PREGNANCY AND LACTATION: Do not use during pregnancy unless clearly necessary. Contraception advised during and up to 3 months after treatment (either for women of childbearing potential or their male partners when receiving Halaven). Do not use during breast-feeding.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES: Do not drive or use machines if experiencing tiredness or dizziness.

UNDESIRABLE EFFECTS: Refer to SmPC for information on all side effects. The incidence rates of adverse reactions observed in breast cancer and soft tissue sarcoma patients who received the recommended eribulin dose in Phase 2 and Phase 3 studies:

- Very common (≥1/10): Neutropenia, leukaemia, anaemia; Decreased appetite; Peripheral neuropathy, headache; Dyspnœa, cough; Nausea, constipation, diarrhoea, vomiting; Alopecia; Arthralgia and myalgia, back pain, pain in extremity; Fatigue/asthenia, pyrexia; Weight decreased. Common (≥1/100 to <1/10): Urinary tract infection, pneumonia, oral candidiasis, oral herpes, upper respiratory tract infection, nasopharyngitis, rhinitis; herpes zoster; Lymphopenia, febrile neutropenia, thrombocytopenia; Hypokalaemia, hypomagnesaemia, dehydration; Pruritus, alopecia; hypoglycaemia, hypophosphataemia, hypocalcaemia; Insomnia, depression; Dysgeusia, dizziness, hypoesthesia, lethargy, neurotoxicity; Lactation increased, convulsities; Vertigo, tinnitus; Tachycardia; Hot flush, pulmonary embolism; Oropharyngeal pain, epistaxis, rhinorrhoea; Abdominal pain, stomatitis, dry mouth, dyspepsia, gastroesophageal reflux disease, abdominal distension; Alanine aminotransferase increased, aspartate aminotransferase increased, gamma glutamyl transferase increased, hyperbilirubinaemia; Rash, pruritus, nail disorder, night sweats, dry skin, erythema, hyperhidrosis, palmar plantar erythrodysaesthesia; Bone pain, muscle spasms, musculoskeletal pain, musculoskeletal chest pain, muscular weakness; Dysuria; Mucosal inflammation, peripheral oedema, pain, chills, chest pain, influenza like illness. Serious but uncommon (≥1/1,000 to <1/100): Sepsis, neutropenic sepsis, septic shock; Deep vein thrombosis; Intestinal lung disease; Mouth ulceration, pancreatitis; Hepatotoxicity; Angioedema; Haematuria, proteinuria, renal failure. Serious but rare (≥1/10,000 to <1/1,000): Disseminated intravascular coagulation. Serious but frequency not known: Stevens-Johnson syndrome / Toxic epidermal necrolysis.

OVERDOSE: No known antidote. Closely monitor and manage with supportive medical interventions.

LEGAL CATEGORY: POM

Basic UK NHS Cost: Eribulin 0.44mg/ml 2ml vial: £361 per vial

Marketing authorisation number: Eribulin 0.44mg/ml 2ml vial x 1: EU/1/11/678/001

Marketing authorisation holder: Eisai GmbH.

Further Information from: Eisai Ltd., Mosquito Way, Hatfield, Hertfordshire, AL10 9SN, United Kingdom

Date of preparation: March 2019. UK-HAL-19-00039

Adverse events should be reported. Reporting forms and Information can be found at www.mhra.gov.uk/yellowcard or search for the MHRA Yellow Card in the Google Play or Apple App Store, or Ireland: www.hpra.ie. Adverse events should also be reported to Eisai Ltd on +44 (0)845 676 1400 / +44 (0)208 600 1400 or Eumedinfo@eisai.net

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