Suicidality and Antidepressant Drugs

Antidepressants increased the risk compared to placebo of clinically significant increases in suicidal symptoms or behavior in children, adolescents, and adults treated with antidepressants in clinical trials (MDD and other psychiatric disorders). As a result, all antidepressants should be used with caution in these patients.

Suicidality Risk and Depression Severity

Suicidality may arise during the acute treatment phase following a manic or depressive episode.

PRECAUTIONS

The above symptoms, especially if they are new or worsening, require close monitoring and follow-up. The diagnosis and treatment of depression and any other psychiatric disorder, particularly bipolar disorder, should be made under close supervision of a psychiatrist. The risk of suicide can be reduced by monitoring patients for these symptoms, as well as by following the treatment plan, and by following the approved directions for the use of the medication in the safest manner.

It is unknown whether the increased risk of suicidality occurs at an earlier stage of treatment than the latency to onset of suicidality symptoms in an antidepressant trial. Short-term trials with antidepressants showed an increase in frequency of suicidal or worsening behavior.

Tardive Dyskinesia

A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with antipsychotic drugs and with amoxapine (classically, with higher potency neuroleptics such as haloperidol, risperidone, and olanzapine).

The diagnostic evaluation of patients with this syndrome is complicated. In some cases, the clinical presentation includes both symptoms of severe depression and the emergence of suicidality. Therefore, it is important to identify the consciousness level. However, some patients may require treatment despite the findings.

The diagnostic evaluation of patients with this syndrome includes the following: 1) initial symptomatology, 2) severity of illness, and 3) response to treatment. The need for continued treatment should be assessed periodically.

In some cases, the syndrome may appear to be a conversion of a depressive episode into an antidepressant. In such cases, the clinical presentation includes both symptoms of severe depression and the emergence of suicidality. Therefore, it is important to identify the consciousness level. However, some patients may require treatment despite the findings.

General

In prescribing the drug, it should be borne in mind that the risk of a manic or depressive episode may be increased during the initial treatment phase following a manic or depressive episode.

Screening Patients for Bipolar Disorder

A major depressive episode may be the initial manifestation of bipolar disorder. Therefore, it is important to identify the consciousness level. However, some patients may require treatment despite the findings.

Screening for Depressive Symptoms

The above symptoms, especially if they are new or worsening, require close monitoring and follow-up. The diagnosis and treatment of depression and any other psychiatric disorder, particularly bipolar disorder, should be made under close supervision of a psychiatrist. The risk of suicide can be reduced by monitoring patients for these symptoms, as well as by following the treatment plan, and by following the approved directions for the use of the medication in the safest manner.

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patients, their families, and their caregivers to read the Medication Guide and should assist them in understanding its contents. Patients should be given the opportunity to discuss the contents of the Medication Guide and to obtain answers to any questions they may have. The complete text of the Medication Guide is reprinted at the end of this document.

Patients should be advised of the following issues and asked to alert their prescriber if these occur while taking amoxapine.

