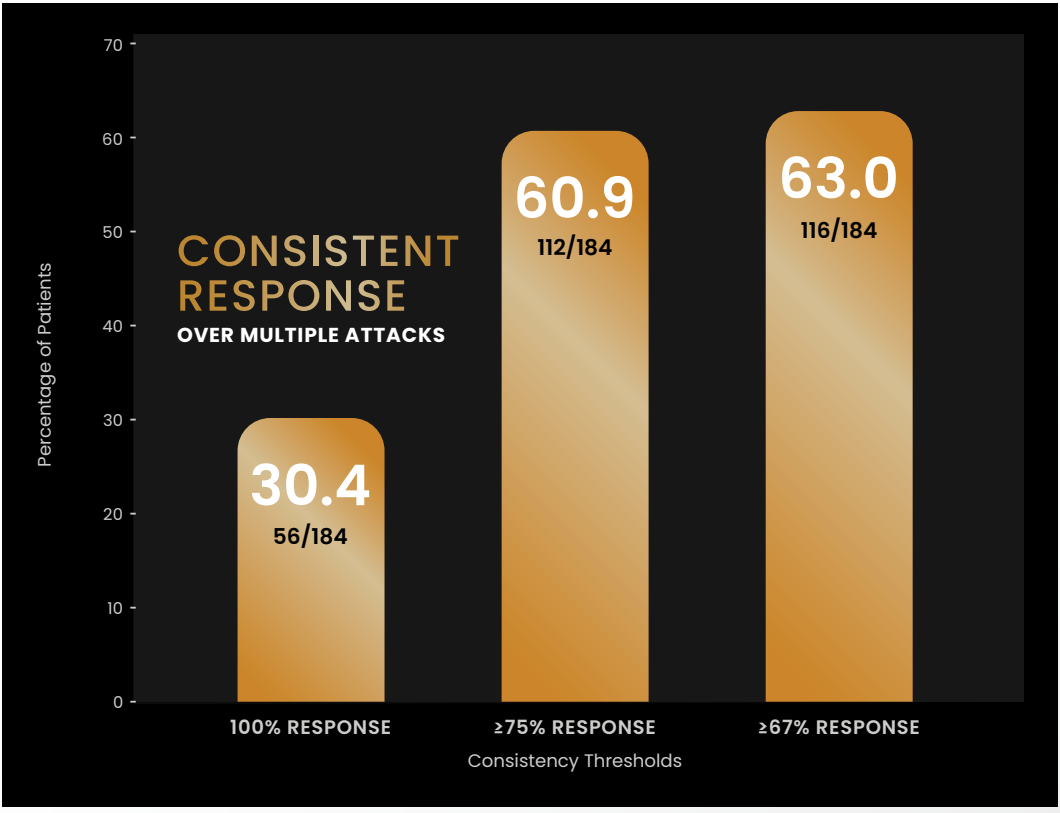
Consistent pain relief[9]

Measuring response at 2 hours for patients with ≥4 migraine attacks treated with Trudhesa over 12 weeks (N=184). Trudhesa maintained high levels of within-patient consistency.*



*Patients were asked to treat as early as possible, and at times baseline pain was not recorded.

Important Safety Information (cont'd)

Warnings and Precautions

Trudhesa may cause:

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- **Cerebrovascular events:** Cerebrovascular events (eg, cerebral hemorrhage, subarachnoid hemorrhage, and stroke) have been reported, particularly with dihydroergotamine mesylate injection
- **Vasospasm/elevated blood pressure:** Dihydroergotamine may cause vasospasm or elevation in blood pressure

