

Reference number(s)

2-H

# Quantity Limit 5-HT<sub>1</sub> Agonists, Combinations (All Dosage Forms)

# **Products Referenced by this Document**

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
almotriptan (all brands)	almotriptan
Frova	frovatriptan
Imitrex	sumatriptan
Maxalt/Maxalt-MLT	rizatriptan
naratriptan (all brands)	naratriptan
Onzetra Xsail	sumatriptan
Relpax	eletriptan
RizaFilm	rizatriptan
Symbravo	meloxicam/rizatriptan
Tosymra	sumatriptan
Treximet	sumatriptan/naproxen
Zembrace SymTouch	sumatriptan
Zomig	zolmitriptan
zolmitriptan (all other brands)	zolmitriptan

# **Indications**

## **FDA-approved Indications**

## Almotriptan

Adults: Almotriptan tablets are indicated for the acute treatment of migraine attacks in patients with a history of migraine with or without aura.

Adolescents Age 12 to 17 Years: Almotriptan tablets are indicated for the acute treatment of migraine headache pain in patients with a history of migraine attacks with or without aura usually lasting 4 hours or more (when untreated).

#### **Limitations of Use**

Almotriptan tablets should only be used where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with almotriptan tablets, the diagnosis of migraine should be reconsidered before almotriptan tablets are administered to treat any subsequent attacks. In adolescents age 12 to 17 years, efficacy of almotriptan tablets on migraine-associated symptoms (nausea, photophobia, and phonophobia) was not established. Almotriptan tablets are not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness of almotriptan tablets have not been established for cluster headache which is present in an older, predominantly male population.

#### Frova

Frova is indicated for the acute treatment of migraine with or without aura in adults.

#### **Limitations of Use**

Use only if a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Frova, reconsider the diagnosis of migraine before Frova is administered to treat any subsequent attacks. Frova is not indicated for the prevention of migraine attacks. Safety and effectiveness of Frova have not been established for cluster headache.

## **Imitrex Injection**

Imitrex injection is indicated in adults for (1) the acute treatment of migraine, with or without aura, and (2) the acute treatment of cluster headache.

#### **Limitations of Use**

Use only if a clear diagnosis of migraine or cluster headache has been established. If a patient has no response to the first migraine or cluster headache attack treated with Imitrex injection, reconsider the diagnosis before Imitrex injection is administered to treat any subsequent attacks. Imitrex injection is not indicated for the prevention of migraine or cluster headache attacks.

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## **Imitrex Nasal Spray and Imitrex Tablets**

Imitrex nasal spray and Imitrex tablets are indicated for the acute treatment of migraine with or without aura in adults.

#### **Limitations of Use**

Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with Imitrex, reconsider the diagnosis of migraine before Imitrex is administered to treat any subsequent attacks. Imitrex is not indicated for the prevention of migraine attacks. Safety and effectiveness of Imitrex nasal spray and Imitrex tablets have not been established for cluster headache.

#### Maxalt and Maxalt-MLT

Maxalt and Maxalt-MLT are indicated for the acute treatment of migraine with or without aura in adults and in pediatric patients 6 to 17 years old.

#### **Limitations of Use**

Maxalt should only be used where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Maxalt, the diagnosis of migraine should be reconsidered before Maxalt is administered to treat any subsequent attacks. Maxalt is not indicated for use in the management of hemiplegic or basilar migraine. Maxalt is not indicated for the prevention of migraine attacks. Safety and effectiveness of Maxalt have not been established for cluster headache.

## Naratriptan

Naratriptan tablets are indicated for the acute treatment of migraine with or without aura in adults.

#### **Limitations of Use**

Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with naratriptan tablets reconsider the diagnosis of migraine before naratriptan tablets are administered to treat any subsequent attacks. Naratriptan tablets are not indicated for the prevention of migraine attacks. Safety and effectiveness of naratriptan tablets have not been established for cluster headaches.

#### Onzetra Xsail

Onzetra Xsail is indicated for the acute treatment of migraine with or without aura in adults.

#### **Limitations of Use**

Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Onzetra Xsail, reconsider the diagnosis of migraine before treatment of subsequent attacks with Onzetra Xsail. Onzetra Xsail is not indicated for the prevention of migraine attacks. Safety and effectiveness of Onzetra Xsail have not been established for the treatment of cluster headache.

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## Relpax

Relpax is indicated for the acute treatment of migraine attacks with or without aura in adults.

#### **Limitations of Use**

Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Relpax, reconsider the diagnosis of migraine before Relpax is administered to treat any subsequent attacks. Relpax is not indicated for the prevention of migraine attacks. Safety and effectiveness of Relpax have not been established for the treatment of cluster headache.

