

Safety Alert

Jun 2024

Mabthera

EDA performs label update to include the following:

Indications/Uses:

ANCA-associated vasculitis (AAV): Granulomatosis with polyangiitis/microscopic polyangiitis (GPA/MPA)

MabThera in combination with **glucocorticoids** is indicated for the treatment of **adult** patients with severe active ANCA-associated vasculitis (granulomatosis with polyangiitis [GPA, also known as Wegener's granulomatosis] and microscopic polyangiitis [MPA]).

Warnings and precautions:

Skin reactions

Severe skin reactions, such as toxic epidermal necrolysis, Stevens-Johnson syndrome and **pyoderma gangrenosum**, some of which were fatal, have been reported (see "Undesirable effects"). In such an event, with a suspected relationship to MabThera, treatment should be permanently discontinued.

Pregnancy, lactation:

Maternal IgG enters breast milk, and rituximab has been reported to be excreted at low concentrations in human breast milk. As it is not known what clinical significance this has for neonates/infants, women should not breastfeed during and for **6 months after treatment with MabThera**.

Limited data on rituximab excretion into breast milk suggest very low rituximab concentrations in breast milk (relative infant dose less than 0.4%). In two cases in which follow-ups were performed in infants who were breastfed during maternal treatment with rituximab, normal growth and development were reported up to the age of 2 years.

Undesirable effects:

Skin and subcutaneous tissue disorders

Not known: Pyoderma gangrenosum

Description of specific adverse reactions and additional information:

Experience from clinical studies in adults with *rheumatoid arthritis or ANCA-associated vasculitis*

Frequencies are defined as very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1000$), very rare ($< 1/10,000$) and **not known (cannot be estimated from the available data)**.

Infections and infestations

Not known: serious viral infections.

Undesirable effects from the post-marketing phase

Safety Alert

Jun 2024

Infections and infestations

Cases of progressive multifocal leukoencephalopathy (PML) and reactivation of hepatitis B infection have been reported. Other serious viral infections, some of which were fatal, have been reported in patients treated with MabThera.

Background:

Mabthera is indicated for:

- Non-Hodgkin's lymphoma (NHL)
- Rheumatoid arthritis (RA)
- ANCA-associated vasculitis (AAV): Granulomatosis with polyangiitis/microscopic polyangiitis (GPA/MPA)

References:

Swissmedic:

<https://ch.oddb.org/de/gcc/fachinfo/reg/54378>