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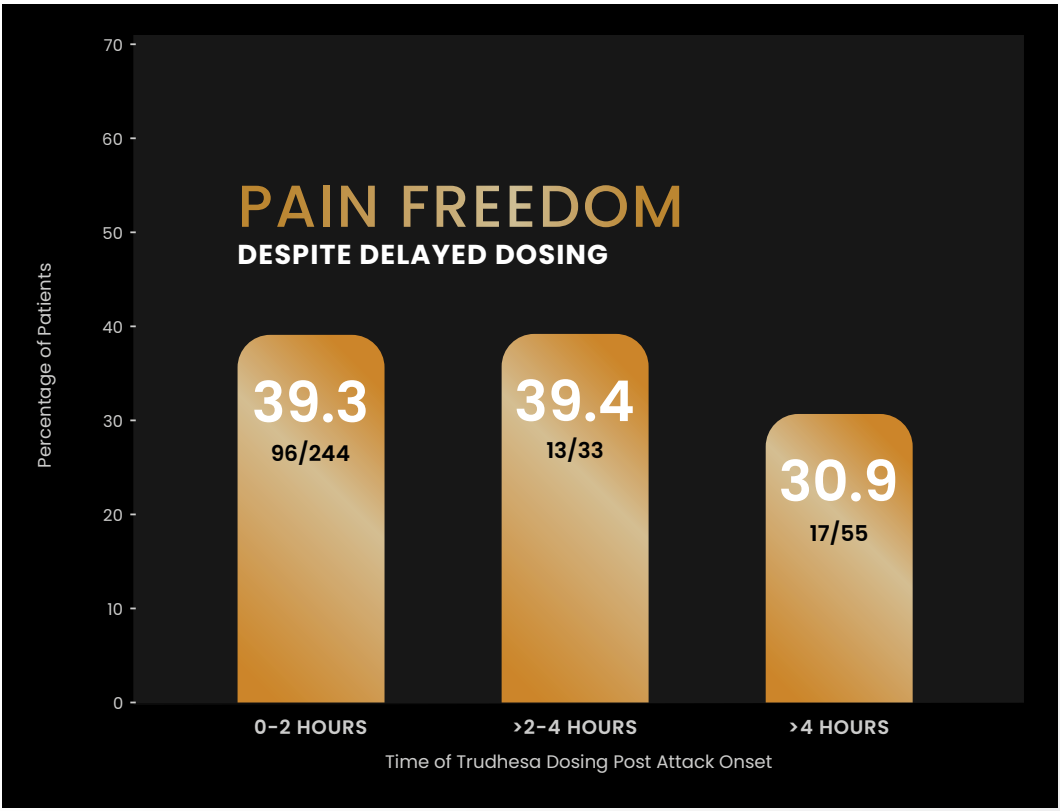
No limited dosing window[4,7]

Patients taking Trudhesa reported they achieved pain freedom despite delayed administration.



Important Safety Information (cont'd)

Warnings and Precautions (cont'd)

- **Fibrotic complications:** Rare cases have been reported following prolonged daily use of dihydroergotamine mesylate. Administration of Trudhesa should not exceed the dosing guidelines or be used for chronic daily administration
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- **Preterm labor:** Advise pregnant women of the risk
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Trudhesa safety study

Study design*

- This was a phase 3, open-label safety study with exploratory efficacy end points. During the study, migraine attacks were treated via self-administration, intermittent use of Trudhesa for up to 52 weeks.[4]
- The full safety set (FSS) comprised 354 patients who received at least one dose of Trudhesa. The primary safety set comprised 185 patients who took 2 or more doses of Trudhesa per 28-day period during the 24-week treatment period.[79]
- A subset of 73 patients continued into a 28-week treatment extension period to 52 weeks total, of which 90% completed.[79]

Primary end points[4]

- Treatment-emergent adverse events
- Change in nasal mucosa and olfactory function

Secondary end points[4]

- Changes in vital signs, physical examinations, 12-lead electrocardiogram (ECG), and laboratory evaluations

Exploratory end points were self-reported efficacy outcomes, including[4]:

- Pain freedom, most bothersome symptom freedom at 2, >2 to 4, and >4 hours
- Pain relief at 2 hours
- Recurrence of migraine pain through 24 and 48 hours

*Patients were excluded if they had a history of CV events or presented with significant risk factors for CV disease. Patients with a history of hypertension could enroll if hypertension was stable and well controlled on current therapies for >6 months, provided no other risks were present.

Important Safety Information (cont'd)

Most Common Adverse Reactions

Most common adverse reactions (incidence >1%) were rhinitis, nausea, altered sense of taste, application site reactions, dizziness, vomiting, somnolence, pharyngitis, and diarrhea.

Use in Special Populations

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Patient mean baseline characteristics† (N=354)

PATIENT CHARACTERISTICS AND DEMOGRAPHICS[4]

Mean age (years)	41.3
Body mass index (BMI)	30.4
Duration of migraine history (years)	19.5
Migraine attacks during the 28-day screening period	4.6

PERCENT OF PATIENTS WITH COMORBID CONDITIONS[4,7]

Gastrointestinal (GI) disorders	38.4%
Gastroesophageal reflux disease (GERD)	20.3%
Cardiac disorders	5.1%*

*Patients were excluded if they had a history of CV events or presented with significant risk factors for CV disease. Patients with a history of hypertension could enroll if hypertension was stable and well controlled on current therapies for >6 months, provided no other risks were present.

†Baseline consisted of the optimal migraine medications, or "best usual care" established by the patient or healthcare professional and was self-administered to treat migraine attacks in the 28-day prestudy period, with response comprising baseline.

Actor portrayal.

Important Safety Information (cont'd)

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The risk information provided here is not comprehensive. The FDA-approved product labeling can be found at www.trudhesaHCP.com or 1-800-555-DRUG. You can also call 1-833-TRUDHESA (1-833-878-3437) for additional information.

