Rimegepant for acute treatment of migraine with or without aura in adults. Prescribing Support Information for primary care.

This information is provided to support primary care clinicians prescribing Rimegepant (VYDURA 75 mg oral lyophilisate) for acute migraine in Bedfordshire, Luton and Milton Keynes ICS.

Category	• Analgesic • Rimegepant is a calcitonin gene-related peptide (CGRP) receptor antagonist which inhibits the function of CGRP, thereby preventing migraine attacks. • Rimegepant selectively binds with high affinity to the human calcitonin gene-related peptide (CGRP) receptor and antagonises CGRP receptor function.
Therapeutic indications	Rimegepant is indicated for the **acute treatment** of migraine with or without aura in adults. It is also indicated for preventive treatment of episodic migraine in adults who have at least 4 migraine attacks per month. However, this is beyond the scope of this document, which is to support prescribing in primary care for the acute management of migraine in adults.
Pharmaceutical form	75 mg Oral lyophilisate tablet. Rimegepant (Vydura) is available in 2 pack sizes: packs of 2 or packs of 8. Initial supplies should be restricted to 4 tablets per patient on a trial basis. For acute prescribing only, no repeat prescribing until efficacy and individual patient need can be established.
NICE guidance	**Rimegepant for treating migraine, TA919, October 2023** https://www.nice.org.uk/guidance/ta919 NICE TA919 recommends Rimegepant as an option for the **acute treatment** of migraine with or without aura in adults, **only** if for previous migraines: • at least 2 triptans were tried and they did not work well enough or • triptans were contraindicated or not tolerated, and nonsteroidal anti-inflammatory drugs (NSAIDs) and paracetamol were tried but did not work well enough.
Responsibilities	GPs/primary care prescribers can prescribe Rimegepant in accordance with the recommendations in NICE TA 919 (see section on NICE guidance above). Prescribers may refer to the NICE Clinical Knowledge Summary on Migraine.

This information does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

The following organisations contribute to and participate in the BLMK APC – Bedfordshire, Luton and Milton Keynes Integrated Care Board; Bedfordshire Hospitals NHS Foundation Trust; Cambridgeshire Community Services NHS Trust; Central and North West London NHS Foundation Trust; East London NHS Foundation Trust; Milton Keynes University Hospital NHS Foundation Trust

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	https://cks.nice.org.uk/topics/migraine/ for further information about the assessment, diagnosis, and management of migraine. In summary • Rimegepant for the treatment of migraine should only be prescribed in line with NICE recommendations, i.e., after triptan failure or if triptans are not suitable. • Concomitant use of Rimegepant with triptans for treatment of acute migraine is not recommended. • Rimegepant should not be prescribed for prevention or prophylaxis in primary care.
Triptan failure	There are 7 licenced triptans available – please refer to the formularies for local choices. https://medicines.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/categories/formulary/ All triptans work on the same pathway, but different individuals may find one triptan suits them best. • Lack of response to one triptan does not predict response to other triptans. • General efficacy is defined as a particular triptan being effective for 2 out of 3 attacks. • If a particular triptan type does not produce relief within 2 hours, then it is probably not effective. • Consider combination treatment. The combination of triptan and an NSAID is more effective than taking either of these separately. • After 2 treatment failures with a particular triptan, a trial with an alternative triptan is recommended. This rationale is based on the finding that in patients who experienced treatment failure in two attacks, 70% failed to respond in the third attack. • Around 30% of patients of do not respond to any triptan. • All acute therapies should be limited to two days a week. If required for more than 2 days a week, consider whether there may be medication overuse headache. Headache diaries should be kept. • Oral triptans may not work if the patient is vomiting - consider antiemetics or nasal / subcutaneous triptan. Please refer to the formularies for local choices. https://medicines.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/categories/formulary/
Dosing Advice	**Treatment of acute migraine in adults** The recommended dose of rimegepant is 75 mg, as needed, once daily by mouth. The maximum dose per day is 75 mg.
Special patient populations	**Elderly** (aged 65 and over) - No dose adjustment is required. **Renal impairment** Mild, moderate, or severe renal impairment - No dose adjustment is required. Severe renal impairment - Caution should be exercised during frequent use. End-stage renal disease (CrCl < 15 ml/min) - should be avoided.

