

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrMAR-PAROXETINE

Paroxetine Tablets USP

Read this carefully before you start taking **MAR-PAROXETINE** 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 **MAR-PAROXETINE**.

What is MAR-PAROXETINE used for?

MAR-PAROXETINE is used in adults (18 years of age and older) to relieve symptoms of:

- **Major Depressive Disorder** (feeling sad, a change in appetite or weight, difficulty concentrating or sleeping, feeling tired, headaches, unexplained aches and pain).
- **Obsessive Compulsive Disorder** (recurrent and intrusive thoughts, feelings, ideas or sensations; recurrent pattern of behaviour, or unwanted thoughts or actions).
- **Panic Disorder (with or without agoraphobia)** (panic attacks).
- **Social Phobia (social anxiety disorder)** (avoidance and/or fear of social situations).
- **Generalized Anxiety Disorder** (anxiety or nervousness).
- **Post-Traumatic Stress Disorder** (anxiety following a traumatic event, for example a car crash, physical assault, natural disaster such as an earthquake).

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

How does MAR-PAROXETINE work?

MAR-PAROXETINE belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). MAR-PAROXETINE is thought to work by increasing the levels of a chemical in the brain called serotonin (5-hydroxytryptamine). This helps to relieve your symptoms of depression, obsessive compulsive disorder, panic disorder, social phobia, generalized anxiety disorder or post-traumatic stress disorder. MAR-PAROXETINE may take a number of weeks to work.

What are the ingredients in MAR-PAROXETINE?

Medicinal ingredients: Paroxetine hydrochloride.

Non-medicinal ingredients: Dibasic calcium phosphate dehydrate USP, Hypromellose, Sodium Starch Glycolate, Magnesium Stearate, Titanium Dioxide, Macrogol/PEG 400, Polysorbate 80.

MAR-PAROXETINE 10 mg tablets also contain D&C Yellow No. 10 aluminum lake and FD&C yellow No. 6/Sunset yellow FCF aluminium lake.

MAR-PAROXETINE 20 mg tablets also contain D&C Red No. 30 Helindon Pink aluminum lake.

MAR-PAROXETINE 30 mg tablets also contain FD&C Blue No. 2-Indigo carmine aluminum lake.

MAR-PAROXETINE comes in the following dosage forms:

- 10 mg tablets (yellow), 20 mg tablets (pink) and 30 mg tablets (blue)

Do not use MAR-PAROXETINE if:

- you are allergic to paroxetine hydrochloride or to any of the non-medicinal ingredients in MAR-PAROXETINE (see What are the ingredients in MAR-PAROXETINE).
- you are currently taking or have recently taken any monoamine oxidase (MAO) inhibitor antidepressants (e.g. phenelzine sulphate, moclobemide) or a MAO inhibitor antibiotic (e.g. linezolid).
- you are going to have, or recently had methylene blue, dye injected into a vein during surgery, x-rays or other imaging procedures.
- you are currently taking or have recently taken other medicines used to treat mental health problems such as; thioridazine or pimozide. If you are unsure, ask your healthcare professional.

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

- have epilepsy or a history of seizures,
- have a history of liver or kidney problems,
- have heart problems,
- have a history or family history of mania/hypomania or bipolar disorder,
- have high cholesterol,
- have low levels of sodium in your blood,
- have had a recent bone fracture or were told you have osteoporosis or risk factors for osteoporosis,
- have a bleeding disorder or have been told that you have low platelets,
- are pregnant or thinking about becoming pregnant, or are breast feeding,
- have a history of alcohol or drug abuse,
- have ever had any allergic reaction to medications, food, etc.

Other warnings you should know about:

During treatment with MAR-PAROXETINE, it is important that you and your health care professional talk regularly about how you are feeling.

New or worsened emotional or behaviour problems:

Discussing your feelings and treatment with a friend or relative who can tell you if they think you are getting worse is helpful.

Some patients may feel worse when first starting or changing the dose of drugs such as MAR-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 MAR-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 MAR-PAROXETINE as it takes time to work.

Self-harm:

If you have thoughts of harming or killing yourself at any time, contact your health care professional or go to a hospital **right away**. You may find it helpful to tell a relative or close friend that you are

depressed or have other mental illnesses. Ask them to read this leaflet. You might ask them to tell you if they:

- think your depression or mental illness is getting worse, or
- are worried about changes in your behaviour

Pregnancy:

Only take MAR-PAROXETINE during pregnancy if you and your doctor have discussed the risks and have decided that you should. If you take MAR-PAROXETINE near the end of your pregnancy, you are at a higher risk of heavy vaginal bleeding shortly after birth. If you become pregnant while taking MAR-PAROXETINE, tell your doctor **right away**.

