

How to take SUVEXX[®]



ONE pill that takes on migraine attacks
with **BOTH** a triptan and an NSAID

SUVEXX[®] (sumatriptan succinate and naproxen sodium) is indicated for the acute treatment of migraine attacks with or without aura in adults.

Pr **Suvexx**[®]

Sumatriptan/naproxen sodium tablets (85/500 mg)

How to take SUVEXX[®]



RECOMMENDED DOSE

Take 1 tablet
as early as possible during migraine attack



Tablets should not be split, crushed or chewed

Please see the Product Monograph for complete dosing and administration instructions.



The maximum recommended dosage
in a 24-hour period is 2 tablets,
taken at least 2 hours apart.

SUVEXX CAN BE TAKEN WITH OR WITHOUT FOOD

INDICATIONS AND CLINICAL USE:

SUVEXX (sumatriptan succinate and naproxen sodium) is indicated for the acute treatment of migraine attacks with or without aura in adults.

SUVEXX is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic, basilar, or ophthalmoplegic migraine. Safety and efficacy of SUVEXX has not been established for cluster headache, which is present in an older, predominantly male population.

SUVEXX should only be used if a clear diagnosis of migraine headache has been established.

The safety and efficacy of SUVEXX in pediatric patients (<18 years) and the elderly population (>65 years of age) have not been established. SUVEXX is not indicated for use in pediatric patients.

CONTRAINDICATIONS:

- Ischemic coronary artery disease (CAD) (angina pectoris, history of myocardial infarction, or documented silent ischemia) or coronary artery vasospasm, including Prinzmetal's angina.
- In the setting of coronary artery bypass graft surgery.
- Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders.
- History of stroke or transient ischemic attack or history of hemiplegic, basilar, or ophthalmoplegic migraine because these patients are at a higher risk of stroke.

- Peripheral vascular disease.
- Ischemic bowel disease.
- Uncontrolled hypertension.
- Recent use (i.e., within 24 hours) of ergotamine-containing medication, ergot-type medication (such as dihydroergotamine or methysergide), or another 5-hydroxytryptamine₁ agonist.
- Concurrent administration of a monoamine oxidase (MAO)-A inhibitor or recent (within 2 weeks) use of an MAO-A inhibitor.
- History of asthma, urticaria, or allergic-type reactions after taking acetylsalicylic acid (ASA) or other nonsteroidal anti-inflammatory (NSAID). Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients. The potential for cross-reactivity between different NSAIDs must be kept in mind.
- Third trimester of pregnancy because of risk of premature closure of the ductus arteriosus and prolonged parturition.
- Breastfeeding women.
- Moderate or severe hepatic impairment or active liver disease.
- Severe uncontrolled heart failure.
- Active gastric/duodenal/peptic ulcer, active GI bleeding.
- Cerebrovascular bleeding or other bleeding disorders.
- Inflammatory bowel disease.
- Severe renal impairment (creatinine clearance <30 mL/min or 0.5 mL/sec) or deteriorating renal disease (individuals with

lesser degrees of renal impairment are at risk of deterioration of their renal function when prescribed NSAIDs and must be monitored).

- Known hyperkalemia.

MOST SERIOUS WARNINGS AND PRECAUTIONS:

Risk of cardiovascular adverse events:

Sumatriptan, a component of SUVEXX, can cause coronary artery vasospasm. SUVEXX is contraindicated in patients with uncontrolled hypertension, ischemic CAD, cardiac arrhythmias, and those with history of myocardial infarction. SUVEXX is not recommended in patients with family history or risk factors predictive of CAD.

Naproxen sodium, a component of SUVEXX, is a NSAID. Use of some NSAIDs is associated with an increased incidence of cardiovascular adverse events (such as myocardial infarction, stroke or thrombotic events) which can be fatal. The risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

Caution should be exercised in prescribing NSAIDs such as naproxen sodium, which is a component of SUVEXX to any patient with ischemic heart disease (including but NOT limited to acute myocardial infarction, history of myocardial infarction and/or angina), cerebrovascular disease (including but NOT limited to stroke, cerebrovascular accident, transient ischemic attacks and/or amaurosis fugax) and/or congestive heart failure (NYHA II-IV).

Use of NSAIDs, such as naproxen sodium, which is a component of SUVEXX, can promote sodium retention in a dose-dependent manner, through a renal mechanism, which can result in increased blood pressure and/or exacerbation of congestive heart failure.

Risk of gastrointestinal (GI) adverse events:

Use of NSAIDs, such as naproxen sodium, which is a component of SUVEXX, is associated with an increased incidence of gastrointestinal (GI) adverse events (such as peptic/duodenal ulceration, perforation and obstruction of the upper and lower gastrointestinal tract, and gastrointestinal bleeding). These events can occur at any time during use and without warning symptoms. Elderly patients and those with history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

Risk in pregnancy:

Caution should be exercised in prescribing SUVEXX during the first and second trimesters of pregnancy. Use of NSAIDs at approximately 20 weeks of gestation or later may cause fetal renal dysfunction leading to oligohydramnios and neonatal renal impairment or failure. SUVEXX is contraindicated for use during the third trimester because of risk of premature closure of the ductus arteriosus and uterine inertia.

OTHER RELEVANT WARNINGS AND PRECAUTIONS:

- Use only when a clear migraine diagnosis has been established.
- Use in cluster headache.
- Psychomotor impairment.
- Use in medication overuse headache.
- Not recommended for use with other NSAIDs, except low-dose ASA for cardiovascular prophylaxis.
- Serious cardiac events and fatalities associated with 5-HT₁ agonists.
- Cerebrovascular events and fatalities with 5-HT₁ agonists.
- Other vasospasm-related events.
- Increased blood pressure; use with caution in patients with controlled hypertension.
- Congestive heart failure and edema.
- Interference of platelet function.
- Use with anticoagulants.
- Anti-platelet effects.
- Blood dyscrasias.
- Increased liver enzymes; evaluate patients with signs of liver dysfunction.
- Hypersensitivity and anaphylactoid reactions.
- Do not use in ASA-intolerance.
- Cross-sensitivity to other NSAIDs.
- Masking of inflammation and fever.
- Excluding other neurologic conditions.
- History of seizures.
- Serotonin syndrome; monitor patients on other serotonergic treatments.
- Blurred and/or diminished vision.

- Renal impairment; use with caution in patients with severe dehydration or pre-existing kidney disease.
- Sodium retention and hyperkalemia.
- ASA-induced asthma.
- May impair fertility; not recommended in women trying to conceive.
- Serious skin reactions (e.g., drug reaction with eosinophilia and systemic symptoms [DRESS], Stevens-Johnson syndrome, toxic epidermal necrolysis, exfoliative dermatitis and erythema multiforme).
- Use with caution during first and second trimesters; evaluate risk-benefit.
- Not recommended during labour and delivery.
- Use in breastfeeding women.

FOR MORE INFORMATION:

Please consult the Product Monograph at: <https://www.miravohealthcare.com/wp-content/uploads/2022/01/Suvexx-PM-ENG-Dec2021.pdf> for adverse reactions, interactions, dosing and conditions of clinical use.

The Product Monograph is also available by calling Miravo Medical Information at 1-866-391-4503.



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