

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### <sup>Pr</sup>**Mylan-Escitalopram** **Escitalopram Oxalate Tablets**

Read this carefully before you start taking **Mylan-Escitalopram** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Mylan-Escitalopram**.

#### **What is Mylan-Escitalopram used for?**

Mylan-Escitalopram is used to relieve the symptoms of depression or obsessive compulsive disorder (OCD) in adults. Your doctor will keep evaluating if Mylan-Escitalopram is still safe and effective for you if you take it for a long time.

#### **How does Mylan-Escitalopram work?**

Mylan-Escitalopram is known as an antidepressant and belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs).

Mylan-Escitalopram works by increasing the levels of a chemical in the brain called serotonin. Changes in the amount of serotonin in your brain can contribute to the development of depression and related diseases.

#### **What are the ingredients in Mylan-Escitalopram?**

Medicinal ingredient: Escitalopram oxalate

Non-medicinal ingredients: Colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, purified talc, titanium dioxide.

#### **Mylan-Escitalopram comes in the following dosage forms:**

As tablets containing 10 mg or 20 mg escitalopram (as escitalopram oxalate)

#### **Do not use Mylan-Escitalopram if:**

- you are allergic to escitalopram oxalate
- you are allergic to any of the other ingredients in Mylan-Escitalopram or to a component of the container
- you are also taking the medicine pimozide, used to treat schizophrenia
- you are currently taking or have recently taken medicines called monoamine oxidase antidepressants such as phenelzine sulphate, tranylcypromine or moclobemide, or other monoamine oxidase inhibitors such as linezolid, methylene blue, selegiline.
- you have been told that you have QT interval prolongation or have been diagnosed with a congenital long QT syndrome

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Mylan-Escitalopram. Talk about any health conditions or problems you may have, including if you:**

- have heart problems
- have diabetes. Mylan-Escitalopram may make it more difficult to control your blood sugar
- have liver or kidney problems
- have or have had a seizure disorder
- have or have had manic episodes or have been diagnosed with bipolar disorders
- are receiving Electroconvulsive Therapy (ECT)
- have a bleeding disorder or have been told that you have low platelets
- have a family history of QT/QTc prolongation (abnormal electrical activity of the heart).
- have electrolyte disturbances like low blood potassium, magnesium, or calcium levels) or conditions that could lead to this such as vomiting, diarrhea, dehydration
- had a recent bone fracture or were told you have osteoporosis or risk factors for osteoporosis
- are taking any medications (prescription or non-prescription) or have taken within the last 14 days, especially monoamine oxidase inhibitors, pimozide, any other antidepressants, triptans used to treat migraines, lithium, opioids (including to treat pain, or drug dependence) or drugs containing tryptophan.
- ever had an allergic reaction to any medication or any of the ingredients mentioned in this leaflet.
- have habits of alcohol and/or street drug consumption.
- are taking St. John's Wort, an herbal product used to treat depression

**Other warnings you should know about:**

It is important that you and your doctor talk regularly about how you are feeling while you are taking Mylan-Escitalopram.

Mylan-Escitalopram should not be used in children and adolescents under 18 years of age.

**New or Worsened Emotional or Behavioural Problems**

When you first start taking Mylan-Escitalopram, or when your dose is changed, you might feel worse instead of better. You may get new or worsened feelings of agitation, hostility or anxiety.

**Self-harm and suicide**

Suicidal thoughts and actions can occur in any age group but may be more likely in patients 18 to 24 years old. If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital **right away**. This is more likely if you have had thoughts of harming or killing yourself in the past. Tell your doctor if you have had these thoughts before. This way, they will monitor you more closely while you are taking Mylan-Escitalopram.

You may also find it helpful to tell a relative or close friend that you are depressed. Ask them to read this leaflet. Ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour. Seek medical help if they notice these getting worse.

**Activation of Mania**

Tell your doctor if you have or have had manic episodes in the past or if you have been diagnosed with bipolar disorder. Mylan-Escitalopram should be used with caution if you have a history of

mania/hypomania. Some patients with bipolar disorder (also known as manic depression) may enter into a manic phase when they start taking Mylan-Escitalopram. Tell your doctor if you experience symptoms of mania such as excessive physical activity, overactive behaviour or thoughts, increased energy, trouble sleeping, racing thoughts, reckless behaviour, excessive happiness or irritability, talking more or faster than usual.

