Repatha® (evolocumab) Brief Prescribing Information

Please refer to the Summary of Product Characteristics (SmPC) before prescribing Repatha. **Pharmaceutical Form:** Pre-filled pen (SureClick®) containing 140 mg of evolocumab in 1 mL solution for injection. **Indication:** Hypercholesterolaemia and mixed dyslipidaemia: Repatha is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, and in paediatric patients aged 10 years and over with heterozygous familial hypercholesterolaemia (HeFH), as an adjunct to diet: in combination with a statin or statin with other lipid lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin or; alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated. Homozygous familial hypercholesterolaemia (HoFH): Repatha is indicated in adults and paediatric patients aged 10 years and over with HoFH in combination with other lipid-lowering therapies. Established atherosclerotic cardiovascular disease: Repatha is indicated in adults with established atherosclerotic cardiovascular disease (myocardial infarction, stroke or peripheral arterial disease) to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors: in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies or; alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated. For study results with respect to effects on LDL-C, cardiovascular events and populations studied see section 5.1 of the SmPC. **Dosage and Administration:** Repatha is for subcutaneous injection into the abdomen, thigh or upper arm region. Repatha is intended for patient self-administration after proper training. Prior to initiating Repatha, secondary causes of hyperlipidaemia or mixed dyslipidaemia (e.g., nephrotic syndrome, hypothyroidism) should be excluded. Primary hypercholesterolaemia and mixed dyslipidaemia in adults and paediatric patients aged 10 years and over with HeFH: The recommended dose of Repatha is either 140 mg every two weeks or 420 mg once monthly; both doses are clinically equivalent. HoFH in adults and paediatric patients aged 10 years and over: The initial recommended dose is 420 mg once monthly. After 12 weeks of treatment, dose frequency can be up titrated to 420 mg once every 2 weeks if a clinically meaningful response is not achieved. Patients on apheresis may initiate treatment with 420 mg every two weeks to correspond with their apheresis schedule. Paediatric patients: The safety and effectiveness of Repatha have not been established in paediatric patients with HeFH or HoFH who are younger than 10 years old or in paediatric patients with other types of hyperlipidaemia. Established atherosclerotic cardiovascular disease in adults: The recommended dose of Repatha is either 140 mg every two weeks or 420 mg once monthly; both doses are clinically equivalent. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Special Warnings and Precautions:** Traceability: Clearly record the name and batch number of administered product to improve traceability of biological products. Hepatic impairment: In patients with moderate hepatic impairment, a reduction in total evolocumab exposure was observed that may lead to a reduced effect on LDL-C reduction. Therefore, close monitoring may be warranted in these patients. Patients with severe hepatic impairment (Child-Pugh C) have not been studied. Repatha should be used with caution in patients with severe hepatic impairment. Dry natural rubber: The needle cover of the glass pre-filled pen (SureClick®) is made from dry natural rubber (a derivative of latex), which may cause severe allergic reactions. **Interactions:** No interaction studies have been performed. **Fertility, pregnancy and lactation:** There are no or limited amount of data from the use of Repatha in pregnant women. It is unknown whether evolocumab is excreted in human milk. A risk to breastfed newborns/infants cannot be excluded. No data on the effect of evolocumab on human fertility are available. **Undesirable Effects:** Adverse reactions reported in pivotal, controlled clinical studies and from spontaneous reporting: common (≥1/100 to < 1/10) influenza, nasopharyngitis, upper respiratory tract infection, hypersensitivity, rash, headache, nausea, back pain, arthralgia, myalgia, injection site reactions; rare (≥ 1/10,000 to < 1/1,000) angioedema. Please consult the SmPC for a full description of undesirable effects. **Pharmaceutical Precautions:** Store in a refrigerator (2°C – 8°C). Do not freeze. Store the pre-filled pen (SureClick®) in the original carton in order to protect from light. If removed from the refrigerator, Repatha may be stored at room temperature (up to 25°C) in the original carton and must be used within 1 month. **Legal Category:** POM. **Presentation, Basic Costs and Marketing Authorisation Number Great Britain (GB):** Repatha pre-filled pen (SureClick®) 140 mg/1mL: Pack of 2 pre-filled pens: £340.20; PLGB 13832/0043. **Marketing Authorisation Holder GB:** Amgen Limited, 216 Cambridge Science Park, Milton Road, Cambridge, CB4 0WA, UK. **Presentation, Basic Costs and Marketing Authorisation Number Northern Ireland (XI):** Repatha pre-filled pen (SureClick®) 140 mg/1mL: Pack of 2 pre-filled pens: £340.20; EU/1/15/1016/003. **Marketing Authorisation Holder XI:** Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, The Netherlands. Further information is available from Amgen Limited, 216 Cambridge Science Park, Milton Road, Cambridge, CB4 0WA, UK. Repatha is a registered trademark of Amgen Inc. **Date of PI preparation:** March 2022 (Ref: GB-REP-0322-00004).

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk. Adverse events should also be reported to Amgen Limited on +44 (0) 1223 436441.