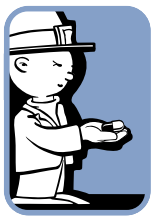
NEW INDICATION

Rituximab (MABTHERA° OR OTHER BRANDS) **in certain non-Hodgkin lymphomas in children**



POSSIBLY HELPFUL

Rituximab has been authorised in the European Union as first-line treatment for children with certain non-Hodgkin lymphomas. In one trial in 328 children with aggressive advanced-stage B-cell non-Hodgkin lymphoma, addition of *rituximab* to standard chemotherapy increased the proportion of patients alive at 3 years (95% versus 87%), at a cost of an increase in serious adverse events. In this trial, life-threatening adverse events were more frequently reported with addition of *rituximab*: in 43% versus 37% of children, with an increase in infections, including septicaemia and febrile neutropenia, and gastrointestinal disorders. Cardiotoxicity, with an abnormal left ventricular ejection fraction, was reported in 10% of patients in the *rituximab* group versus 3% in the control group. There were two secondary cancers in the *rituximab* group (one melanoma and one histiocytic sarcoma) versus none in the control group. The harm-benefit balance of *rituximab* in children seems to be similar to that in adults.

MABTHERA° – *rituximab* solution for dilution for intravenous infusion

- **100 mg** or **500 mg** of *rituximab* per vial (10 mg/ml)

■ **Antineoplastic; anti-CD20 monoclonal antibody**

■ **New indication**: in combination with chemotherapy, in patients aged 6 months to 17 years with previously untreated CD20-positive diffuse large B-cell lymphoma, Burkitt lymphoma or leukaemia, or Burkitt-like lymphoma. [EU centralised procedure]

■ **New dose**: 375 mg/m2 body surface area, by intravenous infusion, with 6 infusions in total, spread over the "induction" and "consolidation" phases of the treatment.

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Prescrire's ratings

Our judgement is based on the therapeutic advance of the product in the relevant clinical situation. It considers not only the inherent value of each product in terms of its harm-benefit balance, but also its advantages and disadvantages relative to existing treatments. Note that the relative value of new products can vary from one country to another.

BRAVO
The product is a major therapeutic advance in an area where previously no treatment was available.

A REAL ADVANCE
The product is an important therapeutic advance but has certain limitations.

OFFERS AN ADVANTAGE
The product has some value but does not fundamentally change the present therapeutic practice.

POSSIBLY HELPFUL
The product has minimal additional value, and should not change prescribing habits except in rare circumstances.

NOTHING NEW
The product is a new substance but with no evidence that it has more clinical value than other substances of the same group. It can be a me-too or a near me-too.

NOT ACCEPTABLE
Product without evident benefit but with potential or real disadvantages.

JUDGEMENT RESERVED
The editors postpone their rating until better data and a more thorough evaluation of the drug are available.

Quality of information from pharmaceutical companies

In response to our systematic requests

Company provided detailed information including unpublished data and packaging items.

Company provided information limited to published administrative data or packaging items.

Company provided minimal information, mainly administrative and packaging items.

Company provided no information.

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