### **Bleeding Problems**

Before taking Mylan-Escitalopram tell your doctor if you have a bleeding disorder including low blood platelets. Drugs from the class that Mylan-Escitalopram belongs to may increase the chance of a bleeding event such as nose bleeds, bruising and even life-threatening bleeding. This is more likely if you have a history of a bleeding disorder or are taking other drugs that are known to affect blood clotting. Talk to your doctor about drugs that might increase bleeding.

### **Pregnancy**

Before taking Mylan-Escitalopram, tell your doctor if you are pregnant, think you might be pregnant or are planning to become pregnant. You should not take Mylan-Escitalopram if you are pregnant unless you and your doctor have discussed the risks and decided that you should take it. Tell your doctor right away if you become pregnant while taking Mylan-Escitalopram. If you take Mylan-Escitalopram near the end of your pregnancy, you could have heavy vaginal bleeding shortly after giving birth.

### **Effects on Newborns**

Some newborn babies whose mothers took medications such as Mylan-Escitalopram during pregnancy have developed problems at birth. These problems include prolonged hospitalisation, breathing support and tube feeding. Symptoms can include:

- feeding and/or breathing difficulties
- bluish skin
- seizures
- body temperature changes
- vomiting
- low blood sugar
- tense or overly relaxed muscles
- vivid reflexes
- tremor
- jitteriness
- irritability
- weakness
- sleepiness, sleeping difficulties and constant crying.

In most cases, these medications were taken during the third trimester of pregnancy. These symptoms are caused by the medication itself or from the effects of suddenly stopping the medication. These symptoms normally go away over time. However, if your baby experiences any of these symptoms, contact your doctor as soon as you can.

### **Persistent Pulmonary Hypertension (PPHN):**

If you take Mylan-Escitalopram towards the end of your pregnancy, your newborn may be at risk of having a serious lung condition called Persistent Pulmonary Hypertension of the Newborn (PPHN). This causes breathing problems in newborns soon after birth. Newborn babies may breathe faster and

appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your newborn baby, get immediate medical help for them.

### **Breastfeeding**

Tell your doctor if you are breastfeeding or planning to breastfeed. Mylan-Escitalopram is released into breast milk. It is not known if this is safe for your baby. You should not breastfeed a baby if you are taking Mylan-Escitalopram unless you and your doctor have discussed the risks and decided that you should.

### **Effects on the electrical activity of the heart**

Mylan-Escitalopram has an effect on the electrical activity of the heart known as QT/QTc prolongation (abnormal electrical activity of the heart). This can lead to disturbances in heart rhythm (arrhythmias/dysrhythmias) that could result in dizziness, palpitations (sensation of rapid, pounding, or irregular heart beat), fainting or cardiac arrest. This is more likely in patients with risk factors, such as heart disease, heart attack, or in the presence of certain drugs that could interact with the activity of the heart. If you experience any symptoms of a possible heart rhythm disturbance (abnormal heart rate or rhythm), such as dizziness, palpitations (sensation of rapid, pounding, or irregular heart beat), fainting, you should seek immediate medical attention.

### **Serotonin Toxicity**

Serotonin toxicity (also known as Serotonin syndrome): Mylan-Escitalopram can cause Serotonin toxicity, a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles and digestive system work. You may develop Serotonin toxicity if you take Mylan-Escitalopram with certain anti-depressants or migraine medications.

Serotonin toxicity symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
- muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination
- fast heartbeat, changes in blood pressure;
- confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma

### **Effects on Sexual Function:**

Taking medicines like Mylan-Escitalopram may cause symptoms of sexual dysfunction. In some cases these symptoms have continued after stopping Mylan-Escitalopram treatment. Talk to your healthcare professional if you experience symptoms such as a decrease in sexual desire, performance or satisfaction.

### **Risk of Bone Fractures**

Taking Mylan-Escitalopram may increase your risk of breaking a bone if you are elderly, have osteoporosis or other major risk factors for breaking a bone. You should take extra care to avoid falls especially if you get dizzy or have low blood pressure.

