SHERI SPIRT

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**STRATTERA**

**10mg. – 100mg.**

 **a non controlled alternative. Not a psychostimulant but a NRi, that may have antidepressant efficacy.**

**Absorption**

Bioavailability: 63-94%

Onset: 2-4 wk

Peak plasma time: 1-2 hr

**Distribution**

Vd: 0.85 L/kg (IV)

Protein bound: 98%

Vd: 0.85 L/kg

**Metabolism**

Metabolized in liver by CYP2D6

Metabolites: 4-Hydroxyatomoxetine (equipotent), N-desmethylatomoxetine (less potent)

**Elimination**

Half-life: 5.2 hr

Total body clearance: 0.35 L/hr/kg

Excretion: Urine (80%), feces (17%)

## Adverse Effects

### >10%

Xerostomia (dry mouth) (21%)

Headache (2-19%)

Abdominal pain (7-18%)

Decreased appetite (11-16%)

Insomnia (2-15%)

Cough (11%)

Somnolence (11%)

Vomiting (3-11%)

### 1-10%

Nausea (10%)

Increases in blood pressure (BP; ≥15-20 mm Hg) and heart rate (HR; ≥20 beats/min) (5-10%)

Erectile dysfunction (9%)

Hot flashes (8%)

Dizziness (5-8%)

Urinary hesitation or retention (7%)

Decreased weight (4-7%)

Depression (4-7%)

Irritability (<6%)

Dyspepsia (4%)

Ejaculation disorder (3%)

Sinus headache (3%)

Constipation (2%)

Dermatitis (2%)

Menstrual disorder (2%)

Mood swings (1-2%)

### Postmarketing Reports

Paresthesia

Cardiovascular: QT prolongation, syncope

Peripheral vascular: Raynaud phenomenon

General: Lethargy

Neurologic: Hypesthesia, paresthesia in children and adolescents, sensory disturbances, tics

Psychiatric: Depression and depressed mood, anxiety

Seizures: Cases include patients with preexisting seizure disorders and those with identified risk factors for seizures, as well as patients with neither history of nor identified risk factors for seizures; exact relation between atomoxetine and seizures is difficult to evaluate because of uncertainty about background risk of seizures in patients with attention-deficit/hyperactivity disorder (ADHD)

Skin: Hyperhidrosis

Urogenital: Male pelvic pain, urinary hesitation or retention in children and adolescents

Musculoskeletal: Rhabdomyolysis

## Pregnancy & Lactation

Pregnancy category: C

Lactation: Unknown whether drug is excreted in milk; use with caution

## Warnings

### Black Box Warnings

Atomoxetine use has been associated with increased risk of suicidal ideation in short-term studies in children or adolescents with ADHD; this risk must be balanced against clinical need in patients with ADHD

Monitor patients closely for suicidal thinking and behavior, clinical worsening, or unusual behavioral changes; families and caregivers should be advised of need for close observation and communication with prescribing healthcare provider

Average risk of suicidal ideation in patients receiving atomoxetine has been shown to be ~0.4% (5/1357 patients)

### Contraindications

Hypersensitivity

Narrow-angle glaucoma

Administration concomitantly with or within 14 days of monoamine oxidase inhibitor (MAOI) therapy; risk of potentially fatal reaction, including hyperthermia, myoclonus, altered mental status, and neuroleptic malignant syndrome (NMS)-like symptoms

Pheochromocytoma: Serious reactions, including elevated blood pressure and tachyarrhythmia, have been reported in patients with current or previous pheochromocytoma

Severe cardiovascular disorders where condition would deteriorate because BP increases by 15-20 mm Hg or HR increases by 20 beats/min; risk is greater in poor CYP2D6 metabolizers

### Cautions

If drug is given concomitantly with CYP2D6 inhibitor, wait 4 weeks after initiation before adjusting dosage

