

Safety Alert

Apr 2023

A new warning about Risk of Toxic Epidermal Necrolysis (TEN) for Gabapentinoids

EDA performs label update to include the following:

CLINICAL PARTICULARS

Special warnings and precautions for use

Severe cutaneous adverse reactions (SCARs) Severe cutaneous adverse reactions (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 in association with gabapentin treatment. At the time of prescription 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 If signs and symptoms suggestive of these reactions appear, gabapentin should be withdrawn immediately and an alternative treatment considered (as appropriate).

Undesirable effects

Skin and subcutaneous tissue disorders

Common: facial oedema, purpura most often described as bruises resulting from physical trauma, rash, pruritus, acne

Not known: Stevens-Johnson syndrome, toxic epidermal necrolysis, angioedema, erythema multiforme, alopecia, drug rash with eosinophilia and systemic symptoms (see section 4.4)

Background on the safety concerns

”Toxic Epidermal Necrolysis ”

Toxic epidermal necrolysis (TEN) is a rare, life-threatening skin reaction, usually caused by a medication. It's a severe form of Stevens-Johnson syndrome (SJS). In people with SJS, TEN is diagnosed when more than 30% of the skin surface is affected and the moist linings of the body (mucous membranes) have extensive damage.

TEN is a life-threatening condition that affects people of all ages. TEN is usually treated in a hospital. While the skin heals, supportive care includes controlling pain, caring for wounds and making sure you're getting enough fluids. Recovery can take weeks to months.

If your condition was caused by a medication, you'll need to permanently avoid that drug and those related to it.

Symptoms of Toxic Epidermal Necrolysis

Toxic epidermal necrolysis signs and symptoms include:

- Widespread skin pain
- A spreading rash covering more than 30% of the body
- Blisters and large areas of peeling skin
- Sores, swelling and crusting on the mucous membranes, including the mouth, eyes and vagina.

References:

HPRA ([Click here](#))