### **Angle-closure Glaucoma**

Mylan-Escitalopram can cause dilation of the pupil. This may cause an acute glaucoma attack in an individual with narrow ocular angles. Having your eyes examined before you take Mylan-Escitalopram could help identify if you are at risk of having angle-closure glaucoma. Get immediate medical attention if you experience:

- eye pain

- changes in vision
- swelling or redness in or around the eye.

### **Driving and using machines**

Mylan-Escitalopram may impair your ability to drive or to use machines. Wait until you know how Mylan-Escitalopram affects you before driving or using machines. Do not drive or use machines if Mylan-Escitalopram impairs your ability to do so safely.

### **Discontinuation Symptoms**

Contact your doctor before stopping or reducing your dosage of Mylan-Escitalopram. If you stop or reduce the dosage of Mylan-Escitalopram abruptly, or if you miss a dose, you may experience symptoms such as dizziness, abnormal dreams, sensory disturbances like electric shock sensations, agitation, anxiety, emotional indifference, difficulty concentrating, headache, migraine, tremor (shakiness), nausea, vomiting, sweating or other symptoms. Tell your doctor immediately if you have these or any other symptoms. Your doctor may adjust the dosage of Mylan-Escitalopram to reduce the symptoms.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

### **Serious Drug Interactions**

**Do not use Mylan-Escitalopram if you are taking or have recently taken:**

- Monoamine oxidase inhibitor such as phenelzine, tranylcypromine, moclobemide or selegiline, linezolid (as antibiotic) or Methylene blue (intravenous)
- Pimozide

**The following may interact with Mylan-Escitalopram:**

- drugs to treat heart rhythm disturbances (antiarrhythmics)
- antipsychotics, used to treat schizophrenia
- opioids (including for pain, drug dependence or anesthesia) such as methadone, buprenorphine, tramadol, fentanyl, tapentadol, meperidine or pentazocine.
- drugs to treat infections
- diuretics (water pills)
- laxatives (including enemas)
- other SSRIs (citalopram) or any other antidepressant (e.g., imipramine, desipramine) used to treat depressions
- lithium, used to treat mood disorder
- tryptophan, for sleep aid or treating anxiety
- cimetidine, for acidity problems
- triptans (e.g., sumatriptan, zolmitriptan, naratriptan), for Migraine
- fluconazole, for treating fungal infection
- ketoconazole, for treating fungal infection
- itraconazole, for treating fungal infection
- warfarin, used to prevent clot of blood
- omeprazole, used to treat stomach problems
- any herbal product such as St. John's Wort

- certain medicines which may affect blood clotting and increase bleeding, such as oral anticoagulants (e.g., warfarin, dabigatran), acetylsalicylic acid (e.g., Aspirin®) and other non-steroidal anti-inflammatory drugs (e.g., ibuprofen)
- certain medicines used to treat cough, such as dextromethorphan.

Avoid drinking alcohol while taking Mylan-Escitalopram.

**How to take Mylan-Escitalopram:**

- Take Mylan-Escitalopram exactly as your doctor has told you
- Swallow tablets whole with water. Do not chew them.
- You can take Mylan-Escitalopram with or without food
- Take Mylan-Escitalopram once a day at the same time every day
- Continue taking Mylan-Escitalopram even if you do not feel better. It may take several weeks for it to work and improvement may be gradual
- Keep taking Mylan-Escitalopram for as long as your doctor recommends. Do not stop taking Mylan-Escitalopram abruptly even if you feel better unless your doctor has told you to.
- Never take more Mylan-Escitalopram than your doctor has prescribed for you.
- Follow all instructions given to you by your doctor.

**Usual dose:**

The usual dose is one 10 mg tablet once a day. Your doctor might prescribe a lower dose to you if you are elderly, have liver problems or in other situations.

**Overdose:**

Some of the signs of an overdose could be dizziness, tremor, agitation, sweating, drowsiness, coma, nausea, vomiting, change in heart rhythm, decreased blood pressure and seizure.

If you think you, or a person you are caring for, have taken too much Mylan-Escitalopram, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you forget a dose, take the next dose as planned. Do not take a double dose to make up for a forgotten dose.

