Suvexx™

Sumatriptan/naproxen sodium tablets

Prescribing Information for Suvexx
Suvexx 85 mg/457 mg film-coated tablets (sumatriptan/ naproxen)

For more information, please refer to the product Summary of Product Characteristics (SmPC) before prescribing.

Presentations: Film-coated tablets containing 119 mg sumatriptan succinate corresponding to 85 mg sumatriptan and 500 mg naproxen sodium corresponding to 457 mg naproxen.

Indications: For the acute treatment of the headache phase of migraine attacks with or without aura in adults where treatment with a mono-entity product has been insufficient. Use in elderly patients (over 65 years of age) is not recommended.

Dosage and Administration: One tablet taken as soon as possible after the onset of migraine headache. Tablets should be swallowed whole with water and may be taken with or without food. If the patient does not respond to the first dose of Suvexx, a second dose should not be given for the same migraine headache. If the patient has responded to the first dose but the symptoms recur, a second dose may be given provided that there is a minimum interval of two hours between the two doses. The maximum recommended dosage in a 24-hour period is two tablets, taken at least two hours apart. The safety of treating an average of more than five migraine attacks in a 30-day period has not been established. *Hepatic Impairment:* Not recommended in mild hepatic impairment. If there is a need to use, only 1 dose within a 24 hour period with monitoring. *Renal impairment:* In mild or moderate renal impairment, only 1 dose within 24-hour period with monitoring.

Contraindications: Hypersensitivity to the active substances or to any of the excipients. Severe cardiac failure, history of myocardial infarction or ischaemic heart disease, coronary vasospasm (Prinzmetal's angina), peripheral vascular disease or symptoms or signs consistent with ischaemic heart disease. History of ischaemic stroke or transient ischemic attack. Previous hypersensitivity reactions in response to ibuprofen, aspirin or other NSAIDs. History of upper gastrointestinal bleeding or perforation, related to previous NSAIDs therapy. Active acute peptic ulcer or gastrointestinal bleeding or recurring previous episodes. Moderate and severe hypertension and mild uncontrolled hypertension. Severe renal impairment. Moderate and severe hepatic impairment. Suvexx must not be used concomitantly with ergotamine or derivatives of ergotamine or any triptan/5-hydroxytryptamine1 receptor agonist, concomitantly with reversible or irreversible monoamine oxidase inhibitors, within 2 weeks of discontinuation of therapy with MAOIs, or during pregnancy (last trimester).

Precautions and Warnings for Use: Only to be used where there is a clear diagnosis of migraine. Suvexx is not indicated for use in the management of hemiplegic, basilar or ophthalmoplegic migraine. Before treating with Suvexx, care should be taken to exclude potentially serious neurological conditions if the patient presents with atypical symptoms or if they have not received an appropriate diagnosis for sumatriptan use. Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms. Patients treated with NSAIDs long-term should undergo regular medical supervision to monitor for adverse events. Prolonged use could cause medication overuse headache, treatment should be stopped. *Sumatriptan:* not recommended in patients with family history or other risk factors for coronary artery disease. Special consideration should be given to postmenopausal women and males over 40 with risk factors. Treatment should be stopped if transient symptoms including chest pain and tightness believed to indicate ischaemic heart disease occur. Appropriate observation is advised if concomitant treatment with a SSRI or a SNRI is clinically warranted. Used with caution in patients with a history of seizures or other risk factors which lower the seizure threshold. Undesirable effects may be more common during concomitant use with herbal preparations containing St John's Wort. Naproxen: Associated with an increased incidence of cardiovascular adverse events; risk may increase with duration of use. Patients with uncontrolled hypertension, congestive heart failure, established ischaemic cardiac disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with naproxen after careful consideration. *Naproxen* can result in increased blood pressure, exacerbation of congestive heart failure and a slightly increased risk of arterial thrombosis. Treatment should be stopped if gastrointestinal bleeding or ulceration occurs; risk is increased in elderly patients and those with previous gastrointestinal bleeding. Stevens-Johnson's syndrome, toxic epidermal necrolysis, exfoliative dermatitis and eosinophilia and systemic symptoms may occur with naproxen, treatment should be permanently discontinued in these cases. Discontinue treatment and monitor patients with pseudoporphyria. Increased risk of aseptic meningitis in patients with systemic lupus erythematosus and mixed connective tissue disorders. Avoid treatment in cases of varicella. Patients with coagulation disorders or on treatment that interferes with haemostasis should be monitored. Caution is advised in patients with history of dehydration, bronchial asthma or allergic disease, elderly and or debilitated patients. Anaphylactic, including fatal reactions may occur. Impaired renal function, renal failure, acute interstitial nephritis, haematuria, proteinuria, renal papillary necrosis, occasionally nephrotic syndrome, elevation of liver enzymes, severe hepatic reactions including jaundice and fatal hepatitis have been associated with naproxen. Renal function should be monitored before and during treatment in patients with reduced renal perfusion. Patients who develop visual disorders should have an ophthalmological evaluation. Co-administration with other NSAIDS or ticlopidine is not recommended. Caution is advised with concomitant administration of methotrexate, cardiac glycosides, lithium, ciclosporin and tacrolimus.

Fertility, pregnancy and lactation: Should not be used during the first and second trimester of the pregnancy unless this is absolutely necessary. Discontinued in case of oligohydramnios or ductus arteriosus constriction. Contraindicated in third trimester. Not recommended in nursing mothers and in women attempting to conceive.

Very Common and Common Side Effects: *Sumatriptan:* Dizziness, tingling, drowsiness, sensory disturbance, transient increases in blood pressure, flushing, dyspnoea, nausea and vomiting, myalgia, fatigue. The following side effects are usually transient and may affect any part of the body including the chest and throat: pain, sensations of heat or cold, pressure or tightness. *Naproxen:* headache, dizziness, light-headedness, visual disturbances, tinnitus, hearing disorders, worsening of heart failure, upper abdominal pain, heartburn, nausea, constipation, stomatitis, diarrhoea, vomiting, dyspepsia, pruritus, skin, rashes, urticaria, increased sweating, purpura, ecchymosis, tiredness. Prescribers should refer to the SmPC (section 4.8) in relation to other adverse effects.

Legal Category: POM

Pack Contents: 9 x film-coated tablets

Price & Product Licence Number: £36, PL 27925/0131

Marketing Authorisation Holder:
Orion Corporation, Orionintie 1, FI-02200 Espoo, Finland.

UK Distributor:
Orion Pharma (UK) Ltd, 9th Floor, The Blade, Abbey Square, Reading, RG1 3BE, UK.

Full prescribing information is available on request.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

Adverse events should also be reported to Orion Pharma (UK) Ltd on 01635 520300

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