

## Safety Alert

Sep. 2025

### Sertraline – Risk of Multiple acyl-coenzyme A dehydrogenase deficiency (MADD)-like disorder

EDA performs label update to include the following:

#### Undesirable effects

Musculoskeletal and connective tissue disorders

Multiple acyl-coenzyme A dehydrogenase deficiency (MADD)-like disorder: Not known Frequency

#### Background:

#### Multiple acyl-coenzyme A dehydrogenase deficiency (MADD) like disorder

- Sertraline is associated with an acquired disorder that clinically and biochemically mimics late-onset Multiple acyl-CoA Dehydrogenase Deficiency (MADD).
- This condition is sometimes referred to as Sertraline-Associated Lipid Storage Myopathy or Acquired MADD-like Syndrome.
- Patients typically present with symptoms characteristic of late-onset (Type III) MADD, including progressive muscle weakness (myopathy), exercise intolerance, fatigue, and sometimes episodes of rhabdomyolysis (severe muscle breakdown)

#### Therapeutic Indication

- Depression and prevention of recurrence of depression (in adults).
- Social anxiety disorder (in adults).
- Post traumatic stress disorder (PTSD) (in adults).
- Panic disorder (in adults).
- Obsessive compulsive disorder (OCD) (in adults and children and adolescents aged 6-17 years old).

#### Reference

EMA ([click Here](#))