Mulpleo®▼ (lusutrombopag) 3 mg film-coated tablets. Refer to full Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** Each film-coated tablet contains 3 mg of lusutrombopag. **Indication:** Treatment of severe thrombocytopenia in adult patients with chronic liver disease undergoing invasive procedures. **Dosage and administration:** The recommended dose is one oral tablet once daily, with or without food, for 7 days. The procedure should be performed from day 9 after the start of treatment. Platelet count should be measured prior to the procedure. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings and precautions:** Caution should be exercised with respect to thromboembolic events after invasive procedures as well as post-treatment regardless of platelet counts. Patients with thrombosis or thromboembolism, with a history of thrombosis or thromboembolism, with absence of hepatopetal blood flow in the main trunk of the portal vein, or patients with congenital coagulopathy should be clinically monitored when treated with lusutrombopag. Lusutrombopag should only be used in patients with severe (Child-Pugh class C) hepatic impairment if the expected benefit outweighs the expected risks. Due to the unstable nature of these patients, they should be supported in line with clinical practice by close monitoring for early signs of worsening or new onset hepatic encephalopathy, ascites, and thrombotic or bleeding tendency, through monitoring of liver function tests, tests used for assessing clotting status and through imaging of portal vasculature as needed. In patients with Child-Pugh class C liver disease and in patients with body weight <45 Kg platelet count should be measured at least once approximately 5 days after the first dose and as necessary thereafter and appropriate measures such as discontinuation of lusutrombopag should be taken, if the platelet count reaches ≥50,000/µL as a result of a 20,000/µL increase from baseline. The efficacy and safety of lusutrombopag have not been established when administered before laparotomy, thoracotomy, open-heart surgery, craniotomy or excision of organs. Platelet count should be carefully monitored in patients with a history of splenectomy treated with lusutrombopag. Interferon preparations have been known to reduce platelet counts, therefore, this should be considered when co-administering lusutrombopag with interferon preparations. A potential interaction with either P-gp or BCRP inhibitors cannot be excluded, but no dose adjustment is necessary at the recommended clinical dosage of 3 mg in adults. **Pregnancy and lactation:** Should be used with contraception, not recommended during pregnancy and in women of child-bearing potential not using contraception. Should not be administered to breast-feeding women. **Undesirable effects:** Common: headache, nausea, portal vein thrombosis and rash. **Legal classification:** Prescription only medicine. **MA number:** EU/1/18/1348 (NI); PLGB 50999/0007 (GB). **Pack sizes and cost:** 7 tablets £800.00. **MA holder:** Shionogi B. V., Herengracht 464, 1017CA, Asterdam, The Netherlands.

**Date of preparation:** March 2023.

**▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. 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 Shionogi on 02030534190 or via contact@shionogi.eu**

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NP-UK-LUS-0028 Date of prep: March 2023