

Making History

1969. The crew of the Apollo 11 were the first to walk on the moon.

This giant leap for mankind was a real breakthrough, changing our view of the future.

2006. The first and only selective B cell therapy is approved for RA treatment.

Each course of two infusions offers an unprecedented 6-12 months of lasting treatment success. MabThera™ will change the way you treat RA.

MABTHERA®
RITUXIMAB

B CELL THERAPY. LASTING SUCCESS.

MABTHERA® – Prescribing information

Marketing authorisation holder: Roche Registration Ltd., Welwyn, Great Britain.

Marketing authorisation numbers: EU/1/98/067/001, EU/1/98/067/002.

Active substance: Rituximabum. ATC Code: L01X C02.

Indications: **Rheumatoid arthritis:** In combination with methotrexate, treatment of adult patients with severe active rheumatoid arthritis who have had an inadequate response or intolerance to other disease-modifying anti-rheumatic drugs including one or more tumour necrosis factor (TNF) inhibitor therapies.

Non-Hodgkin's lymphomas: Treatment of stage III and IV of follicular lymphoma (a) as monotherapy in patients who are in their second or subsequent relapse after chemotherapy or who are chemoresistant, (b) in combination with CHOP-chemotherapy in so far untreated patients; MabThera™ maintenance therapy in patients with relapsed/refractory follicular lymphoma, responding to induction chemotherapy with or without MabThera™; in combination with CHOP chemotherapy, treatment of patients with CD20-positive diffuse large B-cell malignant Non-Hodgkin's lymphoma.

Contraindications: Well-known hypersensitivity to any MabThera™ compound or murine proteins. Rheumatoid arthritis: active severe infections; severe heart failure (Class IV, according to NYHA) or severe uncontrolled heart disease. Note: Patients with a big tumour burden or a great number of circulating malignant cells are endangered by cytokine release syndrome that could be associated with symptoms of tumour lysis syndrome or acute respiratory failure and death of a patient. After an intravenous single administration of proteins, anaphylactic or other hypersensitivity reactions were recorded. Hypotension may occur during the infusion administration. It is not possible to administer the prepared MabThera™ solution as an intravenous injection. **Pediatric:** Safety and efficacy of MabThera™ in children has not yet been established. **Pregnancy and lactation:** During pregnancy and lactation, MabThera™ should not be administered, as long

as advantage potentials are lower than potential risks. **Rheumatoid arthritis:** During the treatment, some serious infections may rarely occur. There are no data available on simultaneous vaccination. Live virus vaccines are not recommended. Simultaneous/subsequent administration of other than indicated DMARDs is not recommended.

Clinically significant interactions: There are no data available on any interactions of MabThera™. Simultaneous methotrexate administration has no influence on the MabThera™ pharmacokinetics.

Main clinically significant adverse events: Acute infusion-related symptoms. Cytokine-release syndrome (particularly during the first infusion), occasionally associated to tumour lysis syndrome symptoms, leading to multorgan failure/respiratory failure and renal failure; exacerbation of pre-existing heart disorders. For other adverse events that occurred in patients treated with MabThera™ monotherapy or combined with chemotherapy/antirheumatic agents and knowledge gained after MabThera™ introduction, we refer to valid MabThera™ Summary of product characteristics.

Dosage and administration route: See MabThera™ Summary of product characteristics. **Overdose:** There is no experience with the overdose in Human Studies. **Drug packaging available:** MabThera™ 100 mg concentrate for preparation of infusion solution. **Storing conditions:** 2 °C – 8 °C, avoid sunlight. **Last revision made:** 12/01/2007.

MabThera™ is a prescription drug. The costs are covered with public health insurance assets.

For further information, we refer to valid MabThera™ Summary of product characteristics or contact us at the following address: Roche s.r.o., Dukelských hrdinů 52, 170 00 Praha 7, CZECH REPUBLIC, phone: 220 382 111.

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