PRESCRIBING INFORMATION

PrMETHOPRAZINE

Methotrimeprazine Maleate Tablets

2 mg, 5 mg, 25 mg and 50 mg

House Standard

Neuroleptic

AA PHARMA INC.
1165 Creditstone Road, Unit#1
Vaughan, Ontario
L4K 4N7

DATE OF PREPARATION:
August 31, 2012

Control Number: 053783, 158247

PRESCRIBING INFORMATION

[Pr]METHOPRAZINE
Methotrimeprazine Maleate Tablets
2 mg, 5 mg, 25 mg and 50 mg

THERAPEUTIC CLASSIFICATION

Neuroleptic

ACTIONS AND CLINICAL PHARMACOLOGY

Methotrimeprazine possesses antipsychotic, tranquilizing, anxiolytic, sedative and analgesic properties and it is also a potent potentiator of anesthetics.

Methotrimeprazine possesses strong sedative properties. It potentiates ether and hexobarbital anesthesia as well as morphine analgesia. It also exerts a potent anti-apomorphine effect, a hypothermic action 3 times more potent than that of chlorpromazine and strong antispasmodic and anti-histaminic effects. Methotrimeprazine is capable of reversing epinephrine-induced hypertension but has practically no effect against norepinephrine and acetylcholine. It readily protects rats against traumatic shock and produces deep local anesthesia following parasciatic injections.

Comparative Bioavailability

A comparative bioavailability study was performed using healthy human volunteers. The rate and extent of absorption of methotrimeprazine were measured and compared following a single oral 25 mg dose of METHOPRAZINE or Nozinan. The results from measured data are summarized as follows:

Summary Table of the Comparative Bioavailability Data
Methotrimeprazine Tablets (Dose: 25 mg)
From Measured Data

Parameter	Geometric Mean Arithmetic Mean (CV%) METHOPRAZINE	Geometric Mean Arithmetic Mean (CV%) Nozinan®†	Ratio of Geometric Means (%)
AUC_T (ng·hr/mL)	26.9 40.5 (87)	27.9 41.1 (80)	96.4
AUC_I (ng·hr/mL)	34.3 47.3 (82)	35.1 47.1 (73)	97.7
C_{max} (ng/mL)	3.44 4.66 (76)	3.67 4.96 (73)	93.7
T_{max} (h)*	2.96 (26)	2.73 (33)	--
$t_{1/2}$ (h)*	10.8 (49)	10.3 (49)	--

* Arithmetic means only (CV%).
† Nozinan® (Rhône-Poulenc Rorer Inc.) was purchased at a Canadian retail pharmacy.

INDICATIONS AND CLINICAL USE

Psychotic disturbances: acute and chronic schizophrenias, senile psychoses, manic-depressive syndromes.

Conditions associated with anxiety and tension: autonomic disturbances, personality disturbances, emotional troubles secondary to such physical conditions as resistant pruritus, etc.

As an analgesic: In pain due to cancer, zona, trigeminal neuralgia and neurocostal neuralgia and in phantom limb pains and muscular discomforts.

As a potentiator of anesthetics: In general anesthesia where it can be used as both a pre- and post-operative sedative and analgesic.

As an anti-emetic: For the treatment of nausea and vomiting of central origin.

As a sedative: For the management of insomnia.

CONTRAINDICATIONS

METHOPRAZINE (methotrimeprazine maleate) is contraindicated in cases of coma or CNS depression due to alcohol, hypnotics, analgesics or narcotics.

It is also contraindicated in patients with blood dyscrasia, hepatic troubles or a sensitivity to phenothiazines.

WARNINGS

Occupational Hazards: Methotrimeprazine can reduce psychomotor activity especially during the first few days of treatment. Patients should therefore be cautioned not to drive a motor vehicle or to participate in activities requiring total mental alertness.

Non-Teratogenic Effects: Neonates exposed to antipsychotic drugs (including METHOPRAZINE) during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress and feeding disorder in these neonates. These complications have varied in severity; while in some cases symptoms have been self-limited, in other cases neonates have required intensive care unit support and prolonged hospitalization.

METHOPRAZINE should not be used during pregnancy unless the expected benefits to the mother markedly outweigh the potential risks to the fetus.

PRECAUTIONS

In high oral doses, orthostatic hypotension may be encountered at the start of treatment. Patients whose treatment is started with high oral doses should be kept in bed during the first few days.

METHOPRAZINE (methotrimeprazine) therapy should be initiated at low doses in patients with arteriosclerosis or cardiovascular problems.

Methotrimeprazine potentiates the action of other phenothiazines and CNS depressants (barbiturates, analgesics, narcotics and antihistaminics). The usual doses of these agents should be reduced by half if they

are to be given concomitantly with methotrimeprazine until the dosage of the latter has been established.

