Obinutuzimab (Gazyvaro®)

Reduce direct handling to a minimum and wear appropriate protective clothing.

CAUTION: High Administration Risk Rating

Form & Storage	Prepared in Pharmacy Aseptic Unit for inpatients	Store in a fridge at 2 - 8°C
Reconstitution	Already in solution	
Compatibility & Stability	Follow storage instructions provided by pharmacy	
Premedication	Administer premedication as charted Allow 60 minutes after discontinuing steroids before starting infusion **Methylprednisolone 100mg/100mL Sodium chloride 0.9% IV over 30 minutes** completed at least 1 hour prior to infusion **Chlorphenamine 10mg IV** at least 30 minutes prior to infusion **Paracetamol 1G PO** at least 30 minutes prior to infusion	
Administration	**IV Infusion** The dose and schedule of Obinutuzimab is individualized for each patient and defined by the consultant's clinical judgment and patient's underlying condition **IV infusion** (all indications): • Start the infusion at a rate of 50mg/hour for 30 minutes. • Rate may be increased by increments of 50mg/hour every 30 minutes, if tolerated, to a maximum of 400mg/hour See rate sheets below	
Monitoring	• Apply BP cuff to opposite arm and oxygen saturation probe and set for half hourly intervals to coincide with rate increase (see flow sheet) • Most frequently reported (≥ 5%) symptoms associated with an infusion-related reactions (IRR) were nausea, vomiting, diarrhoea, headache, dizziness, fatigue, chills, pyrexia, hypotension, flushing, hypertension, tachycardia, dyspnoea, and chest discomfort. Respiratory symptoms such as bronchospasm, larynx and throat irritation, wheezing, laryngeal oedema and cardiac symptoms such as atrial fibrillation have also been reported • Mild or moderate IRR usually respond to a reduction in the rate of infusion. The infusion rate may be increased upon improvement of symptoms. • Patients who develop evidence of severe reactions, especially severe dyspnoea, bronchospasm or hypoxia should have the infusion interrupted immediately. • Monitor IV site for infiltration • Patients should be closely monitored for thrombocytopenia, especially during the first cycle	
Adverse Effects	**Worsening of pre-existing cardiac conditions**	

This information has been summarised to act as a guide for those administering IV medication. The monograph should be used in conjunction with the drug data sheet and BNF for information on dose, adverse effects, cautions and contra-indications. Further information is available from Pharmacy on 22146 or 22542

	Cases of arrhythmias (such as atrial fibrillation and tachyarrhythmia), angina pectoris, acute coronary syndrome, myocardial infarction and heart failure have occurred when treated with obinutuzimab. These events may occur as part of an IRR and can be fatal. These patients should be hydrated with caution in order to prevent a potential fluid overload. **Laboratory abnormalities** Transient elevation in liver enzymes (aspartate aminotransferase [AST], alanine aminotransferase [ALT], alkaline phosphatase) has been observed shortly after the first infusion of obinutuzimab. **Severe and life-threatening thrombocytopenia** including acute thrombocytopenia (occurring within 24 hours after the infusion) has been observed during treatment with. Patients with renal impairment (CrCl < 50 mL/min) are more at risk of thrombocytopenia. Fatal haemorrhagic events have also been reported in Cycle 1 in patients treated with obinutuzumab.
Disposal	Dispose of infusion bag and administration set in purple-lidded bin.
Additional Information	• Hypotension may occur during obinutuzimab intravenous infusions. Therefore, withholding of antihypertensive treatments should be considered for 12 hours prior to and throughout each obinutuzimab infusion and for the first hour after administration. Patients at acute risk of hypertensive crisis should be evaluated for the benefits and risks of withholding their anti-hypertensive medicine. • Use of any concomitant therapies which could possibly worsen thrombocytopenia-related events, such as platelet inhibitors and anticoagulants, should also be taken into consideration, especially during the first cycle. • Obinutuzimab should not be administered in the presence of an active infection and caution should be exercised when considering the use of obinutuzimab in patients with a history of recurring or chronic infections

Information provided relates to Gazyvaro® (Roche)