Consumer Update

Feb 2022

Dexamethasone in systemic route and risk of hypertrophic cardiomyopathy and neonatal hypoglycemia

EDA performs label update to include the following:

Special warnings and precautions for use

Paediatric use

Corticosteroids cause growth retardation in infancy, childhood and adolescence, which may be irreversible and therefore long-term administration of pharmacological doses, should be avoided. If prolonged therapy is necessary, treatment should be limited to the minimum suppression of the hypothalamic-pituitary-adrenal axis and growth retardation, the growth and development of infants and children should be closely monitored. Children are at special risk from raised intracranial pressure.

Hypertrophic cardiomyopathy has been reported after administration of dexamethasone to prematurely born infants, therefore appropriate diagnostic evaluation and monitoring of cardiac function and structure should be performed. In the majority of cases reported to date, the effect is temporary and can reverse on with-drawal of treatment.

Undesirable effects

Cardiac disorders:

Hypertrophic cardiomyopathy (in prematurely born infants)

<u>References:</u> AEMPS (Click here)