GB Prescribing Information - Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Trecondi® (treosulfan) 1g/5g powder for solution for infusion

Qualitative and quantitative composition: One vial Trecondi 1g (5g) powder for solution for infusion contains 1g (5g) of treosulfan. When reconstituted, 1mL of the solution for infusion contains 50mg treosulfan. **Therapeutic indications:** Treosulfan in combination with fludarabine is indicated as part of conditioning treatment prior to allogeneic haematopoietic stem cell transplantation (alloHSCT) in adult patients and in paediatric patients older than one month with malignant and non-malignant diseases. **Posology and method of administration:** Administration should be supervised by a physician experienced in conditioning treatment followed by alloHSCT. A*dults with malignant disease:* Treosulfan is given in combination with fludarabine. Treosulfan 10g/m² body surface area (BSA) per day as a two hour intravenous infusion, given on three consecutive days (day -4, -3, -2) before stem cell infusion (day 0). The total treosulfan dose is 30g/m²; Treosulfan should be administered before fludarabine. *Adults with non malignant disease*: Treosulfan is given in combination with fludarabine with or without thiotepa. Treosulfan 14g/m² body surface area (BSA) per day as a two hour intravenous infusion, given on three consecutive days (day -6, -5, -4) before stem cell infusion (day 0). The total treosulfan dose is 42g/m²; Treosulfan should be administered before fludarabine. *Paediatric population:* Treosulfan is given in combination with fludarabine, with or without thiotepa. **Contraindications:** Hypersensitivity to the active substance; active non-controlled infectious disease; severe concomitant cardiac, lung, liver, and renal impairment; Fanconi anaemia and other DNA breakage repair disorders; pregnancy; administration of live vaccine. **Undesirable effects:** *Infections, infestations:* Very commonly infections (bacterial, viral, fungal)**.** Common**ly s**epsis. Septic shock. *Neoplasms:* Treatment related second malignancy. *Blood, lymphatic system:* Very commonly myelosuppression, pancytopenia, febrile neutropenia. *Immune system:* Commonly hypersensitivity. *Metabolism and nutrition:* Commonly decreased appetite. Uncommonly hyperglycaemia. Acidosis, glucose tolerance impaired, electrolyte imbalance, alkalosis, hypomagnesaemia. *Psychiatric:* Commonly insomnia. Uncommonly confusional state. Agitation. *Nervous system:* Commonly headache, dizziness. Uncommonly peripheral sensory neuropathy. Encephalopathy, intracranial haemorrhage, extrapyramidal disorder, syncope, paraesthesia, seizure. *Eye:* Dry eye, conjunctival haemorrhage. *Cardiac:* Commonly cardiac arrhythmias (e.g. atrial fibrillation, sinus arrhythmia). Cardiac arrest, cardiac failure, myocardial infarction, pericardial effusion. *Vascular:* Commonly hypertension, flushing. Uncommon haematoma, hypotension. Embolism, haemorrhage, capillary leak syndrome. *Respiratory, thoracic, mediastinal:* Commonly dyspnoea, epistaxis, oropharyngeal pain. Uncommonly pneumonitis, pleural effusion, pharyngeal or laryngeal inflammation, cough, laryngeal pain, hiccups. Hypoxia, dysphonia. *Gastrointestinal:* Very commonly stomatitis/mucositis, diarrhoea, nausea, vomiting, abdominal pain. Commonly oral pain, gastritis, dyspepsia, constipation, dysphagia. Uncommonly mouth haemorrhage, abdominal distension, oesophageal or gastrointestinal pain, dry mouth. Gastrointestinal haemorrhage, neutropenic colitis, oesophagitis, anal inflammation, mouth ulceration, proctitis. *Hepatobiliary:* Uncommonly veno occlusive liver disease, hepatotoxicity. Hepatic failure, hepatomegaly, hepatic pain. *Skin, subcutaneous tissue:* Very commonly pruritus. Commonly maculo-papular rash, purpura, erythema, palmar plantar erythrodysaesthesia syndrome, alopecia, skin hyperpigmentation, dermatitis exfoliative, pain of skin. Uncommonly erythema multiforme, dermatitis acneiform, rash, hyperhidrosis. Generalised erythema, dermatitis, skin necrosis or ulcer, dry skin, urticaria, dermatitis bullous, dermatitis diaper. *Musculoskeletal and connective tissue:* Commonly pain in extremities, back pain, bone pain, arthralgia, myalgia. Muscular weakness. *Renal, urinary:* Commonly acute kidney injury, haematuria. Renal failure, (noninfective) cystitis, dysuria. *Reproductive system:* Scrotal erythema. *General, administration site:* Very commonly asthenic conditions (fatigue, asthenia, lethargy), pyrexia. Commonly oedema, chills. Uncommonly non cardiac chest pain, pain. Injection site reaction, feeling cold. *Investigations:* Very commonly bilirubin increased. Commonly transaminases (ALT/AST) increased, γGT increased, blood alkaline phosphatase increased, C-reactive protein increased, weight decreased, weight increased. Blood creatinine increased, blood lactate dehydrogenase (LDH) increased. See SmPC for details of other adverse events.

Legal classification: POM (prescription only medicine).

Basic NHS Price: 1g x 5 = £494.40 5g x 5 = £2434.25

Marketing authorisation holder: medac GmbH, Theaterstraße 6; 22880 Wedel, Germany.

Product information in the UK: medac Pharma, Scion House, Stirling University Innovation Park, Stirling FK9 4NF. T: 01786 458086, F: 01786 458032. info@medacpharma.co.uk

Marketing authorisation number: PLGB 11587/0118, PLGB 11587/0119

Date of revision of text: 06/03/2024

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to medac drug safety at: drugsafety@medac.de

NI Prescribing Information - Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

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Marketing authorisation number: EU/1/18/1351/002, EU/1/18/1351/004

Date of revision of text: 11/2023

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