Consumer Update Feb 2022

Pregabalin and risks of Steven Johnson syndrome and Toxic Epidermal Necrolysis

EDA performs label update to include the following:

Special warnings and precautions for use

Severe cutaneous adverse reactions (SCARs) including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), which can be life-threatening or fatal, have been reported rarely in association with pregabalin 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 If signs and symptoms suggestive of these reactions appear, pregabalin should be withdrawn immediately and an alternative treatment considered (as appropriate).

Undesirable effects

The following adverse reaction should be added under the SOC Skin and subcutaneous tissue disorders: Frequency 'rare': Toxic Epidermal Necrolysis.

Background

INDICATIONS AND CLINICAL USE

Adults

Pregabalin is indicated for the management of neuropathic pain associated with:

- Diabetic peripheral neuropathy
- Postherpeticneuralgia

Pregabalin is indicated for the management of pain associated with fibromyalgia.

The efficacy of pregabalin in the management of pain associated with fibromyalgia for up to 6 months was demonstrated in a placebo-controlled trial in patients who had initially responded to pregabalin during a 6-week open-label phase.

Geriatrics (65 years of age): Pregabalin oral clearance tended to decrease with increasing age. This decrease in pregabalin oral clearance is consistent with age-related decreases in creatinine clearance. Reduction of pregabalin dose may be required in patients who have age-related compromised renal function

Pediatrics (<18 years of age): The safety and efficacy of pregabalin in pediatric patients (<18 years of age) have not been established and its use in this patient population is not indicated

References: *EMA (Click here)*