

Safety Alert

March 2024

Gabapentin– Risk of SCARs and toxic epidermal necrolysis

EDA performs label update to include the following:

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Severe cutaneous adverse reactions (SCARs)

SCARs including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and Drug rash with eosinophilia and systemic symptoms (DRESS), which can be life-threatening or fatal, have been reported rarely in association with gabapentin treatment. At the time of prescribing patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of these reactions appear, gabapentin should be withdrawn immediately, and an alternative treatment considered (as appropriate).

If the patient has developed a serious reaction such as SJS, TEN or DRESS with the use of gabapentin, treatment with gabapentin must not be restarted at any time.

Additional post-marketing adverse events reported include blood creatine phosphokinase increased,

4.8 - Adverse effects (undesirable effects)

Post-marketing experience

The following adverse events have been reported in patients receiving gabapentin post-marketing, however, the data are insufficient to support an estimate of their incidence or to establish causation.

Sudden, unexplained deaths have been reported where a causal relationship to treatment with gabapentin has not been established.

rhabdomyolysis, abnormal liver function, acute kidney failure, allergic reaction including urticaria, alopecia, anaphylaxis, agitation, anaemia, angioedema, hyperglycaemia and hypoglycaemia (most often observed in patients with diabetes), breast hypertrophy, gynaecomastia, cardiac arrest, chest pain, convulsions, depersonalisation, drug rash with eosinophilia and systemic symptoms, erythema multiforme, **toxic epidermal necrolysis**, hypersensitivity including systemic reactions, jaundice, movement disorders such as choreoathetosis, dyskinesia and dystonia, myoclonus, palpitation, pancreatitis, renal impairment, speech disorder, sexual dysfunction (including changes in libido, ejaculation disorders and anorgasmia), fall, hyponatraemia, loss of consciousness, Stevens-Johnson syndrome, tachycardia, thrombocytopenia,

Background:

THERAPEUTIC INDICATIONS

Gabapentin is indicated for the treatment of partial seizures, including secondarily generalised tonic-clonic seizures, initially as add-on therapy in adults and children age 3 years and above who have not achieved adequate control with standard antiepileptic medicines.

Gabapentin is indicated for the treatment of neuropathic pain.

References:

TGA ([Click here](#))