Effects on Newborns:

In some cases, babies born to a mother taking MAR-PAROXETINE during pregnancy may require hospitalization, breathing support and tube feeding. Be ready to seek medical help for your newborn if they:

- Have trouble breathing or feeding
- Have muscle stiffness, or floppy muscles (like a rag doll),
- Have seizures (fits),
- Are shaking (jitteriness),
- Are constantly crying

If you take MAR-PAROXETINE:

- During early pregnancy, there is a possible slight increased risk that your newborn may have birth defects, particularly a heart defect.
- During late pregnancy, your newborn may be at risk of having a serious lung condition called Persistent Pulmonary Hypertension of the Newborn (PPHN), which causes breathing problems.

Effects on Fertility and Sexual Function:

Taking medicines like MAR-PAROXETINE may increase your risk of having sexual problems. This may continue after MAR-PAROXETINE has been discontinued, including for months or years afterwards in some cases. Tell your doctor if you experience symptoms such as a decrease in sexual desire, performance or satisfaction. Medicines like MAR-PAROXETINE may affect sperm quality. Fertility in some men may be reduced while taking MAR-PAROXETINE.

Falls and Fractures:

MAR-PAROXETINE can cause you to feel dizzy or lightheaded and can affect your balance. This increases your risk of falling. In addition MAR-PAROXETINE may increase your risk of breaking a bone if you are:

- elderly,
- 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.

Driving and Using Machines:

MAR-PAROXETINE may make you feel sleepy. Avoid driving a vehicle or using machinery until you know how it affects you.

Angle-closure Glaucoma:

MAR-PAROXETINE can cause an acute attack of glaucoma. Having your eyes examined before you take MAR-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.

Cholesterol and Blood Tests: MAR-PAROXETINE can cause abnormal blood test results, including elevated levels of cholesterol. Your health care professional will decide when to perform blood tests and will interpret the results.

Do NOT stop taking MAR-PAROXETINE without talking to your healthcare professional first. If stopped abruptly, MAR-PAROXETINE may cause unwanted side effects such as:

- light-headedness,
- nausea and vomiting,
- agitation/restlessness,
- anxiety,
- sweating,
- headache,
- sleep disturbance,
- electric shock sensations,
- tinnitus (buzzing, hissing, whistling, ringing or other persistent noise in the ears).

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 MAR-PAROXETINE if you are taking or have recently taken in the last 2 weeks:

- Monoamine oxidase inhibitor [e.g., linezolid, methylthioninium chloride (methylene blue)]
- other medicines used to treat mental health problems such as Thioridazine and Pimozide

The following may interact with MAR-PAROXETINE:

- other antidepressants, such as SSRIs, SNRIs and certain tricyclics.
- other drugs that affect serotonin such as, lithium (used to treat bipolar depression), linezolid (antibiotic), tramadol (used to treat pain), tryptophan (used to treat anxiety or used as a sleep aid) and triptans (used to treat migraines).
- drugs used to prevent fits or treat epilepsy (anticonvulsants) such as carbamazepine, phenytoin, sodium valproate.
- drugs used to treat pain, such as fentanyl (used in anaesthesia or to treat chronic pain), tramadol, tapentadol, meperidine, methadone, pentazocine.
- drugs used to treat breast cancer or fertility problems, such as tamoxifen.
- drugs used to treat patients with irregular heart beats (arrhythmias).
- drugs used to treat schizophrenia.
- drugs used to treat Human Immunodeficiency Virus (HIV) infection, such as a combination of

fosamprenavir and ritonavir.

- drugs used to treat Parkinson's Disease or other movement disorders, such as procyclidine.
- drugs used to treat high blood pressure and angina, such as metoprolol.
- drugs 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).
- drugs that affect the central nervous system, such as haloperidol, amylbarbitone or oxazepam.
- drugs used to treat cough, such as dextromethorphan.
- drug to treat heartburn such as cimetidine.
- drugs to treat respiratory diseases (chronic obstructive pulmonary disease (COPD) and asthma) such as theophylline.
- any natural or herbal products (e.g. St. John's Wort).
- alcohol.