Because of its anticholinergic effects, methotrimeprazine must be administered with caution in patients with glaucoma or prostatic hypertrophy.

During long-term therapy, periodic liver function tests should be performed. In addition, blood counts should be conducted regularly, particularly during the first 2 or 3 months of treatment, and physicians should watch for any signs of blood dyscrasia.

Methotrimeprazine does not alter EEG activity. Nevertheless, since phenothiazines can lower the threshold of cortical excitation, it is advisable to administer an appropriate anticonvulsant medication to epileptic patients receiving METHOPRAZINE therapy.

Endocrine and Metabolism:

Hyperglycemia: Diabetic ketoacidosis (DKA) has occurred in patients with no reported history of hyperglycemia. Patients should have baseline and periodic monitoring of blood glucose and body weight.

Hyperprolactinemia: Long-standing hyperprolactinemia when associated with hypogonadism may lead to decreased bone mineral density in both female and male subjects.

Genitourinary: Rare cases of priapism have been reported with antipsychotic use, such as METHOPRAZINE. This adverse reaction, as with other psychotropic drugs, did not appear to be dose-dependent and did not correlate with the duration of treatment.

Venous thromboembolism (VTE), including fatal pulmonary embolism, has been reported with antipsychotic drugs, including METHOPRAZINE, in case reports and/or observational studies. When prescribing METHOPRAZINE all potential risk factors for VTE should be identified and preventative measures undertaken.

ADVERSE REACTIONS

Neutropenia, granulocytopenia and agranulocytosis have been reported during antipsychotic use. Therefore,

it is recommended that patients have their complete blood count (CBC) tested prior to starting METHOPRAZINE and then periodically throughout treatment.

Patients should be advised of the risk of severe constipation during METHOPRAZINE treatment, and that they should tell their doctor if constipation occurs or worsens, as they may need laxatives.

May be classified as follows:

CNS: Drowsiness may appear early in treatment but will gradually disappear during the first weeks or with an adjustment in the dosage.

Extrapyramidal effects are rare and usually appear only after prolonged therapy at high doses. These reactions may be corrected either by reducing the dose of METHOPRAZINE (methotrimeprazine) or by administering an antiparkinsonian agent.

Autonomic Nervous System: Dryness of the mouth and, in older patients occasional urinary retention, constipation and tachycardia.

Cardiovascular: Orthostatic hypotension may be encountered at the start of treatment with high oral doses.

Blood: Rare instances of agranulocytosis have been reported.

Endocrine: Weight gain has been occasionally reported in patients during prolonged treatment with high doses.

Gastrointestinal: Rare cases of cholestatic jaundice without liver damage have been observed.

Skin Reactions: Skin reactions due to photosensitivity or allergies are extremely rare.

SYMPTOMS AND TREATMENT OF OVERDOSAGE

For management of a suspected drug overdose, contact your regional Poison Control Centre.

Symptoms of acute intoxication may include simple CNS depression, spasms, tremor or tonic and clonic

convulsions, coma accompanied by hypotension and respiratory depression.

There is no specific antidote. After gastric lavage, treatment is symptomatic. Centrally acting emetics are ineffective because of the anti-emetic action of methotrimeprazine.

Hypotension: A 5% glucose solution may be administered. If a hypertensive agent is required, norepinephrine or phenylephrine may be used, but **not** epinephrine which can aggravate hypotension.

Respiratory infection: Oxygen by inhalation or controlled respiration after tracheal intubation.

Respiratory infection: Wide spectrum antibiotics.

Extrapyramidal reactions: An antiparkinsonian agent or chloral hydrate, however the latter must be used with caution because of its depressant effect of respiration.

Any CNS stimulant should be used with caution.

DOSAGE AND ADMINISTRATION

Dosage must be adjusted according to the indication and individual needs of the patient. If sedation during the day is too pronounced, lower doses may be given during the day and higher doses at night.

Adults

Minor conditions in which methotrimeprazine may be given in low doses as a tranquilizer, anxiolytic, analgesic or sedative: begin treatment with 6 to 25 mg/day in 3 divided doses at mealtimes. Increase the dosage until the optimum level has been reached. As a sedative, a single night time dose of 10 to 25 mg is usually sufficient.

Severe Conditions: Such as pyschoses or intense pain in which methotrimeprazine is employed at higher doses: Begin treatment with 50 to 75 mg/day divided into 2 or 3 daily doses; increase the dosage until the desired effect is obtained. In certain psychotics, doses may reach 1 g or more/day. If it is necessary to start therapy with higher doses, i.e., 100 to 200 mg day, administer the drug in divided daily doses and keep the patient in bed for the first few days.

