

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for daclizumab beta, the scientific conclusions of CHMP are as follows:

Sarcoidosis

Twelve cases of sarcoidosis confirmed by health-care professionals were reported from clinical trials cumulatively. No risk factors or alternative aetiology have been reported in any of these cases. There is also a plausible mechanism of action for the development of sarcoidosis due to the immunomodulatory effects of daclizumab beta and involvement of daclizumab beta in the origin of other immune-mediated events. The causal relationship between daclizumab beta and sarcoidosis is considered possible.

Colitis

Four new serious cases of colitis confirmed by health-care professionals have been received during this period. Cumulatively, 24 cases of colitis have been retrieved from clinical trials. There is a plausible mechanism of action for the development of this colitis due to immunomodulatory properties of daclizumab beta and involvement of daclizumab beta in the origin of other immune-mediated events. The causal relationship between daclizumab beta and colitis is possible.

Section 4.8 of the SmPC has been reviewed to add the adverse reaction sarcoidosis with a frequency uncommon and the adverse reaction colitis with a frequency common.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for daclizumab beta the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing daclizumab beta is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.