PART III: CONSUMER INFORMATION

[Pr]pms-PAROXETINE
Paroxetine Tablets, USP
10 mg, 20 mg, 30 mg and 40 mg
Paroxetine (as paroxetine hydrochloride)

This leaflet is part III of a three-part "Product Monograph" published when pms-PAROXETINE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about pms-PAROXETINE. Contact your doctor or pharmacist if you have any questions about the drug.

Please read this information before you start to take your medication, even if you have taken this drug before. Keep this information with your medicine in case you need to read it again.

ABOUT THIS MEDICATION

What the medication is used for:
pms-PAROXETINE has been prescribed to you by your doctor to relieve your symptoms of:
- depression (feeling sad, a change in appetite or weight, difficulty concentrating or sleeping, feeling tired, headaches, unexplained aches and pain)
- panic attacks
- social phobia (social anxiety disorder) - avoidance and/or fear of social situations
- generalized anxiety or nervousness
- obsessive compulsive disorder (recurrent and intrusive thought, feeling, idea or sensation; recurrent pattern of behaviour, or unwanted thoughts or actions), or
- post-traumatic stress disorder (anxiety following a traumatic event, for example a car crash, physical assault, natural disaster such as an earthquake)

What it does:
pms-PAROXETINE belongs to the family of medicines called selective serotonin reuptake inhibitors. pms-PAROXETINE is thought to work by increasing the levels of a chemical in the brain called serotonin (5-hydroxytryptamine).

When it should not be used:
Do not use pms-PAROXETINE if you are:
- allergic to it or any of the components of its formulation (see list of components at the end of this section)
- currently taking or have recently taken monoamine oxidase (MAO) inhibitor antidepressants (e.g., phenelzine sulphate, moclobemide) or linezolid, a MAO inhibitor antibiotic
- currently taking or have recently taken thioridazine or pimozide .

What the medicinal ingredient is:
Paroxetine hydrochloride.

What the non-medicinal ingredients are:
Colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol and titanium dioxide.

pms-PAROXETINE 10 mg also contains D&C yellow #10 aluminum lake, FD&C yellow #6/sunset yellow FCF aluminum lake, hypromellose, polydextrose and triacetin.

pms-PAROXETINE 20 mg also contains D&C red #30 aluminum lake, FD&C red #40, hypromellose, polydextrose and triacetin.

pms-PAROXETINE 30 mg also contains FD&C blue #2/indigo carmine aluminum lake, hypromellose, polydextrose and triacetin.

pms-PAROXETINE 40 mg also contains D&C yellow #10 aluminum lake, FD&C blue #2/indigo carmine aluminum lake, lecithin, polyvinyl alcohol and talc.

What dosage forms it comes in:
pms-PAROXETINE is available as a 10 mg yellow tablet, a 20 mg pink tablet, a 30 mg blue tablet and a 40 mg green tablet.

WARNINGS AND PRECAUTIONS

During treatment with these types of medications it is important that you and your doctor have good ongoing communication about how you are feeling.

pms-PAROXETINE is not for use in children under 18 years of age.

Changes in Feelings and Behaviour:
It is important that you have good communication with your doctor about how you feel. Discussing your feelings and treatment with a friend or relative who can tell you if they think you are getting worse is also useful.

Some patients may feel worse when first starting or changing the dose of drugs such as pms-PAROXETINE. You may feel more anxious or may have thoughts of hurting yourself or others, especially if you have had thoughts of hurting yourself before. These changes in feelings can happen in patients treated with drugs like pms-PAROXETINE for any condition, and at any age, although it may be more likely if you are aged 18 to 24 years old. **If this happens, see your doctor immediately.** Do not stop taking pms-PAROXETINE on your own.

Taking pms-PAROXETINE may increase your risk of breaking a bone if you are elderly or have osteoporosis or have 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.

Medicines like pms-PAROXETINE may affect your sperm. Fertility in some men may be reduced while taking pms-PAROXETINE.

