



Ventus®

Escitalopram Oxalate USP

Description

Ventus® is an oral drug that is used for treating depression and generalized anxiety disorder. It works by affecting neurotransmitters in the brain, the chemical messengers that nerves use to communicate with one another. Neurotransmitters are made and released by nerves and then travel to other nearby nerves where they attach to receptors on the nerves. Some neurotransmitters that are released do not bind to receptors and are taken up by the nerves that produced them. This is referred to as "reuptake." Many experts believe that an imbalance of neurotransmitters is the cause of depression. Escitalopram prevents the reuptake of one neurotransmitter, serotonin, by nerves, an action which results in more serotonin in the brain to attach to receptors. Chemically, escitalopram is very similar to citalopram. Both are in the class of drugs called selective serotonin reuptake inhibitors (SSRIs).

Active Ingredients

Ventus® 5 mg Tablet: Each film-coated tablet contains Escitalopram Oxalate USP equivalent to Escitalopram 5 mg.

Ventus® 10 mg Tablet: Each film-coated tablet contains Escitalopram Oxalate USP equivalent to Escitalopram 10 mg.

Indication

Escitalopram is approved for the treatment of depression and generalized anxiety disorder. Drugs in the SSRI class also have been studied in persons with obsessive-compulsive disorders and panic disorders.

Contraindication

Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated. Concomitant use in patients taking pimozide is contraindicated. Ventus® is contraindicated in patients with a hypersensitivity to escitalopram or citalopram or any of the inactive ingredients.

Side Effects

The most commonly-noted side effects associated with escitalopram are agitation or restlessness, blurred vision, diarrhea, difficulty sleeping, drowsiness, dry mouth, fever, frequent urination, headache, indigestion, nausea, increased or decreased appetite, increased sweating, sexual difficulties (decreased sexual ability or desire, ejaculatory delay), taste alterations, tremor (shaking), weight changes. Although changes in sexual desire, sexual performance and sexual satisfaction often occur as a result of depression itself, they also may be a consequence of the drugs used to treat depression. In particular, about one in 11 men given escitalopram report difficulties experiencing ejaculation.

Precaution

During marketing of escitalopram and other SSRIs and SNRIs (Serotonin and Norepinephrine Reuptake Inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, and hypomania. While these events are generally self-limiting, there have been reports of serious discontinuation symptoms. Patients should be monitored for these symptoms when discontinuing treatment with escitalopram. A gradual

Insert for prescribing information

reduction in the dose rather than abrupt cessation is recommended whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate.

Dosage & Administration

The usual starting dose of Escitalopram is 10 mg once daily. Benefit may not be seen until treatment has been given for up to 4 weeks. Escitalopram can be taken with or without food. Older and younger persons require similar doses.

Drug-interactions

All SSRIs, including Escitalopram, should not be taken together with any drugs of the MAO (mono-amine oxidase) inhibitor-class of antidepressants, for example, isocarboxazid, phenelzine, tranylcypromine, and procarbazine. Such combinations may lead to confusion, high blood pressure, high fevers, tremor or muscle rigidity, and increased activity. This same type of interaction also may occur with selegiline, fenfluramine and dexfenfluramine. Tryptophan can cause headache, nausea, sweating, and dizziness when taken with any SSRI. At least 14 days should elapse after discontinuing escitalopram before starting a MAO inhibitor.

Pregnancy

The safety of Escitalopram during pregnancy and lactation has not been established. Therefore, Escitalopram should not be used during pregnancy unless, in the opinion of the physician, the expected benefits to the patient outweigh the possible hazards to the fetus.

Nursing Mothers

Escitalopram is excreted in human milk. Escitalopram should not be given to nursing mothers unless, in the opinion of the physician, the expected benefits to the patient outweigh the possible hazards to the child.

Storage

Store at temperature not exceeding 30° C in a dry place. Protect from light and humidity.

Commercial Pack

Ventus® 5 mg Tablet: Each box containing 3X10's tablets in Alu-PVC blister strips.

Ventus® 10 mg Tablet: Each box containing 3X10's tablets in Alu-PVC blister strips.

For child safety: Keeping medicines out of reach



MAKS
Manufactured for
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by NAAFCO Pharma Ltd.
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