Children

The initial dose has been established at 1/4 mg/kg daily in 2 or 3 divided doses. This dosage may be increased gradually until an effective level is reached which should not surpass 40 mg/day for a child less than 12 years of age.

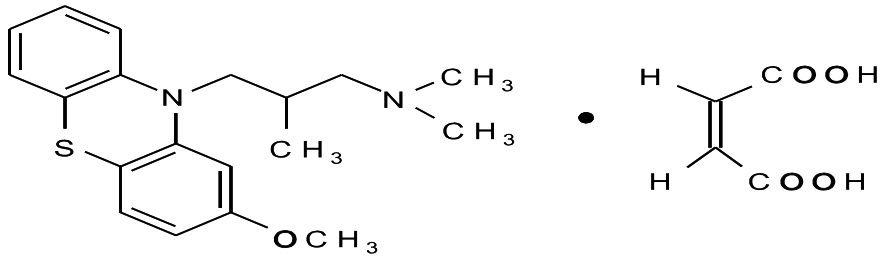
PHARMACEUTICAL INFORMATION

Drug Substance

Proper Name: methotrimeprazine maleate

Chemical Name: (1)10*H*-phenothiazine-10-propanamine, 2-methoxy-*N,N,β*-trimethyl-, (-)- maleate
(2) (-)-10-[3-(dimethylamino)-2-methylpropyl]-2- methoxyphenothiazine maleate

Structural Formula:



Molecular Formula: $C_{19}H_{24}N_2OS \bullet C_4H_4O_4$

Molecular Weight: 444.6

Description: Methotrimeprazine is a fine, white, practically odorless, crystalline powder which melts at about 126°C. It is practically insoluble in water; freely soluble in chloroform and in ether; sparingly soluble in methanol. It is sparingly soluble in alcohol at 25°C, but is freely soluble in boiling alcohol.

Stability and Storage Recommendations

Store at room temperature 15 to 30°C. Protect from light. Keep blisters in carton.

AVAILABILITY OF DOSAGE FORMS

METHOPRAZINE 2 mg: Each yellow, round, biconvex, film-coated tablet engraved '2' on one side, contains methotrimeprazine maleate equivalent to 2 mg of methotrimeprazine. Available in bottles of 100 and 500 and unit dose packages of 30 and 100.

METHOPRAZINE 5 mg: Each yellow, round, biconvex, film-coated tablet engraved `5' on one side, contains methotrimeprazine maleate equivalent to 5 mg of methotrimeprazine. Available in bottles of 100 and 500 and unit dose packages of 30 and 100.

METHOPRAZINE 25 mg: Each yellow, round, biconvex, film-coated tablet engraved `25' on one side, contains methotrimeprazine maleate equivalent to 25 mg of methotrimeprazine. Available in bottles of 100 and 500 and unit dose packages of 30 and 100.

METHOPRAZINE 50 mg: Each yellow, round, biconvex, film-coated tablet engraved `50' on one side, contains methotrimeprazine maleate equivalent to 50 mg of methotrimeprazine. Available in bottles of 100 and 500 and unit dose packages of 30 and 100.

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PART III: CONSUMER INFORMATION

PrMETHOPRAZINE
Methotrimeprazine Maleate Tablets

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

ABOUT THIS MEDICATION

What the medication is used for:

METHOPRAZINE is used for:

- Mental illnesses including schizophrenia, disorders in the elderly, manic-depressive syndromes
- Conditions associated with anxiety and tension
- Pain due to cancer, shingles, trigeminal neuralgia, neurocostal neuralgia, phantom limb pains and muscular discomforts
- Before and after surgery as a sedative and to control pain
- Nausea and vomiting
- Insomnia.

What it does:

METHOPRAZINE is an antipsychotic medication which affects chemicals in the brain that allow communication between nerve cells (neurotransmitters). These chemicals are called dopamine and serotonin. Exactly how METHOPRAZINE works is unknown. However, it seems to readjust the balance of dopamine and serotonin.

When it should not be used:

You should not use METHOPRAZINE if you have:

- An allergy to methotrimeprazine maleate, to any of its ingredients or to phenothiazines
- A medical condition known as pheochromocytoma (a tumor of the adrenal gland)
- A severe heart or blood vessel disorder
- Severe kidney problems
- Had brain damage
- Liver disease
- A blood cell disorder such as anemia, low white blood cell counts, or low platelets
- Drowsiness, slow breathing, weak pulse
- Decreased alertness caused by taking certain medications or drinking alcohol
- You are going to receive anesthesia in the spine or for a region (such as an arm, leg or the lower part of your body)

What the medicinal ingredient is:

Methotrimeprazine Maleate

What the nonmedicinal ingredients are:

Carnauba wax, colloidal silicon dioxide, corn starch, d & c yellow #10 aluminum lake 16% (2 mg), d & c yellow aluminum lake 14-18% (5 mg, 25 mg and 50 mg), hydroxypropyl cellulose, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, purified water, sunset yellow aluminum lake 40%, titanium dioxide.

