MAXALT® (rizatriptan) **MAXALT® Melt** (rizatriptan)

PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics (SPC) before prescribing.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MSD, UK (Tel: 01992 467272).
By clicking the above link you will leave the MSD website and be taken to the MHRA website.

PRESENTATION
'Maxalt' Tablets: 5 mg and 10 mg tablets each containing either 5 mg or 10 mg of rizatriptan (as benzoate).

'Maxalt' Melt oral lyophilisates (wafers): 10 mg oral lyophilisates containing 10 mg of rizatriptan (as benzoate)

USES: Acute treatment of the headache phase of migraine attacks with or without aura in adults.

DOSAGE AND ADMINISTRATION
Do not use prophylactically. *Adults 18 years of age and older:* 10 mg. *Redosing:* Separate doses by at least two hours, with no more than two doses to be taken in any 24-hour period. *For headache recurrence within 24 hours*: one further dose may be taken, observing the above dosing limits. *After non-response*: Patients not responding to the first dose should not take a second dose for the same attack. Patients not responding to treatment of an attack are still likely to respond to treatment for subsequent attacks.

The absorption of rizatriptan is delayed by approximately one hour when administered together with food. Therefore onset of effect may be delayed if 'Maxalt' is administered after meals.
5 mg of 'Maxalt', is recommended for patients on propranolol, with administration of the two drugs separated by at least two hours, and for patients with mild or moderate renal insufficiency or with mild to moderate hepatic insufficiency.

Children and Adolescents (under 18 years): The safety and efficacy has not yet been established. *Elderly (over 65 years):* Safety and effectiveness have not been evaluated.

CONTRA-INDICATIONS: Hypersensitivity. Concurrent administration of monoamine oxidase (MAO) inhibitors or use within two weeks of their discontinuation. Severe hepatic or renal insufficiency. Previous cerebrovascular accident (CVA) or transient ischaemic attack (TIA). Moderately severe or severe hypertension, or untreated mild hypertension. Established coronary artery disease, including ischaemic heart disease (angina pectoris, history of myocardial infarction, or documented silent ischaemia), signs and symptoms of ischaemic heart disease, or Prinzmetal's angina. Peripheral vascular disease. Concomitant use with ergotamine, ergot derivatives (including methysergide), or other 5-$HT_{1B/1D}$ receptor agonists.

PRECAUTIONS: Only use 'Maxalt' when there is a clear diagnosis of migraine. Do not use for basilar or hemiplegic migraine, or to treat 'atypical' headaches, i.e. those that might be associated with potentially serious medical conditions, (e.g. CVA, ruptured aneurysm).
'Maxalt' can be associated with transient symptoms including chest pain and tightness which may be intense and involve the throat. Stop dosing and evaluate in instances where such symptoms are thought to indicate ischaemic heart disease.

As with other 5-$HT_{1B/1D}$ receptor agonists, do not give 'Maxalt' without prior evaluation to patients where unrecognised cardiac disease is likely, or patients at risk for coronary artery disease (CAD), [e.g. patients with hypertension, diabetics, smokers or users of nicotine substitution therapy, men over 40 years of age, post-menopausal women, patients with bundle branch block, and those with a strong family history for CAD]. Do not use 'Maxalt' in those in whom CAD is established.

5-$HT_{1B/1D}$ receptor agonists have been associated with coronary vasospasm. In rare cases, myocardial ischaemia or infarction have been reported with 5-$HT_{1B/1D}$ receptor agonists including 'Maxalt'

Place patients experiencing hypersensitivity, e.g. angioedema, under medical supervision until symptoms have resolved. Discontinue triptan therapy promptly and replace by an agent belonging to another class of drugs.

Wait at least six hours following use of rizatriptan before administering ergotamine-type medications, (e.g. ergotamine, dihydro-ergotamine or methysergide). Wait at least 24 hours after administration of an ergotamine-containing preparation before giving rizatriptan. Additive effects are theoretically possible.