Liver injury reported within 120 days of initiation of atomoxetine; patients may present with elevated liver enzymes (>20 × ULN) and jaundice with significantly elevated bilirubin levels (>2 × ULN), followed by recovery upon discontinuance of atomoxetine

Orthostatic hypotension and syncope reported

Risk of suicidal thoughts in children and adolescents

Small risk of allergic reaction

Use caution in hypertension, tachycardia (see Contraindications)

Sudden deaths, stroke, and myocardial infarction reported in patients with structural cardiac abnormalities or other serious heart problems taking stimulants at usual doses; patients should have a careful history and physical exam to assess for presence of cardiovascular disease; consider not using atomoxetine in adults with clinically significant cardiac abnormalities

Patients who develop symptoms such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease during stimulant treatment should undergo a prompt cardiac evaluation

Particular care should be taken in using stimulants to treat ADHD patients with comorbid bipolar disorder because of concern for possible induction of mixed/manic episode in such patients

Aggressive behavior or hostility is often observed in children and adolescents with ADHD; monitor for the appearance of or worsening of aggressive behavior or hostility

Monitor growth of children ages 7 to 10 years during treatment with stimulants; may need to interrupt therapy in patients not growing or gaining weight as expected

Urinary hesitancy or sexual dysfunction may occur

Rare instances of priapism reported, sometimes necessitating surgical intervention; typically not reported during initiation but often occurring subsequent to dosage increase; immediate medical attention should be sought for abnormally sustained or frequent and painful erections

Drug can be discontinued without being tapered

Hypesthesia, paresthesia in children and adolescents, sensory disturbances

Rare reports of allergic reactions, including anaphylactic reactions, angioneurotic edema, urticaria, and rash

Use with caution in patietns with bipolar disorder, history of hypertension, hepatic impairment, existing anxiety disorder, history of urinary retention, or tics related to Tourette disorder

**Patient Education**atomoxetine oral

IMPORTANT: HOW TO USE THIS INFORMATION: This is a summary and does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

ATOMOXETINE - ORAL

(A-toe-MOX-e-teen)

COMMON BRAND NAME(S): Strattera

WARNING: A small number of people (especially children/teenagers) who take atomoxetine for attention-deficit hyperactivity disorder (ADHD) may experience worsening of their condition, other mental/mood symptoms, or suicidal thoughts/attempts. Therefore, it is very important to talk with the doctor about the risks and benefits of this medication (especially for children/teenagers).

Tell the doctor right away if you notice worsening of your condition/other psychiatric conditions, unusual behavior changes (including possible suicidal thoughts/attempts), or other mental/mood changes (including new/worsening anxiety, panic attacks, trouble sleeping, irritability, hostile/angry feelings, hallucinations, delusions, impulsive actions, severe restlessness, very rapid speech). Be especially watchful for these symptoms when you first start this medication or when the dose is changed.

USES:
Atomoxetine is used to treat attention-deficit hyperactivity disorder (ADHD) as part of a total treatment plan, including psychological, social, and other treatments. It may help to increase the ability to pay attention, concentrate, stay focused, and stop fidgeting. It is thought to work by restoring the balance of certain natural substances (neurotransmitters) in the brain.

HOW TO USE:
Read the Medication Guide provided by your pharmacist before you start using atomoxetine and each time you get a refill. If you have any questions, ask your doctor or pharmacist.

Take this medication with or without food as directed by your doctor, usually 1 to 2 times a day. The first dose is usually taken when you wake up in the morning. If a second dose is prescribed, take it as directed by your doctor, usually in the late afternoon/early evening. Taking this medication late in the day may cause trouble sleeping (insomnia).

Swallow the capsules whole. Do not crush, chew, or open the capsules. If the capsule is accidentally opened or broken, avoid contact with the powder and wash away any loose powder as soon as possible with water. If the powder gets in your eyes, flush with plenty of water right away and contact your doctor.