**What are possible side effects from using Mylan-Escitalopram?**

These are not all the possible side effects you may have when taking Mylan-Escitalopram. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- nausea,
- increased sweating,
- diarrhea,
- fatigue,
- fever,
- constipation,
- clogged or runny nose,

- sleep disturbance,
- loss of appetite,
- increased appetite,
- increased weight,
- decreased interest in sex,
- decreased ability to reach orgasm,
- erectile dysfunction,
- anxiety,
- restlessness,
- abnormal dreams,
- difficulties falling asleep,
- drowsiness,
- yawning,
- tremor (shakiness),
- prickling of the skin,
- dizziness,
- dry mouth,
- heartburn,
- pain in muscles and joints,
- stomach pain and changes in heart rate,
- bone fracture.

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>UNCOMMON</b>			
<b>Allergic reactions:</b> Red skin, hives, itching, swelling of the lips, face, tongue, throat, trouble breathing, wheezing, shortness of breath, skin rashes, blisters of the skin, sores or pain in the mouth or eyes			<b>X</b>
<b>Allergic reactions:</b> Skin rash alone, hives alone		<b>X</b>	
<b>Alteration of blood sugar control in patients with diabetes: Hypoglycemia</b> (Low blood sugar): dizziness, lack of energy, drowsiness, headache, trembling, sweating or <b>Hyperglycemia</b> (high blood sugar): increased thirst, increased urination, weakness, confusion, fruity breath odour		<b>X</b>	

<b>Bleeding problems:</b> Bruising or bleeding from the skin, nose or other areas for longer than usual		X	
<b>Hallucinations:</b> Strange visions or sounds		X	
<b>Mania:</b> Excessive physical activity, overactive behaviour or thoughts, increased energy, trouble sleeping, racing thoughts, reckless behaviour, excessive happiness or irritability, talking more or faster than usual		X	
<b>Uncontrollable movements of the body or face</b>		X	
<b>Inability to urinate</b>		X	
<b>RARE</b>			
<b>Serotonin Toxicity and Neuroleptic Malignant Syndrome</b> (various symptoms due to high level of serotonin level in the body): a combination of most or all of the following: confusion, restlessness, sweating, shaking, shivering, high fever, hallucinations, sudden jerking of the muscles, muscle stiffness, feeling very agitated or irritable, fast heartbeat. The severity can increase, leading to loss of consciousness.			X
<b>Low sodium level in blood:</b> tiredness, weakness, confusion combined with achy, stiff or uncoordinated muscles		X	
<b>Angle-closure Glaucoma</b> (Increased pressure in eyes, change in vision such as hazy or blurred vision): Eye pain, change in vision, swelling or redness in or around the eye			X
<b>VERY RARE</b>			
<b>Seizures (fits):</b> Loss of consciousness with uncontrollable shaking			X
<b>Liver disorder:</b> Symptoms include nausea, vomiting, loss of appetite combined with itching, yellowing of the skin or eyes, dark urine			X
<b>Gastrointestinal bleeding:</b> Vomiting blood or passing blood in stools			X
<b>New or Worsened Emotional or Behavioural Problems:</b>		X	



Anxiety, hostility or impulsivity <b>Akathisia:</b> Feeling restless and unable to sit or stand still			
<b>Self-harm and suicide:</b> Have thoughts of harming or killing yourself			<b>X</b>
<b>UNKNOWN</b>			
<b>Heart rhythm disturbance</b> (Abnormal heart rate or rhythm): dizziness, palpitations (sensation of rapid, pounding or irregular heart beat), fainting		<b>X</b>	
<b>Postpartum haemorrhage</b> (Heavy vaginal bleeding shortly after birth): Excessive vaginal bleeding after child birth		<b>X</b>	
<b>Symptoms after discontinuation or dose reduction:</b> Dizziness, abnormal dreams, sensory disturbance like electric shock sensations, agitation, anxiety, emotional indifference, difficulty concentrating, headache, migraine, tremor (shakiness), nausea, vomiting, sweating		<b>X</b>	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

- Keep Mylan-Escitalopram out of the reach and sight of children.
- Store your tablets at room temperature (15°C - 30°C) in a dry place and keep the container tightly closed.

### If you want more information about Mylan-Escitalopram:

- Talk to your healthcare professional

- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.mylan.ca](http://www.mylan.ca), or by calling 1-844-596-9526.

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