#### RizaFilm

RizaFilm is indicated for the acute treatment of migraine with or without aura in adults and in pediatric patients 12 to 17 years of age weighing 40 kg or more.

#### **Limitations of Use**

RizaFilm should only be used where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with RizaFilm, the diagnosis of migraine should be reconsidered before RizaFilm is administered to treat any subsequent attacks. RizaFilm is not indicated for the preventive treatment of migraine. Safety and effectiveness of RizaFilm have not been established for cluster headache.

## Symbravo

Symbravo is indicated for the acute treatment of migraine with or without aura in adults.

#### **Limitations of Use**

Symbravo should only be used where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Symbravo, the diagnosis of migraine should be reconsidered before Symbravo is administered to treat any subsequent attacks. Symbravo is not indicated for the preventive treatment of migraine attacks. Symbravo is not indicated for the treatment of cluster headache.

#### Tosymra

Tosymra is indicated for the acute treatment of migraine with or without aura in adults.

#### **Limitations of Use**

Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Tosymra, reconsider the diagnosis before Tosymra is administered to treat any subsequent attacks. Tosymra is not indicated for the preventive treatment of migraine. Tosymra is not indicated for the treatment of cluster headache.

### **Treximet**

Treximet is indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older.

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#### **Limitations of Use**

Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with Treximet, reconsider the diagnosis of migraine before Treximet is administered to treat any subsequent attacks. Treximet is not indicated for the prevention of migraine attacks. Safety and effectiveness of Treximet have not been established for cluster headache.

## Zembrace SymTouch

Zembrace SymTouch is indicated for the acute treatment of migraine with or without aura in adults.

#### **Limitations of Use**

Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Zembrace SymTouch, reconsider the diagnosis before Zembrace SymTouch is administered to treat any subsequent attacks. Zembrace SymTouch injection is not indicated for the prevention of migraine attacks.

## Zolmitriptan ODT

Zolmitriptan orally disintegrating tablets are indicated for the acute treatment of migraine with or without aura in adults.

#### **Limitations of Use**

Only use zolmitriptan if a clear diagnosis of migraine has been established. If a patient has no response to zolmitriptan treatment for the first migraine attack, reconsider the diagnosis of migraine before zolmitriptan is administered to treat any subsequent attacks. Zolmitriptan orally disintegrating tablets are not indicated for the prevention of migraine attacks. Safety and effectiveness of zolmitriptan have not been established for cluster headache.

## **Zomig Nasal Spray**

Zomig nasal spray is indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older.

#### **Limitations of Use**

Only use Zomig if a clear diagnosis of migraine has been established. If a patient has no response to Zomig treatment for the first migraine attack, reconsider the diagnosis of migraine before Zomig is administered to treat any subsequent attacks. Zomig is not indicated for the prevention of migraine attacks. Safety and effectiveness of Zomig have not been established for cluster headache. Not recommended in patients with moderate or severe hepatic impairment.

## **Zomig Tablets**

Zomig is indicated for the acute treatment of migraine with or without aura in adults.

#### **Limitations of Use**

Only use Zomig if a clear diagnosis of migraine has been established. If a patient has no response to Zomig treatment for the first migraine attack, reconsider the diagnosis of migraine before Zomig is administered

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to treat any subsequent attacks. Zomig is not indicated for the prevention of migraine attacks. Safety and effectiveness of Zomig have not been established for cluster headache.

# **Initial Limit Quantity**

The intent is for the patient to receive only one drug from this drug class at a time.

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

Utilize higher strength available.

Medication	Strength	Dose per Headache	Maximum dose per 24 hours	Package Size	1 Month Limit 3 Months Limit
almotriptan	6.25 mg	1-2 tablets	2 tablets	6 tablets	12 tablets / 25 days 36 tablets / 75 days
almotriptan	12.5 mg	1-2 tablets	2 tablets 25 mg	6 tablets 12 tablets	12 tablets / 25 days 36 tablets / 75 days
Frova (frovatriptan)	2.5 mg	1-2 tablets	3 tablets 7.5 mg	9 tablets	18 tablets / 25 days 54 tablets / 75 days
Imitrex Injection (sumatriptan) vials	6 mg	1-2 injections	2 injections 12 mg	5 single dose vials 0.5 mL each	12 vials (6 mL) / 25 days 40 vials (20 mL) / 75 days
Imitrex Injection (sumatriptan) syringes STATdose / Refill	4 mg	1-2 injections	3 injections 12 mg	2 prefilled syringes 0.5 mL each	18 syringes (9 mL) / 25 days 54 syringes (27 mL) / 75 days
Imitrex Injection (sumatriptan) syringes	6 mg	1-2 injections	2 injections 12 mg	2 prefilled syringes	12 syringes (6 mL) / 25 days

