

Restraline®

Sertraline

FORMS AND PRESENTATION

Restraline®: Film coated tablets: Box of 20.

COMPOSITION

Restraline®: Each film coated tablet contains Sertraline Hydrochloride equivalent to Sertraline 50 mg.

Excipients: Microcrystalline cellulose, Di-calcium phosphate anhydrous, hydroxypropyl cellulose, magnesium stearate, colloidal silicone dioxide, sodium starch glycolate, croscarmellose sodium, hydroxypropyl methylcellulose, talc, titanium dioxide, triacetate.

Why should you take Restraline®?

Therapeutic class: Psychoanaleptics.

ATC code: N06AB06.

Restraline® is a selective serotonin re-uptake inhibitor (SSRI). Serotonin is among the chemical messengers that manage mood.

Restraline® is indicated for the following conditions:

Major depression, a condition characterized by a depressed mood that affects everyday living. Symptoms include loss of interest in daily activities, changes in sleep habits and appetite, fatigue, lethargy, feeling of guilt or worthlessness, inability or difficulty to concentrate, suicidal thoughts.

Obsessive-compulsive disorder (i.e. repeating certain actions such as hand washing & continuous unwanted thoughts).

Panic disorder (attacks of anxiety).

Social anxiety disorder (i.e. shyness in society to an extent that affects an individual work and social life).

Post traumatic stress disorder (i.e. intrusive thoughts and flashbacks about previously experienced dangerous or life-threatening conditions accompanied with severe psychological distress).

Premenstrual dysphoric disorder (PMDD) occurring during the 2 weeks period preceding menstruation and characterized by a low mood, excessive anxiety, distress, emotional disturbances, and irritability.

What should you know about Restraline®?

Restraline® should not be taken within 2 weeks of administration of any MAO inhibitor. Restraline® must not be co-administered with the drug pimozide.

What is the recommended dosage of Restraline®?

ADULTS

Depression or Obsessive-Compulsive Disorder

The usual starting dose is 50mg once daily taken either in the morning or in the evening. The dose may be increased to a maximum dose of 200mg daily if needed.

Premenstrual Dysphoric Disorder

Restraline® may be prescribed during the 2 weeks period preceding menstruation or throughout the menstrual cycle. The starting dose is 50mg once daily and may be increased by increments of 50mg doses at the beginning of each new menstrual cycle up to a maximum of 100mg daily in the 2-week regimen or 150mg daily in the full-cycle regimen. The usual dose during the first 3 days of the 2-week regimen is limited to 50mg.

Panic Disorder, Post-Traumatic Stress Disorder, and Social Anxiety Disorder.

The usual dose is 25mg once daily during the first week of treatment after which the dose is increased to 50mg once daily. The daily dose may be increased up to a maximum of 200mg daily if needed.

CHILDREN 6 TO 17 YEARS OLD

Obsessive-Compulsive Disorder

Children (6 to 12 years):

The starting dose is 25mg.

Adolescents (13 to 17 years):

The starting dose is 50mg.

Safety and effectiveness have not been established for children under 6 years.

Dosage adjustment may be required in patients with liver diseases.

How is Restraline® taken?

Take Restraline® exactly as prescribed by your physician; once daily either in the morning or in the evening. Effect of Restraline® may take a few days to several weeks to be established. Treatment duration may be extended for at least several months. Dry mouth is one of the side effects caused by Restraline®. It can be relieved by taking a candy, a chewing gum, or water.

What to do if you miss a dose?

Take the forgotten dose as soon as you remember. If it is almost time for your next dose, skip the dose you missed and go back to your regular schedule. Do

not take two doses at the same time.

What to do in case of overdose?

Any medication taken in excess may lead to serious consequences. If you suspect an overdose, seek medical attention.

Common symptoms of Restraline® overdose include:

Nausea, vomiting, dizziness, sleepiness, rapid heartbeat, tremor, and agitation. Other rare possible symptoms include high or low blood pressure; slow, rapid, or irregular heartbeat; coma; stupor; fainting; convulsions; delirium; hallucinations; and mania.

Are there any drug or alcohol interactions with Restraline®?

Restraline® can be taken with most other drugs; however it is important to consult your physician before combining it with any of the following drugs:

Antidepressants such as Paroxetine and Fluoxetine and other antidepressants including tricyclics (such as Amitriptyline and Nortriptyline), Cimetidine, Diazepam, Digitoxin, Flecainide, Lithium, Over-the-counter drugs (such as cold remedies), Propafenone, Sumatriptan, Tolbutamide, and Warfarin.

Restraline® must never be combined with pimozide or any MAO inhibitor. You should not drink alcoholic beverages while taking Restraline®.

What are the side effects of Restraline®?

Side effects may include:

Abdominal pain, diarrhea or loose stools, constipation, indigestion, gas, nausea, vomiting, dry mouth, sore throat, decreased appetite, agitation, anxiety, nervousness, tremor, insomnia, increased sweating, decreased sex drive, difficulty with ejaculation, dizziness, fatigue, headache, pain, rash, sleepiness, tingling sensation, vision problems.

Many people may lose ½ to 1 Kg while taking Restraline®.

Precautions about Restraline®

Patients treated with Restraline® and their caregivers should watch for any change in symptoms and report to their physician any new symptoms that appear suddenly especially agitation, restlessness, anxiety, hostility, panic, extreme hyperactivity, and suicidal thinking or behavior. Be aware at the beginning of treatment or whenever there is a change in the dose. Inform your physician if you are taking Restraline® and you have a history of kidney or liver disorders, heart disease, seizures, or bleeding problems. Consult your physician before combining Restraline® with NSAIDs or blood-thinning medications. Like all antidepressants, Restraline® may induce a manic episode. Inform your physician if this happens. Restraline® has not been found to impair the ability to drive or operate machinery; however you should be cautious until you know how the drug affects you.

What are the cases in which you should not take Restraline®?

Do not use Restraline® while taking a MAO inhibitor or the drug pimozide.

What should you do if you are pregnant or breastfeeding?

Restraline® should be taken during pregnancy only if it is clearly needed. It is not known whether Restraline® appears in breast milk. Caution is advised when using Restraline® during breastfeeding.

How to store Restraline®?

Store below 30° C.

Keep in original pack in intact conditions.

Date of revision: January 2014.

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor
- Medicament: keep out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

Benta S.A.L.
Dbayeh - Lebanon