Serotonin syndrome (including altered mental status, autonomic instability and neuromuscular abnormalities) has been reported following concomitant treatment with triptans and selective serotonin reuptake inhibitors (SSRIs) or serotonin noradrenaline reuptake inhibitors (SNRIs). If concomitant treatment is warranted, ensure appropriate observation of the patient, particularly during treatment initiation, with dose increases, or with addition of another serotonergic medication.

Due to the lactose content of the tablets do not give to patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

Medication overuse headache (MOH): Prolonged use of any headache painkillers can worsen headaches. If this is experienced or suspected, seek medical advice and discontinue treatment. Diagnosis of MOH should be suspected in patients suffering frequent or daily headaches despite (or because of) regular use of headache medications

Aspartame: 'Maxalt' Melt oral lyophilisates contain aspartame, a source of phenylalanine (2.10 mg phenylalanine/10 mg wafer). It may be harmful for patients with phenylketonuria. *Interactions: Beta-blockers*: plasma concentrations of rizatriptan may be increased by concomitant administration of propranolol, therefore use the 5 mg dose of 'Maxalt'. *CYP 2D6 substrates:* the potential for interaction should be considered in patients taking CYP 2D6 substrates. *Herbal*: Undesirable effects may be more common with concomitant use of triptans (5-$HT_{1B/1D}$ receptor agonists) and herbal preparations containing St. John's wort (*Hypericum perforatum*).

PREGNANCY AND LACTATION: *Use during pregnancy:* use only if clearly needed. *Use during lactation:* exercise caution in use of 'Maxalt' in breast-feeding women. Avoid breast-feeding for 24 hours after taking 'Maxalt'.

SIDE EFFECTS
Refer to Summary of Product Characteristics for complete information on side effects
In studies of up to one year, the most common side effects were dizziness, somnolence, and asthenia/fatigue. Side effects evaluated in clinical studies and/or reported in post-marketing experience include:

Common (affects 1 to 10 users in 100): Pain in abdomen or chest, palpitation, nausea, vomiting, dry mouth, diarrhoea, dyspepsia, regional heaviness, neck pain, stiffness, headache, paraesthesia, decreased mental acuity, insomnia, hypoaesthesia, pharyngeal discomfort, and flushing.
Uncommon (affects 1 to 10 users in 1000): muscle weakness, ataxia, vertigo, disorientation, pruritus, urticaria, blurred vision, hypertension, hot flushes/flashes, angioedema (e.g. facial oedema, tongue swelling, pharyngeal oedema), arrhythmia, ECG abnormalities, tachycardia, facial pain, rash, sweating, myalgia, dysgeusia/bad taste, tremor, syncope and dyspnoea.
Rare: [≥1/10,000, <1/1,000]: Wheezing, hypersensitivity reaction, CVA (mostly in patients with risk factors for CAD), bradycardia and anaphylaxis/anaphylactoid reaction have also been reported.
Not known: [cannot be estimated from the available data]: Reports of myocardial ischaemia or infarction, mostly in patients with risk factors for CAD. Toxic epidermal necrolysis, serotonin syndrome, seizure, peripheral vascular ischaemia and ischemic colitis.

PACKAGE QUANTITIES AND BASIC NHS COST:

'Maxalt' tablets 5 mg	6 tablets: £26.74
'Maxalt' tablets 10 mg	3 tablets: £13.37
	6 tablets: £26.74
'Maxalt' Melt 10 mg	3 lyophilisates: £13.37
	6 lyophilisates: £26.74
	12 lyophilisates: £53.48

Marketing Authorisation numbers:
'Maxalt' Tablets 5 mg: PL 00025/0369
'Maxalt' Tablets 10 mg: PL 00025/0370
'Maxalt' Melt 10 mg oral lyophilisate: PL 00025/0372

Marketing Authorisation holder:
Merck Sharp & Dohme Limited,
Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, UK.

Legal Category: POM

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