Trudhesa Direct makes prescribing E³asy

At-home delivery and as little as $10 per prescription for commercially insured, eligible patients*

1 E-Prescribe

Prescribe Trudhesa through either Phil or Carepoint Pharmacy

The digital pharmacy will initiate and manage the prior authorization process

phil Carepoint™ a Specialty Pharmacy

2 Enter the following information to minimize callbacks:

- ICD-10 Code
- Prior medication use
- Patient's mobile number — they'll receive a text with next steps†

3 Explain to your patient what happens next

Give your patient a Trudhesa Direct Information Sheet

- Patients will receive text messages from the pharmacy†
- Trudhesa will be delivered directly to their home free of charge
- Subsequent refills will be prompted via text†

***Terms and Conditions:**

If Trudhesa (dihydroergotamine mesylate) is covered by the patient's insurance plan, the patient pays as little as $10 per fill and can receive up to $4800 maximum benefit per calendar year. **If the patient's insurance plan does not cover Trudhesa,** the patient can receive up to four (4) fills per calendar year and pay as little as $10 per fill.

Patients: The pharmacy will enroll you into the Trudhesa Direct Patient Savings Program. This offer cannot be redeemed for cash. Each time the offer is used, you are certifying that you meet the eligibility criteria and will comply with the terms and conditions described in the Restrictions section below. If you have any questions about this offer, please call **1-833-TRUDHESA**.

Restrictions: This offer is valid in the United States only. Offer is available if a patient has a prescription, is 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 Affairs (VA), patients who are cash-paying, or where prohibited by law. By using this offer, the patient certifies that he or she will comply with any terms of his or her insurance plan. It is illegal to (or offer to) sell, purchase, or trade this offer. Void where prohibited by law. This program does not constitute health insurance. Program managed by ConnectiveRx on behalf of Impel NeuroPharma. The parties reserve the right to rescind, revoke, or amend this offer without notice at any time.

Program expires 12/31/2022.

†Standard text messaging rates apply.

REFERENCES: 1. Trudhesa. Prescribing information. Impel NeuroPharma; 2021. **2.** Smith TR, Aurora S, Hocevar-Trnka J, Shrewsbury S. Acute treatment of migraine with INP104: exploratory efficacy from the phase 3 STOP 301 study. Poster presented at: American Headache Society Virtual Annual Scientific Meeting, June 3-6, 2021. **3.** Silberstein SD, Shrewsbury SB, Hoekman J. Dihydroergotamine (DHE) – then and now: a narrative review. *Headache*. 2020;60(1):40-57. **4.** Smith TR, Winner P, Aurora SK, Jeleva M, Hocevar-Trnka J, Shrewsbury SB. STOP 301: a phase 3, open-label study of safety, tolerability, and exploratory efficacy of INP104, Precision Olfactory Delivery (POD®) of dihydroergotamine mesylate, over 24/52 weeks in acute treatment of migraine attacks in adult patients. *Headache*. 2021;61(8):1214-1226. **5.** Craig K, Jeleva M, Hocevar-Trnka J. Cardiovascular safety results of INP104 (POD-DHE) from the STOP 301 phase 3 study. Poster presented at: American Headache Society Virtual Annual Scientific Meeting, June 3-6, 2021. **6.** Shrewsbury SB, Jeleva M, Satterly KH, Lickliter J, Hoekman J. STOP 101: a phase 1, randomized, open-label, comparative bioavailability study of INP104, dihydroergotamine mesylate (DHE) administered intranasally by a I123 Precision Olfactory Delivery (POD®) Device, in healthy adult subjects. *Headache*. 2019;59(3):394-409. **7.** Data on File. Impel NeuroPharma. 2020. **8.** Tepper SJ, Ailani J, Shrewsbury SB, Aurora SK. Recurrence rates for INP104 for the acute treatment of migraine: results from the phase 3 STOP 301 study. Poster presented at: American Headache Society Virtual Annual Scientific Meeting, June 3-6, 2021. **9.** Shrewsbury SB, Joekman J, Jeleva M. Patient acceptability of a novel upper nasal delivery system for dihydroergotamine mesylate using the precision olfactory delivery (POD®) device – results from the open-label STOP 301 trial. Poster presented at: American Headache Society Virtual Annual Scientific Meeting, June 3-6, 2021. **10.** Aurora SK, Ray S, Satterly K, Shrewsbury SB, Hoekman J. Does dihydroergotamine treat the "whole migraine"? Poster presented at: American Headache Society Virtual Annual Scientific Meeting, June 2020.

PATIENTS WITH MIGRAINE WILL TRY ALMOST ANYTHING

Trudhesa™
(dihydroergotamine mesylate) nasal spray
0.725 mg per spray

THEY HAVEN'T TRIED ANYTHING LIKE THIS

Experience the unique combination of proven DHE efficacy and POD technology for rapid, sustained, consistent relief, with no dosing window.[1,2,4,7,10]

DHE + POD Proven efficacy with high-tech delivery[3]

Well-established safety and tolerability profile[1,6]

Rapid, sustained, consistent relief, with no dosing window[6]

Hassle-free prescribing, low copay, and at-home delivery

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Impel NEUROPHARMA