

## Safety Alert

March 2025

### Atomoxetine-new warning about threatening behavior and thoughts of harming others

EDA performs label update to include the following:

#### Special warnings and precautions for use

##### Aggressive behavior, hostility or emotional lability:

Hostility (predominantly aggression, oppositional behavior and anger) was more frequently observed in clinical trials among children, adolescents and adults treated with Atomoxetine compared to those treated with placebo. Emotional lability was more frequently observed in clinical trials among children treated with Atomoxetine compared to those treated with placebo. Patients should be closely monitored for the appearance or worsening of aggressive behavior, hostility or emotional lability. **Severe cases have been reported concerning pediatric patients, including reports of physical assault, or threatening behavior and thoughts of harming others.** Families and caregivers of pediatric patients treated with atomoxetine should be counselled to alert a healthcare professional immediately if significant changes in mood or patterns of behavior are noted, particularly after starting treatment or changing the dose. Physicians should evaluate the need for dose adjustment or treatment discontinuation in patients experiencing behavioral changes

#### Background:

##### Therapeutic Indication

Atomoxetine is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children of 6 years and older, in adolescents and in adults as part of a comprehensive treatment program. Treatment must be initiated by a specialist in the treatment of ADHD, such as a paediatrician, child/adolescent psychiatrist, or psychiatrist.

In adults, the presence of symptoms of ADHD that were pre-existing in childhood should be confirmed. Third-party corroboration is desirable and atomoxetine should not be initiated when the verification of childhood ADHD symptoms is uncertain. Diagnosis cannot be made solely on the presence of one or more symptoms of ADHD. Based on clinical judgment, patients should have ADHD of at least moderate severity as indicated by at least moderate functional impairment in 2 or more settings (for example, social, academic, and/or occupational functioning), affecting several aspects of an individual's life.

##### References:

BFARM ([Click here](#))