Safety Alert Aug 2023

Methyl Prednisolone- risk of Tumour lysis syndrome & hypothalamic pituitary-adrenal axis suppression

EDA performs label update to include the following:

Special warnings and precautions for use

In post marketing experience **tumour lysis syndrome (TLS) has been reported** in patients with malignancies, including haematological malignancies and solid tumours, following the use of systemic corticosteroids alone or in combination with other chemotherapeutic agents. Patients at high risk of TLS, such as patients with tumours that have a high proliferative rate, high tumour burden and high sensitivity to cytotoxic agents, should be monitored closely and appropriate precautions should be taken.

Adverse effects (undesirable effects)

Endocrine Disorders

Cushingoid, **hypothalamic-pituitary-adrenal axis suppression**, steroid withdrawal syndrome, adrenal insufficiency.

Background on the safety concerns

Therapeutic indications

Methyl Prednisolone is indicated to treat any condition in which rapid and intense corticosteroid effect is required such as:

1. Dermatological disease

Severe erythema multiforme (Stevens-Johnson syndrome)

2. Allergic states

Bronchial asthma

Angioneurotic oedema

Anaphylaxis

3. Gastro-intestinal diseases

Ulcerative colitis

Crohn's disease

4. Respiratory diseases

Aspiration of gastric contents

Fulminating or disseminated tuberculosis (with appropriate antituberculous chemotherapy)

5. Neurological disorders

Cerebral oedema secondary to cerebral tumour

Acute exacerbations of multiple sclerosis superimposed on a relapsingremitting background

6. Miscellaneous

T.B. meningitis (with appropriate antituberculous chemotherapy)

Transplantation

References:

TGA (Click here)