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	Hepatic impairment Mild (Child-Pugh A) / moderate (Child-Pugh B) hepatic impairment - no dose adjustment is required. Severe hepatic impairment - Rimegepant should be avoided. **Paediatric population** The safety and efficacy in paediatric patients (< 18 years of age) has not been established - prescribing is not recommended.
Contraindications	Hypersensitivity to the active substance or to any of the excipients (see SPC for full details).
Cautions (see SPC for full details)	Rimegepant is not recommended: - in patients with severe hepatic impairment. - in patients with end-stage renal disease (CrCl < 15 ml/min). - for concomitant use with strong inhibitors of CYP3A4. - for concomitant use with strong or moderate inducers of CYP3A4. - medication overuse headache.
Adverse effects (see SPC for full details) **▼ drug – report suspected adverse effects to the MHRA**	The most common adverse reaction was nausea for acute treatment (1.2%). Most of the reactions were mild or moderate in severity. Hypersensitivity, including dyspnoea and severe rash, occurred in less than 1% of patients treated. Hypersensitivity reactions, including dyspnoea and rash, can occur days after administration. If a hypersensitivity reaction occurs, Rimegepant should be discontinued.
Pregnancy, lactation and fertility (See SPC for full details)	**Pregnancy** Limited data, as a precautionary measure it is preferable to avoid the use of Rimegepant during pregnancy. **Breast-feeding** Specialist sources indicate present in milk but amount probably too small to be harmful. Consider an alternative medicine if breast-feeding a neonate (pre- or full-term), limited information available. **Fertility** Animal studies showed no clinically relevant impact on female and male fertility.
Interactions (See SPC for full details)	Rimegepant is a substrate of CYP3A4, P-glycoprotein (P-gp) and breast cancer resistance protein (BCRP) efflux transporters. **CYP3A4 inhibitors** increase plasma concentrations of Rimegepant. Another dose of rimegepant within 48 hours should be avoided when it is concomitantly administered with moderate inhibitors of CYP3A4. **CYP3A4 inducers** decrease plasma concentrations of Rimegepant, which may lead to loss of efficacy.

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	P-gp and BCRP inhibitors may increase plasma concentrations of Rimegepant. Another dose of Rimegepant within 48 hours should be avoided when it is concomitantly administered with strong inhibitors of P-gp.
Counselling points	Patients or their carers should be given advice on how to administer Rimegepant oral lyophilisates. Rimegepant oral lyophilisates should be placed on or under the tongue and allowed to dissolve. It will disintegrate in the mouth and can be taken without liquid. Rimegepant should be taken with the onset of headache (not aura). Use dry hands when opening the blister. Rimegepant can be taken with or without meals. **Non pharmaceutical and lifestyle advice** Encourage a routine with regular meals, adequate hydration with water, sleep, and exercise. Keep a headache diary (see resources). Avoid triggers if possible. Consider activities that encourage relaxation such as mindfulness or meditation.
Resources	**Headache diary templates:** https://migrainetrust.org/live-with-migraine/self-management/keeping-a-migraine-diary/ https://www.nationalmigrainecentre.org.uk/headache-diary/ **BLMK migraine resources:** https://medicines.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/?s=migraine
References	1. Summary of product characteristics https://www.medicines.org.uk/emc/product/13928 accessed 23/12/2023. 2. BNF https://bnf.nice.org.uk/drugs/rimegepant/ accessed 16/01/2024. 3. NICE TA919: Rimegepant for treating migraine [TA919] Published: 18 October 2023 https://www.nice.org.uk/guidance/ta919 accessed 23/12/2023. 4. British Association for the Study of Headache (BASH) - National Headache Management System for Adults 2019 https://bash.org.uk/guidelines/ accessed 23/12/2023.

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