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Medication	Strength	Dose per Headache	Maximum dose per 24 hours	Package Size	1 Month Limit 3 Months Limit
STATdose / Refill				0.5 mL each	36 syringes (18 mL) / 75 days
Imitrex Nasal Spray (sumatriptan)	5 mg	1-4 sprays	4 sprays	6 nasal spray units	24 units / 25 days 72 units / 75 days
Imitrex Nasal Spray (sumatriptan)	20 mg	1-2 sprays	2 sprays 40 mg	6 nasal spray units	12 units / 25 days 36 units / 75 days
Imitrex Tablets (sumatriptan)	25 mg, 50 mg	1-2 tablets	2 tablets	9 tablets (brand and generic) 27, 36, 90, 100 tablets (generic)	12 tablets / 25 days 36 tablets / 75 days
Imitrex Tablets (sumatriptan)	100 mg	1-2 tablets	2 tablets 200 mg	9 tablets (brand and generic) 27, 36, 90, 100 tablets (generic)	12 tablets / 25 days 36 tablets / 75 days
Maxalt Maxalt-MLT (rizatriptan)	5 mg	1-2 tablets	3 tablets	12, 18 tablets (generic), 3, 9, 12, 18 orally disintegrating tablets (generic)	18 tablets / 25 days 54 tablets / 75 days
Maxalt Maxalt-MLT (rizatriptan)	10 mg	1-2 tablets	3 tablets 30 mg	18 tablets (brand and generic) 12 tablets (generic), 3 orally disintegrating tablets	18 tablets / 25 days 54 tablets / 75 days

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Medication	Strength	Dose per Headache	Maximum dose per 24 hours	Package Size	1 Month Limit 3 Months Limit
				(brand and generic), 9, 12, 18 orally disintegrating tablets (generic)	
naratriptan	1 mg	1-2 tablets	2 tablets	9 tablets	12 tablets / 25 days 36 tablets / 75 days
naratriptan	2.5 mg	1-2 tablets	2 tablets 5 mg	9 tablets	12 tablets / 25 days 36 tablets / 75 days
Onzetra Xsail (sumatriptan)	11 mg	2 nosepieces	4 nosepieces 44 mg	16 nosepieces – 2 nosepieces per pouch 8 pouches per kit	16 nosepieces / 25 days (1 kit, 8 pouches) 64 nosepieces / 75 days (4 kits, 32 pouches)
Relpax (eletriptan)	20 mg	1-2 tablets	2 tablets	6 tablets	12 tablets / 25 days 36 tablets / 75 days
Relpax (eletriptan)	40 mg	1-2 tablets	2 tablets 80 mg	6 tablets 12 tablets	12 tablets / 25 days 36 tablets / 75 days
RizaFilm (rizatriptan)	10 mg	1-3 oral films	3 oral films 30 mg	6, 12, or 18 individually packaged films	18 films / 25 days 54 films / 75 days
Symbravo (meloxicam/rizatriptan)	20 mg/10 mg	1 tablet	1 tablet 20 mg/10 mg	9 tablets dispense in original container	9 tablets / 25 days 27 tablets / 75 days

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Medication	Strength	Dose per Headache	Maximum dose per 24 hours	Package Size	1 Month Limit 3 Months Limit
Tosymra (sumatriptan nasal)	10 mg	1-3 sprays	3 sprays 30 mg	6 nasal spray units	18 units / 25 days 54 units / 75 days
Treximet (sumatriptan/naproxen)	85 mg/500 mg	1-2 tablets	1-2 tablets 170 mg/1000 mg	9 tablets dispense in original container	9 tablets / 25 days 36 tablets / 75 days
Zembrace SymTouch (sumatriptan)	3 mg	1-4 injections	4 injections 12 mg	4 autoinjectors 0.5 mL each	24 injectors (12 mL) / 25 days 72 injectors (36 mL) / 75 days
Zomig Nasal Spray (zolmitriptan)	2.5 mg	1-2 sprays	2 sprays	6 nasal spray units	12 units / 25 days 36 units / 75 days
Zomig Nasal Spray (zolmitriptan)	5 mg	1-2 sprays	2 sprays 10 mg	6 nasal spray units	12 units / 25 days 36 units / 75 days
Zomig Tablets (zolmitriptan) zolmitriptan ODT	2.5 mg	1/2-2 tablets	2 tablets	6 tablets	12 tablets / 25 days 36 tablets / 75 days
Zomig Tablets (zolmitriptan) zolmitriptan ODT	5 mg	1-2 tablets	2 tablets 10 mg	3 tablets	12 tablets / 25 days 36 tablets / 75 days

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# **Document History**

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