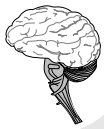

Nomi®

Zolmitriptan

Anti-Migraine

COMPOSITION

Nomi® tablet : Each film coated tablet contains Zolmitriptan INN 2.5 mg.

PHARMACOLOGY

Nomi® (Zolmitriptan) binds to serotonin 5-$HT_{1B/1D}$ receptors on intracranial blood vessels and in sensory nerves of trigeminal system. This results in cranial vessel constriction and inhibition of pro-inflammatory neuropeptide release. Nomi® (Zolmitriptan) is well absorbed after PO use. Peak plasma levels reaches at 2 hours. $t_{1/2}$, elimination is 3 hour (for zolmitriptan and active metabolite). Excreted in feces and urine.

INDICATION

Nomi® (Zolmitriptan) is indicated for the acute treatment of migraine with or without aura.

DOSAGE AND ADMINISTRATION

The recommended dose of Nomi® (Zolmitriptan) to treat a migraine attack is 2.5 mg. If symptoms persist or return within 24 hours, a second dose has been shown to be effective. If a second dose is required, it should not be taken within 2 hours of the initial dose. If a patient does not achieve satisfactory relief with 2.5mg doses, subsequent attacks can be treated with 5 mg doses of Nomi® (Zolmitriptan). In those patients who respond, significant efficacy is apparent within 1 hour of dosing,

Nomi® (Zolmitriptan) is equally effective whenever the tablets are taken during a migraine attack; although it is advisable that Nomi® (Zolmitriptan) tablets are taken as early as possible after the onset of migraine headache.

In the event of recurrent attacks, it is recommended that the total intake of Nomi® (Zolmitriptan) in a 24-hour period should not exceed 15 mg.

Nomi® (Zolmitriptan) is not indicated for prophylaxis of migraine.

Use in children: Safety and efficacy of Nomi® (Zolmitriptan) in paediatric patients have not been established.

Use in patients aged over 65 years: Safety and efficacy of Nomi® (Zolmitriptan) in individuals aged over 65 years have not been systematically evaluated.

Patients with hepatic impairment: There is no clinical or pharmacokinetics experience in patients with hepatic impairment treated with Nomi®

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(Zolmitriptan).

Patients with renal impairment: No dosage adjustment required.

CONTRAINDICATION

Zolmitriptan is contraindicated in patients with known hypersensitivity to any component of the product.

Zolmitriptan must not be given to patients with uncontrolled hypertension.

PRECAUTIONAND WARNING

Zolmitriptan should only be used where a clear diagnosis of migraine has been established. Care should be taken to exclude other potentially serious neurological conditions. There are no data on the use of Zolmitriptan in hemiplegic or basilar migraine.

Zolmitriptan should not be given to patients with symptomatic Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathways.

This class of compounds ($5HT_{1D}$ agonists) has been associated with coronary vasospasm; as a result, patients with ischaemic heart disease were excluded from clinical trials. Zolmitriptan is, therefore, not recommended in this patient group. In patients in whom unrecognised coronary artery disease is likely, cardiovascular evaluation prior to commencement of treatment with $5HT_{1D}$ agonists is recommended.

As with other $5HT_{1D}$ agonists, atypical sensations over the precordium have been reported after the administration of zolmitriptan, but in clinical trials these have not been associated with arrhythmias or ischaemic changes on ECG. Zolmitriptan may cause mild, transient increases in blood pressure (which may be more pronounced in the elderly), however, this has not been associated with clinical sequelae in the clinical trial programme.

DRUG INTERACTION

There is no evidence that concomitant use of migraine prophylactic medications has any effect on the efficacy or unwanted effects of Zolmitriptan (for example beta blockers, oral dihydroergotamine, pizotifen). The pharmacokinetics and tolerability of Zolmitriptan were unaffected by acute symptomatic treatments such as paracetamol, metoclopramide and ergotamine. However, it is recommended that patients should leave at least

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6 hours between taking an ergotamine preparation and starting Zolmitriptan, and vice versa. Concomitant administration of other 5HT1D agonists within 12 hours of Zolmitriptan treatment should be avoided.

Following administration of moclobemide, a specific MAO-A inhibitor, there was a small increase (26%) in AUC for zolmitriptan and a 3-fold increase in AUC of the active metabolite. Therefore, a maximum intake of 7.5 mg Zolmitriptan in 24 hours is recommended in patients taking an MAO-A inhibitor.

SIDE EFFECT

Zolmitriptan is well tolerated. Adverse reactions are typically mild/moderate, transient, not serious and resolve spontaneously without additional treatment. Possible adverse reactions tend to occur within 4 hours of dosing and are no more frequent following repeated dosing.

The following adverse reactions have been the most commonly reported: nausea; dizziness; somnolence; warm sensation; asthenia; dry mouth.

Abnormalities or disturbances of sensation have been reported; heaviness, tightness or pressure may occur in the throat, neck, limbs and chest (with no evidence of ischaemic changes on ECG), as may myalgia, muscle weakness, paraesthesia and dysaesthesia.

STORAGE CONDITION

Keep out of the reach of children. Store at a cool and dry place. Protect from light and moisture.

HOW SUPPLIED

Nomi® tablet : Box containing 2 x 6 tablets in blister pack.

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