BEFORE you use pms-PAROXETINE tell your doctor or pharmacist:

- all your medical conditions, including a history of seizures, liver or kidney disease, heart problems
- any medications (prescription or non-prescription) which you are taking or have recently taken, especially monoamine oxidase inhibitor antidepressants (e.g., phenelzine sulphate, moclobemide) or any other antidepressants, thioridazine, pimozide, drugs used to prevent fits (anticonvulsants), drugs for Parkinson's disease, or drugs containing tryptophan
- if you are taking tamoxifen (used to treat breast cancer)
- if you have ever had any allergic reaction to medications, food, etc.
- any natural or herbal products you are taking (e.g., St. John's Wort)
- if you are pregnant or thinking about becoming pregnant, or if you are breast feeding
- your habits of alcohol and /or street drug consumption
- if you drive a vehicle or perform hazardous tasks during your work
- if you had a recent bone fracture or were told you have osteoporosis or risk factors for osteoporosis
- if you have a bleeding disorder or have been told that you have low platelets

Effects on Pregnancy and Newborns:
As stated above, ask your doctor or pharmacist for advice before taking any medicine including pms-PAROXETINE. **If you are already taking/using pms-PAROXETINE and have just found out that you are pregnant, you should talk to your doctor immediately. You should also talk to your doctor if you are planning to become pregnant.**

Taking pms-PAROXETINE in early stages of pregnancy:
Some studies have suggested an increased risk of birth defects particularly heart defects, in babies whose mothers received pms-PAROXETINE in the first few months of pregnancy. These studies found that about 2 in 100 babies (2%) whose mothers received paroxetine in early pregnancy had a heart defect, compared with the normal rate of 1 in 100 babies (1%) seen in the general population. Also, in cases where pms-PAROXETINE has been used, there have been reports of premature births although it is not known if these premature births are due to the use of pms-PAROXETINE.

Taking pms-PAROXETINE in later stages of pregnancy:

Possible complications at birth (from taking any newer antidepressant, including pms-PAROXETINE):
Post-marketing reports indicate that some newborns whose mothers took an SSRI (selective serotonin reuptake inhibitor) or other newer antidepressant, during pregnancy have developed complications at birth requiring prolonged hospitalization, breathing support and tube feeding. Reported symptoms included feeding and/or breathing difficulties, seizures, tense or overly relaxed muscles, jitteriness and constant crying.

In most cases, the newer antidepressant was taken during the third trimester of pregnancy. These symptoms are consistent with either a direct adverse effect of the antidepressant on the baby, or possibly a discontinuation syndrome caused by sudden withdrawal from the drug. These symptoms normally resolve over time. However, if your baby experiences any of these symptoms, contact your doctor as soon as you can.

Persistent Pulmonary Hypertension (PPHN) and newer antidepressants, including pms-PAROXETINE:
The use of pms-PAROXETINE during pregnancy, particularly during late pregnancy, may increase the risk of a serious lung condition called persistent pulmonary hypertension of the newborn (PPHN) that causes breathing difficulties in newborns soon after birth. In the general population, PPHN is known to occur in about 1 or 2 per 1000 newborns but this may be increased 4 to 6 times in babies whose mothers used pms-PAROXETINE during late pregnancy.

If you are pregnant and taking an SSRI, or other newer antidepressants, you should discuss the risks and benefits of the various treatment options with your doctor. It is very important that you do NOT stop taking these medications without first consulting your doctor. See SIDE EFFECTS AND WHAT TO DO ABOUT THEM section for more information.

Angle-closure Glaucoma:
Paroxetine hydrochloride can cause an acute attack of glaucoma. Having your eyes examined before you take pms-PAROXETINE could help identify if you are at risk of having angle-closure glaucoma. Seek immediate medical attention if you experience:

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

INTERACTIONS WITH THIS MEDICATION

Do not use pms-PAROXETINE if you are taking or have recently taken (within the last 2 weeks) monoamine oxidase inhibitors, methylthioninium chloride (methylene blue), thioridazine, or pimozide.