- Patients should be advised that amoxapine may cause mild to moderate sedation or drowsiness, which may impair alertness or coordination. Patients should be advised to avoid tasks requiring complete alertness or coordination until it is determined that amoxapine does not adversely affect these functions.
- Patients should be advised to avoid the concurrent use of alcohol and amoxapine, as well as the use of other drugs or recreational substances that may cause hypotension or sedation.
- Patients should be advised that amoxapine may cause dizziness, vertigo, or light-headedness, particularly in the morning or when getting up suddenly from a supine or sitting position.
- Patients should be advised to notify their prescriber if they have difficulties sleeping or if their sleep pattern changes during amoxapine therapy.
- Patients should be advised to notify their prescriber if they notice changes in vision, such as blurred vision.
- Patients should be advised that amoxapine may impair judgment, thinking, or memory, particularly after increasing the dose or when amoxapine is taken with alcohol or other drugs that cause sedation.
- Patients should be advised to notify their prescriber if they notice changes in appetite or weight.
- Patients should be advised to notify their prescriber if they experience unusual agitation, nervousness, or restlessness.
- Patients should be advised to notify their prescriber if they experience unusual or increased sweating.
- Patients should be advised to notify their prescriber if they experience any changes in sexual interest or performance, including decreased interest or ability to achieve or maintain an erection.
- Patients should be advised to notify their prescriber if they experience changes in mood, such as new or worsening depression.
- Patients should be advised to notify their prescriber if they experience changes in mental functioning, such as new or worsening confusion or memory loss.
- Patients should be advised to notify their prescriber if they experience changes in energy or fatigue.
- Patients should be advised to notify their prescriber if they experience any changes in vision.
- Patients should be advised to notify their prescriber if they experience any changes in sexual function or the development of breast tenderness or breast enlargement.
- Patients should be advised to notify their prescriber if they experience any changes in physical appearance or weight.
- Patients should be advised to notify their prescriber if they experience any changes in blood pressure or heart rate.
- Patients should be advised to notify their prescriber if they experience any changes in blood chemistry tests.
- Patients should be advised to notify their prescriber if they experience any changes in liver function tests.
- Patients should be advised to notify their prescriber if they experience any changes in urine tests.
- Patients should be advised to notify their prescriber if they experience any changes in stool tests.
- Patients should be advised to notify their prescriber if they experience any changes in physical examination findings.
- Patients should be advised to notify their prescriber if they experience any changes in mental examination findings.
- Patients should be advised to notify their prescriber if they experience any changes in vital signs.
- Patients should be advised to notify their prescriber if they experience any changes in medications or supplements.
- Patients should be advised to notify their prescriber if they experience any changes in medical history or illness.
- Patients should be advised to notify their prescriber if they experience any changes in social history or family history.
- Patients should be advised to notify their prescriber if they experience any changes in lifestyle factors, such as diet or exercise.
- Patients should be advised to notify their prescriber if they experience any changes in psychological factors, such as stress or anxiety.
- Patients should be advised to notify their prescriber if they experience any changes in emotional factors, such as mood or energy level.
- Patients should be advised to notify their prescriber if they experience any changes in cognitive factors, such as memory or concentration.
- Patients should be advised to notify their prescriber if they experience any changes in behavioral factors, such as irritability or aggression.
- Patients should be advised to notify their prescriber if they experience any changes in social factors, such as interpersonal relationships or social activities.
- Patients should be advised to notify their prescriber if they experience any changes in environmental factors, such as noise or light levels.
- Patients should be advised to notify their prescriber if they experience any changes in nutritional factors, such as diet or weight.
- Patients should be advised to notify their prescriber if they experience any changes in physical activity levels.
- Patients should be advised to notify their prescriber if they experience any changes in health care needs or access to care.
- Patients should be advised to notify their prescriber if they experience any changes in health care providers or medications.
- Patients should be advised to notify their prescriber if they experience any changes in family or personal connections.
- Patients should be advised to notify their prescriber if they experience any changes in work or school performance.
- Patients should be advised to notify their prescriber if they experience any changes in leisure or recreational activities.
- Patients should be advised to notify their prescriber if they experience any changes in hobbies or interests.
- Patients should be advised to notify their prescriber if they experience any changes in pets or animals.
- Patients should be advised to notify their prescriber if they experience any changes in financial status or resources.
- Patients should be advised to notify their prescriber if they experience any changes in legal or social status or resources.
- Patients should be advised to notify their prescriber if they experience any changes in religious or spiritual beliefs or practices.
- Patients should be advised to notify their prescriber if they experience any changes in political or social commitments.
- Patients should be advised to notify their prescriber if they experience any changes in cultural or ethnic background.
- Patients should be advised to notify their prescriber if they experience any changes in genetic or family history.
- Patients should be advised to notify their prescriber if they experience any changes in educational or occupational history.
- Patients should be advised to notify their prescriber if they experience any changes in martial status or relationships.
- Patients should be advised to notify their prescriber if they experience any changes in sexual history.
- Patients should be advised to notify their prescriber if they experience any changes in medical or surgical history.
- Patients should be advised to notify their prescriber if they experience any changes in family history.
- Patients should be advised to notify their prescriber if they experience any changes in previous or current use of amoxapine.