How to take MAR-PAROXETINE:

- It is very important that you take MAR-PAROXETINE exactly as your health care professional has instructed.
- Take your tablets in the morning, with or without food.
- Swallow the tablet(s) whole with water. Do not chew tablet(s).
- 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 health care professional tells you to stop.
- Talk to your health care professional 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.

Usual dose:

The starting dose of MAR-PAROXETINE depends on your illness. It is usually 10 mg or 20 mg once a day in the morning, with or without food. Your doctor may gradually increase your dose to help control your symptoms, up to a maximum of 50 mg or 60 mg once a day.

If you are over 65, or have liver or kidney problems, the maximum dose may be reduced.

Overdose:

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

Missed Dose:

If you forget to take your tablet in the morning, take it as soon as possible, unless it is too close to the time of the next dose. 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.

What are possible side effects from using MAR-PAROXETINE?

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

Side effects may include:

- nausea/vomiting
- dry mouth
- drowsiness
- weakness
- dizziness
- sweating
- tremor (shaking)
- nervousness
- feeling agitated
- blurred vision
- sleep disturbances (abnormal dreams including nightmares)
- constipation
- diarrhea
- loss of appetite
- headache
- weight gain
- sexual problems (decreases in sexual desire, performance and satisfaction, and may also lead to further decreases, which may continue after the drug is stopped)
- skin rash or hives alone.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Hallucinations: seeing and hearing things that are not really there		✓	
Urinary retention (inability to pass urine or to empty the bladder): pain Urinary incontinence (involuntary loss of urine)		✓	
Dilated pupils		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Hypotension (low blood pressure): dizziness, light-headedness or fainting when standing up from a sitting down or lying position.		✓	
Mania: elevated or irritable mood, decreased need for sleep, racing thoughts, overactive behaviour and thoughts.		✓	
Seizures (fits): uncontrollable shaking with or without loss of consciousness.			✓
Oedema: swelling of hands, ankles or feet.		✓	
RARE			
Thrombocytopenia (low platelets): bruising or unusual bleeding from the skin or other areas, bleeding for longer than usual if you hurt yourself, fatigue and weakness.		✓	
Hyponatremia (low sodium in blood): tiredness, weakness, muscle twitching, confusion combined with achy, stiff or uncoordinated muscles.		✓	
Akathisia (a type of movement disorder): feeling restless, unable to sit or stand still.		✓	
Gastrointestinal bleeding (bleeding in the stomach or bowels): vomiting blood or passing black, tarry stool, blood in the stool.			✓
Liver disorder: nausea, vomiting, loss of appetite combined with itching, yellowing of the skin or eyes, dark urine.		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Photosensitivity (sensitivity to sunlight): itchy, red skin when exposed to sunlight.	✓		
Angle-closure Glaucoma (eye condition that can cause damage to the optic nerve): increased pressure in your eyes, sudden eye pain, eye and head pain, swelling or redness in or around the eye, hazy or blurred vision, sudden loss of sight.			✓
VERY RARE			
Severe skin reactions (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis, Erythema multiform): any combination of itchy skin rash, redness, blistering and peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands, joint pain, yellowing of the skin or eyes, dark urine.			✓
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.			✓
UNKNOWN			
Uncontrollable movements of the body or face.		✓	
Restless Legs Syndrome: irresistible urge to move the legs.		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Menstrual period disorders: heavy periods, bleeding between periods and absence of periods.		✓	
Serotonin Toxicity 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.			✓
Increase in the hormone prolactin: In women: breast discomfort, leakage of milk from the breasts, missed periods, or other problems with your menstrual cycle In men: decreased body and facial hair, breast swelling, leakage of milk from the breasts, difficulty in getting or maintaining erections, or other sexual dysfunction.		✓	
Changes in feelings or behaviour: anger, anxiety or violent thoughts		✓	
Suicide: thoughts or actions about hurting or killing yourself			✓

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 healthproducts 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 out of reach and sight of children.
- Store at room temperature (15-30°C) in a dry place.
- Keep container tightly closed.
- If your health care professional tells you to stop taking MAR-PAROXETINE please return any leftover medicine to your pharmacist.

If you want more information about MAR-PAROXETINE:

- 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://health.products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website www.marcanpharma.com, or by calling 1-855-627-2261. You may need to read this package insert again. Please do not throw it away until you have finished your medicine.

This leaflet prepared by Marcan Pharmaceuticals Inc.

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