You should tell your doctor if you are taking or have recently taken any medications (prescription, non-prescription or natural/herbal), especially:

- other antidepressants, such as SSRIs and certain tricyclics
- other drugs that affect serotonin such as, lithium, linezolid, tramadol, tryptophan, St. John's Wort, triptans used to treat migraines
- certain medicines used to treat pain, such as fentanyl (used in anaesthesia or to treat chronic pain), tramadol, tapentadol, meperidine, methadone, pentazocine
- tamoxifen, which is used to treat breast cancer or fertility problems
- certain medicines used to treat patients with irregular heart beats (arrhythmias)
- certain medicines used to treat schizophrenia
- certain medicines used to treat bipolar depression, such as lithium

- a combination of fosamprenavir and ritonavir, used to treat Human Immunodeficiency Virus (HIV) infection
- procyclidine, which is used to treat Parkinson's Disease or other movement disorders
- metoprolol, which is used to treat high blood pressure and angina
- certain medicines which may affect blood clotting and increase bleeding, such as oral anti-coagulants (e.g., warfarin, dabigatran), acetylsalicylic acid (e.g., aspirin) and other non-steroidal anti-inflammatory drugs (e.g., ibuprofen)
- certain medicines used to treat epilepsy
- in general, drinking alcoholic beverages should be kept to a minimum or avoided completely while taking pms-PAROXETINE.
- certain medicines used to treat cough, such as dextromethorphan

PROPER USE OF THIS MEDICATION

Usual dose:

- It is very important that you take pms-PAROXETINE exactly as your doctor has instructed. Generally most people take between 20 mg to 40 mg of pms-PAROXETINE per day for depression, obsessive-compulsive disorder, panic disorder, social phobia (social anxiety disorder), generalized anxiety disorder and post-traumatic stress disorder; although your doctor may start you at 10 mg per day for panic disorder.
- Take your tablets in the morning, preferably with food. You should swallow the tablets whole with water. Do not chew them.
- You should continue to take your medicine even if you do not feel better, as it may take a number of weeks for your medicine to work.
- Keep taking your tablets, as instructed, until the doctor tells you to stop.
- Talk to your doctor before you stop taking your medication on your own.

Remember: This medicine has been prescribed only for you. Do not give it to anybody else, as they may experience undesirable effects, which may be serious.

Missed Dose:

If you forget to take your tablet in the morning, take it as soon as you remember. Take your next dose at the normal time the next morning, then carry on as before. Do not try to make up for a missed dose by taking a double dose the next time.

Overdose:

If you have taken a large number of tablets all at once, contact your doctor or the nearest hospital emergency department immediately, even though you may not feel sick. Show the doctor your pack of tablets.

If you think you have taken too much pms-PAROXETINE, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medications, pms-PAROXETINE can cause some side effects. You may not experience any of them. For most patients these side effects are likely to be minor and temporary. However, some may be serious. Some of these side effects may be dose related. Consult your doctor if you experience these or other side effects, as the dose may have to be adjusted.
If you experience an allergic reaction (including skin rash, hives, swelling, trouble breathing) or any severe or unusual side effects, stop taking the drug and contact your doctor immediately.

The most common side effects of pms-PAROXETINE are:

- nausea/vomiting
- dry mouth
- drowsiness
- weakness
- dizziness
- sweating
- tremor
- nervousness
- feeling agitated
- blurred vision
- sleep disturbances
- weight gain
- sexual problems
- Although psychiatric disorders are often associated with decreases in sexual desire, performance and satisfaction, treatment with this medication may lead to further decreases.

Other effects may include loss of appetite, constipation, diarrhea, abnormal dreams (including nightmares), headache and menstrual period disorders (including heavy periods, bleeding between periods and absence of periods).

pms-PAROXETINE does not usually affect people's normal activities. However, some people feel sleepy while taking it, in which case they should not drive or operate machinery.

pms-PAROXETINE may raise cholesterol levels in some patients.

