

Sertraline

Xolvof



50mg Film-Coated Tablet Antidepressant

FORMULATION

Each film-coated tablet contains:
Sertraline Hydrochloride BP
Equivalent to Sertraline.....50 mg
Color: Brilliant Blue & Titanium Dioxide BP

PRODUCT DESCRIPTION

A light blue colored, oval shaped, film coated, plain on one side and breakline on the other side.

PHARMACODYNAMICS

The mechanism of action of Sertraline is presumed to be linked to the inhibition of central nervous system neuronal uptake of serotonin (5HT). Sertraline blocks the uptake of serotonin into human platelets. Sertraline is a specific inhibitor of neuronal serotonin re-uptake and has only very weak effects on the norepinephrine and dopamine neuronal re-uptake. It is devoid of stimulant, sedative or anticholinergic activity or cardiotoxicity in animals.

(For complete details on its Pharmacology please refer to the product insert.)

INDICATIONS

It is used in the treatment of depression, compulsive disorder, panic disorder with or without agoraphobia, social anxiety disorder post-traumatic stress disorder and premenstrual dysphoric disorder.

Panic disorder is characterized by the occurrence of unexpected panic attacks and associated concern about having additional attacks, worry about the implications or consequences of the attacks, and/or a significant change in behavior related to the attacks.

Panic disorder is characterized by recurrent unexpected panic attacks, i.e. a discrete period of intense fear or discomfort in which four (or more) of the following symptoms develop abruptly and reach a peak within 10 minutes: palpitations, pounding heart, or accelerated heart rate; sweating; trembling or shaking; sensations of shortness of breath or smothering; feeling of choking; chest pain or discomfort; nausea or abdominal distress; feeling dizzy, unsteady, lightheaded, or faint; derealization (feelings of unreality) or depersonalization (being detached from oneself); fear of losing control; fear of dying; paresthesia's, (numbness or tingling sensations); chills or hot flushes.

DOSAGE AND ADMINISTRATION

Sertraline should be given as a single daily dose with or without food.

Depression

The starting dose is 50 mg daily and the usual therapeutic dose in depression is 50 mg daily. In difficult to treat patients, the dose may be titrated up in 50 mg increments at 2 weekly intervals, to 150 mg-200 mg.

Obsessive-Compulsive Disorder

The minimum effective dose in OCD is also 50 mg daily and increases above 100 mg daily did not have any additional benefit. Full activity is usually seen after 2-4 weeks and even longer in OCD. Effect may however be seen within 7 days.

Panic Disorder

For panic disorder, the minimum recommended effective dose of Sertraline is 50 mg/day. However, therapy for panic disorder should commence at 25 mg/day, increasing to 50 mg/day after one week. This dosage regimen has been demonstrated to reduce the frequency of early treatment emergent side effects characteristic of panic disorder.

Use in the elderly

No special precautions are required. The usual adult dosage is recommended.

Use in children

The use of Sertraline in children is not recommended, as safety and efficacy have not been established.

CONTRAINDICATIONS

Sertraline is contraindicated in patients with known hypersensitivity to Sertraline. The concomitant use of Sertraline with a monoamine oxidase inhibitor (MAOI) is contraindicated.

WARNINGS AND PRECAUTIONS

Activation of mania/hypomania–hypomania or mania may occur in patients treated with Sertraline. Activation of mania/hypomania has also been reported in a small proportion of patients with Major Affective Disorder treated with other marketed antidepressants and anti-obsessional agents. Safety and efficacy in children under 18 years of age have not been established. “Patients with major depressive disorder, both adults and children, may experience worsening of their depression and/or the emergence of suicidal ideation and behaviour, whether or not they are taking antidepressant medicines. This risk may persist until significant remission occurs. A causal role, however, for antidepressant medicine in inducing such behaviour has not been established. Patients being treated with Sertraline should, nevertheless, be observed closely for clinical worsening and suicidality, especially at the beginning of a course of therapy or at any time of dose changes, either increases or decreases. Because of the possibility of co-morbidity between major depressive disorder and other psychiatric and non-psychiatric disorders, the same precautions observed when treating patients with major depressive disorders should be observed when treating patients with other psychiatric and non-psychiatric disorders.

(For complete details on Warning and Precautions please refer to the product insert.)

ADVERSE DRUG REACTION

Significant: Suicidal thoughts and behaviour, activation of hypomania or mania, seizures, CNS depression, akathisia or psychomotor restlessness; QTc prolongation, torsades de pointes; abnormal bleeding events (e.g. ecchymoses, purpura, haematoma, epistaxis), increased risk of postpartum haemorrhage.

(For complete details on Adverse Drug Reactions please refer to the product insert.)

DRUG INTERACTIONS

Some of the more common Drug Interactions with Sertraline:

Monoamine Oxidase Inhibitors (MAOIs): Other SSRIs or SNRIs: Anticoagulants and Antiplatelet Drugs: Nonsteroidal Anti-inflammatory Drugs (NSAIDs): Triptans (for migraines): St. John’s Wort: Alcohol: Lithium: Antipsychotics: Benzodiazepines: Pimozide & Other Medications Affecting Serotonin Levels:

Always consult a healthcare provider or a pharmacist before starting or stopping any medication while on sertraline. They can provide personalized advice based on your specific medical history and other medications you may be taking.

(For complete details on Drug Interactions please refer to the product insert.)

OVERDOSE AND TREATMENT

Has a wide margin of safety in overdose. Serious sequelae have not been reported following overdoses of Sertraline alone of up to 6 g. Although there have been no deaths reported when Sertraline was taken alone, deaths involving overdoses of Sertraline in combination with other medicines and/or alcohol have been reported.

Therefore, any overdosage should be treated aggressively. No specific therapy is recommended and there are no specific antidotes to Sertraline. Establish and maintain an airway, ensure adequate oxygenation and ventilation. Activated charcoal, which may be used with sorbitol, a cathartic, may be as, or more, effective than emesis or lavage, and should be considered in treating overdosage. Monitoring of cardiac and vital signs is recommended, along with general symptomatic and supportive measures. Due to the large volume of distribution of Sertraline, forced diuresis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be of benefit.

CAUTION

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.
Seek medical attention immediately at the first sign of any adverse drug reaction.

STORAGE CONDITION

Store at temperature not exceeding 30°C. Keep all medicines out of reach of children.

AVAILABILITY

Alu/Alu Blister Pack x 10's (Box of 30's)

DRP- 4921- 01

Date of First Authorization: March 16, 2020

Date of Revision of Package Insert: November 16, 2022

(For complete Product information please refer to the product insert.)