The dosage is based on your medical condition, response to treatment, and other drugs you may be taking. Be sure to tell your doctor and pharmacist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). Do not increase your dose or take this drug more often than directed.

Use this medication regularly to get the most benefit from it. To help you remember, take it at the same time(s) each day.

Tell your doctor if your condition does not improve or if it worsens.

SIDE EFFECTS:
See also Warning section.

Stomach upset, nausea, vomiting, constipation, tiredness, loss of appetite/weight loss, dry mouth, dizziness, drowsiness, trouble sleeping, or decrease in sexual ability/desire may occur. In women, menstrual cramps or missed/irregular periods may also occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly.

To lessen the chance of dizziness, get up slowly from a sitting or lying position.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

This medication may raise your blood pressure. Check your blood pressure regularly and tell your doctor if the results are high.

Tell your doctor right away if you have any serious side effects, including: difficulty urinating, unusually fast/irregular heartbeat, fainting, numbness/tingling.

Atomoxetine may rarely cause serious (possibly fatal) liver disease. Get medical help right away if you have any symptoms of liver damage, including: dark urine, persistent nausea/vomiting/loss of appetite, stomach/abdominal pain, yellowing eyes/skin.

This medication may rarely cause serious problems such as a heart attack or stroke. Get medical help right away if you experience any of the following: chest/jaw/left arm pain, shortness of breath, unusual sweating, weakness on one side of the body, confusion, slurred speech, sudden vision changes.

Rarely, males (including young boys and teens) may have a painful or prolonged erection lasting 4 or more hours while using this medication. Caregivers/parents should also be watchful for this serious side effect in boys. If a painful or prolonged erection occurs, stop using this drug and get medical help right away, or permanent problems could occur. Ask your doctor or pharmacist for more details.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS:
Before taking atomoxetine, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: a certain adrenal problem (pheochromocytoma), bladder or prostate problems, glaucoma, heart problems (such as irregular heartbeat, heart failure, previous heart attack, problems with heart structure), family history of heart problems (such as sudden cardiac death, irregular heartbeat), high blood pressure, liver disease, personal/family history of mental/mood disorders (such as bipolar disorder, depression, psychosis, suicidal thoughts), stroke.

This drug may make you dizzy or drowsy. Do not drive, use machinery, or do any activity that requires alertness until you are sure you can perform such activities safely. Limit alcoholic beverages.

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

If used for a long time, this drug may affect a child's growth rate, weight, and final adult height. To reduce the risk, the doctor may recommend briefly stopping the medication from time to time. Check the child's weight and height regularly, and consult your doctor or pharmacist for more details.

During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor.

It is unknown if this drug passes into breast milk. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:
Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Taking MAO inhibitors with this medication may cause a serious (possibly fatal) drug interaction. Avoid taking MAO inhibitors (isocarboxazid, linezolid, methylene blue, moclobemide, phenelzine, procarbazine, rasagiline, selegiline, tranylcypromine) during treatment with this medication. Most MAO inhibitors should also not be taken for two weeks before and after treatment with this medication. Ask your doctor when to start or stop taking this medication.

Check the labels on all your medicines (such as cough-and-cold products, diet aids) because they may contain ingredients that could increase your heart rate or blood pressure. Ask your pharmacist for more details.

OVERDOSE:
If someone has overdosed and has serious symptoms such as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: unusually fast heartbeat, severe headache.

NOTES:
Do not share this medication with others.

Laboratory and/or medical tests (such as pulse, blood pressure, liver function tests) may be performed periodically to monitor your progress or check for side effects. Consult your doctor for more details.

If you have heart problems, your doctor may perform certain heart tests (EKG, echocardiogram) before you start this medication.

Keep all regular medical and laboratory appointments.

MISSED DOSE:
If you miss a dose, take it as soon as you remember if it is the same day. If it is the next day, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE:
Store at room temperature away from light and moisture. Do not store in the bathroom. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.