Discontinuation Symptoms

Contact your doctor before stopping or reducing your dosage of pms-PAROXETINE. Symptoms such as dizziness, lightheadedness, nausea, vomiting, agitation/restlessness, anxiety, sweating, headache, sleep disturbance, electric shock sensations, tinnitus (buzzing, hissing, whistling, ringing or other persistent noise in the ears) and other symptoms have been reported after stopping treatment, reducing the dosage of pms-PAROXETINE, or when a dose is missed. These symptoms usually disappear without needing treatment. Tell your doctor immediately if you have these or any other symptoms. Your doctor may adjust the dosage of pms-PAROXETINE to alleviate the symptoms. See WARNINGS AND PRECAUTIONS section for more information.

Effects on Newborns

Some newborns whose mothers took an SSRI (Selective Serotonin Reuptake Inhibitor) or other newer antidepressant, such as pms-PAROXETINE, during pregnancy have shown such symptoms as breathing and feeding difficulties, jitteriness and constant crying. If your baby experiences any of these symptoms, contact your doctor as soon as you can. See WARNINGS AND PRECAUTIONS section for more information.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

	Symptom / effect	Talk with your doctor or pharmacist right way		Seek immediate emergency medical assistance
		Only if severe	In all cases	
Uncommon	Hallucinations [strange visions or sounds]		✓	
	Uncontrollable movements of the body or face		✓	
	Inability to urinate or loss of control of the bladder (*urinary incontinence*)		✓	
	Dilated pupils		✓	
	Low blood pressure (may cause dizziness, lightheadedness or fainting when standing up from a sitting down or lying position)		✓	
	Low Platelets [bruising or unusual bleeding from the skin or other areas]		✓	
Rare	Severe allergic reactions [red and lumpy skin rash, hives, itching, swelling of the lips, face, tongue, throat, trouble breathing, wheezing, shortness of breath, skin rashes, collapse or loss of consciousness]			✓
	Allergic reactions (skin rash alone)		✓	
	Low sodium level in blood [symptoms of tiredness, weakness, confusion combined with achy, stiff or uncoordinated muscles]		✓	
	Akathisia [feeling restless and unable to sit or stand still]		✓	
	Mania [overactive behaviour and thoughts]		✓	
	Seizures [loss of consciousness with uncontrollable shaking ("fit")]			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

	Restless Legs Syndrome (irresistible urge to move the legs)		✓	
	Angle-closure Glaucoma [eye pain, changes in vision and swelling or redness in or around the eye]			✓
	Abnormal secretion of breast milk in men and women		✓	
	Increased sensitivity of the skin to sunlight	✓		
	Swelling of hands, ankles or feet		✓	
	Menstrual period disorders (including heavy periods, bleeding between periods and absence of periods)		✓	
Very Rare	Serotonin syndrome and Neuroleptic Malignant Syndrome [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			✓
	Gastrointestinal bleeding [vomiting blood or passing blood in stools]			✓
	Liver disorder [symptoms include nausea, vomiting, loss of appetite combined with itching, yellowing of the skin or eyes, dark urine]		✓	
	A severe widespread rash with blisters and peeling skin, often with sores or pain in the mouth or eyes			✓
	Skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) called *erythema multiforme*			✓
See Warnings & Precautions	– Changes in feelings or behaviour (anger, anxiety, suicidal or violent thoughts) – Thoughts of death or suicide		✓	✓

This is not a complete list of side effects. For any unexpected effects while taking pms-PAROXETINE, contact your doctor or pharmacist.

HOW TO STORE IT

- Keep all medicines out of reach and sight of children.
- Store between 15°C and 30°C in a dry place.
- Keep container tightly closed.
- If your doctor tells you to stop taking pms-PAROXETINE please return any leftover medicine to your pharmacist.

Reporting Side Effects
You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.
3 ways to report:

- Online at MedEffect (http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 1908C
    Ottawa, ON
    K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php).

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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting the sponsor, Pharmascience Inc. at, 1-888-550-6060.

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