

Methotrexate - Risk of Progressive Multifocal Leukoencephalopathy (PML)

[EDA performs label update to include the following:](#)

Warnings and precautions

Progressive multifocal leukoencephalopathy (PML)

Cases of progressive multifocal leukoencephalopathy (PML) have been reported in patients receiving methotrexate, mostly in combination with other immunosuppressive medication. PML can be fatal and should be considered in the differential diagnosis in immunosuppressed patients with new onset or worsening neurological symptoms.

Background:

Therapeutic indications

Methotrexate is for use in the following indications:

In rheumatological and dermatological diseases

- Active rheumatoid arthritis in adult patients.
- Polyarthritic forms of active, severe juvenile idiopathic arthritis (JIA) in adolescents and children aged 3 years and over when the response to non-steroidal anti-inflammatory drugs (NSAIDs) has been inadequate.
- Severe, treatment-refractory, disabling psoriasis which does not respond sufficiently to other forms of treatment such as phototherapy, psoralen and ultraviolet A radiation (PUVA) therapy and retinoids, and severe psoriatic arthritis in adult patients

References: *EMA* ([Click here](#))