



30 May 2008

## **MAXALT MLT NOW FULLY FUNDED FOR NEW ZEALAND MIGRAINE SUFFERERS**

The estimated 400,000<sup>1</sup> New Zealanders who suffer from migraine now have another choice of fully funded medication to battle this debilitating disorder.

MAXALT MLT<sup>®</sup> is unique\* in that it is formulated as a "wafer" that dissolves on the tongue and does not require water. This is good news for the many sufferers who struggle to take tablets due to nausea brought on by migraines.

MAXALT MLT 10mg is a treatment for acute migraine attacks and belongs to the class of medicines known as "triptans" (5HT<sub>1B/1D</sub> agonists).

Managing Director of Merck Sharp & Dohme (MSDNZ), Alister Brown, says "While MAXALT MLT has been available to private paying patients since February 2000; PHARMAC has now agreed to fund MAXALT MLT, without restriction. GPs prescribe approximately 250,000<sup>2</sup> packs of migraine medicine each year and they will now be able to provide patients with another option for treating migraine, which is fully funded.

"Patients will also be pleased to know that clinical studies have shown MAXALT MLT works quickly (as early as 30 minutes)<sup>3</sup> and MAXALT MLT relieved pain for more patients after two hours than other orally administered triptans<sup>4</sup>."

Dr Leo Revell, from Hamilton's Saint Andrews Medical Centre, says, "Migraine attacks have a negative effect on the physical, emotional, and social aspects of daily life. The average migraine sufferer has up to four migraines per month with about eight percent suffering severe attacks requiring bed rest. The frequency and severity of attacks has a large impact on their ability to attend work and school.

"The full funding of MAXALT MLT should encourage doctors to re-evaluate current treatment for their patients, and it should motivate people who suffer from migraines to consult with their GPs to see if MAXALT MLT could be an option for them."

MAXALT has received regulatory approval in 69 countries around the world since the product first launched in 1998.

ENDS

\* In New Zealand

TAPS Approval No: NA 2988

**Please note the Abridged Product Information is contained in the following pages.**

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<sup>1</sup> MOH NZ Health Survey 2002-03

<sup>2</sup> IMS Medical Index MAT March 2008

<sup>3</sup> Láinez MJA, López A, Pascual, AM, Effects on Work Loss, Productivity and Quality of Life of Rizatriptan for Acute Migraine: a workplace study; *Headache*, 2005, 45; 883-890.

Study Design: This prospective, open-label study was conducted at 27 worksites of 20 companies representing various labour sectors from different regions of Spain. Patients with migraine between the ages of 18 and 65 years were invited to participate in this study designed to evaluate the impact of effective treatment for headache on jobs and quality of life. Patients completed 2 questionnaires at baseline and 3 months after beginning therapy with MAXALT. A total of 259 patients completed the study.

<sup>4</sup> Ferrari MD, Roon KI, Lipton R et al. Oral triptans (serotonin 5-HT<sub>1B/1D</sub> agonists) in acute migraine treatment: A meta-analysis of 53 trials. *Lancet* 2001; 358: 1668–1675.

Study Design: This meta-analysis reviewed 53 studies involving 24,089 patients who met the following criteria: randomised, double-blind, controlled clinical trial; treatment of moderate to severe migraine headache within 8 hours of onset; treatment with an oral triptan at a recommended clinical dose; and use of a 4-point scale for pain. Per-patient, first-attack data from placebo-controlled trials, with or without an active comparator, were combined in the meta-analysis. Separate analyses were completed for direct active-comparator trials. For MAXALT, tablet and soluble wafer data were combined because study designs and results were identical. Pharmacokinetic differences between the triptans were also reviewed.

**For further information or to request an interview with Dr Leo Revell please contact:**

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**Abridged Product Information**

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**MAXALT™**  
Rizatriptan, MSD  
10mg wafer

**Indications**

MAXALT is indicated for the acute treatment of migraine attacks with or without aura.

**Dosage and Administration**

The recommended dose is 10 mg.

Doses should be separated by at least 2 hours; no more than 30 mg should be taken in any 24-hour period.

Administration with liquid is not necessary

**Patients receiving propranolol:**

Patients taking propranolol should not take MAXALT.

**Contraindications**

- hypersensitivity to rizatriptan or any of the ingredients
- concurrent administration of monoamine oxidase (MAO) inhibitors
- uncontrolled hypertension
- established coronary artery disease, including ischaemic heart disease (angina pectoris, history of myocardial infarction, or documented silent ischemia), signs and symptoms of ischaemic heart disease, or Prinzmetal's angina.

**Precautions**

MAXALT should only be administered to patients in whom a clear diagnosis of migraine has been established. MAXALT should not be administered to patients with basilar or hemiplegic migraine. MAXALT should not be used to treat "atypical" headaches, i.e., those that might be associated with potentially serious medical conditions (e.g., stroke, ruptured aneurysm) in which cerebrovascular vasoconstriction could be harmful.

There have been rare reports of serious coronary events with this class of medicines including MAXALT.

Other 5-HT<sub>1B/1D</sub> agonists (e.g., sumatriptan) should not be used concomitantly with MAXALT.

Administration of ergotamine-type medications (e.g., ergotamine, dihydro-ergotamine or methysergide) and MAXALT within 6 hours of each other is not recommended.

Cases of life threatening serotonin syndrome have been reported during combined use of selective serotonin reuptake inhibitors (SSRI)/ serotonin norepinephrine reuptake inhibitors (SNRI) and triptans. If concomitant treatment is clinically warranted careful observation is advised during treatment initiation and dosage increases.

**Pregnancy**

There are no clinical studies of rizatriptan in pregnant women. MAXALT should be used during pregnancy only if clearly needed.

**Nursing Mothers**

Rizatriptan is excreted in the milk of lactating rats; however, no data exist in humans.

**Paediatric Use**

MAXALT is not recommended for use in paediatric patients under 18 years of age.

**Medicine Interactions**

Monoamine oxidase inhibitors, beta-blockers (see Dosage and Administration), SSRI and SNRI.

**Adverse Effects**

Most frequent: dizziness, somnolence, and asthenia/fatigue

Others include: Abdominal pain, palpitations, tachycardia, diarrhoea, dyspepsia, thirst, neck pain & stiffness, regional tightness, muscle weakness, decreased mental acuity, insomnia, hypesthesia, tremor, ataxia, nervousness, vertigo, disorientation, dyspnoea, pruritis, sweating, blurred vision and hot flushes.

**Availability/Contents**

10mg wafers are available in packs of 3

API-3

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**About Merck**

Merck & Co., Inc., which operates in many countries as Merck Sharp & Dohme (MSD), is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck discovers, develops, manufactures and markets vaccines and medicines in more than 20 therapeutic categories. The company devotes extensive efforts to increase access to medicines through far-reaching programs that not only donate Merck medicines but help deliver them to the people who need them. Merck also publishes unbiased health information as a not-for-profit service. For more information, visit [www.merck.com](http://www.merck.com).