What dosage forms it comes in:

Tablets: 2 mg, 5 mg, 25 mg and 50 mg

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Studies with various medicines of the group to which METHOPRAZINE belongs, when used in the elderly patients with dementia, have been associated with an increased rate of death. METHOPRAZINE is not indicated in elderly patients with dementia.

BEFORE you use METHOPRAZINE talk to your doctor or pharmacist if:

- You have heart disease, glaucoma or prostatic hypertrophy
- You are addicted to alcohol. You should not take METHOPRAZINE if you are under the effects of alcohol.
- You are pregnant. METHOPRAZINE should not be used during pregnancy unless your doctor considers the benefits to you markedly outweigh the potential risks to the fetus
- You are taking barbiturates, painkillers , narcotics or, antihistamines or other drugs that make you drowsy.
- You have any allergies to this drug or its ingredients
- You have or ever had a blackout or seizure
- You are breast feeding.
- If you are at risk for developing blood clots such as: age over 65, smoking, obesity, recent major surgery (such as hip or knee replacement), immobility due to air travel or other reason, take oral contraceptives ("The Pill").

METHOPRAZINE may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery, especially during the first few days of therapy. You should be cautious when performing potentially hazardous tasks.

Effects on Newborns:
In some cases babies born to a mother taking METHOPRAZINE during pregnancy have experienced symptoms that are severe and require the newborn to be hospitalized. Sometimes, the symptoms may resolve on their own. Be prepared to seek immediate emergency medical attention for your newborn if they have difficulty breathing, are overly sleepy, have muscle stiffness, or floppy muscles (like a rag doll), are shaking, or are having difficulty feeding.

People who take METHOPRAZINE are cautioned:

- Against exposure to extreme heat
- That drugs such as METHOPRAZINE increase the toxicity of certain types of insecticides ("organophosphorous" insecticides) including insecticides for agriculture (farming), treating animals (flea and tick control) and for treating pests around the house and garden. Be cautious if you must use these products while taking METHOPRAZINE.

INTERACTIONS WITH THIS MEDICATION

METHOPRAZINE can add to the effects of alcohol. You should avoid consuming alcoholic beverages while on METHOPRAZINE therapy.

Tell your doctor about all your prescription and over-the-counter medications, vitamins, minerals, herbal products (such as St. John's Wort), and drugs prescribed by other doctors. Do not start a new medication without telling your doctor.

Before using METHOPRAZINE, tell your doctor if you regularly use other medicines that make you sleepy (such as cold or allergy medicine, narcotic pain medicine, sleeping pills, muscle relaxants, and medicine for seizures, depression, or anxiety). You should not take METHOPRAZINE if you have drowsiness caused by other medications.

Drugs that may interact with METHOPRAZINE include:
anti-anxiety agents, antidepressants, muscle relaxants, anti-seizure medicine, high blood pressure medicine, cabergoline, metrizamide, guanethidine, guanadrel, grepafloxacin, sparfloxacin, lithium, cisapride, atropine-like drugs, narcotic pain relievers (e.g., codeine), drugs used to aid sleep, drowsiness-causing antihistamines (e.g., diphenhydramine), other drugs that may make you drowsy.

Many cough-and-cold products contain ingredients that may add a drowsiness effect. Before using cough-and-cold medications, ask your doctor or pharmacist about the safe use of those products. Do not start or stop any medicine without doctor or pharmacist approval.

This list is not complete and there may be other drugs that can interact with METHOPRAZINE.

PROPER USE OF THIS MEDICATION

Take this medication by mouth exactly as prescribed. During the first few days your doctor may gradually increase your dose to allow your body to adjust to the medication. Do not take this more often or increase your dose without consulting your doctor. Your condition will not improve any faster but the risk of serious side effects will be increased. Do not stop taking this drug suddenly without your doctor's approval.

Your doctor will decide which dose is best for you.

Usual dose:

Adults
Minor conditions: begin with 6 to 25 mg/day in 3 divided doses at mealtimes. The dose will be gradually increased until your symptoms are controlled. For insomnia: a single night time dose of 10 to 25 mg can be used.

Severe Conditions: Begin with 50 to 75 mg/day divided into 2 or 3 daily doses. The dose will be gradually increased until your symptoms are controlled. In some cases, doses may reach 1 g or more/day. If it is necessary to start therapy with higher doses, i.e., 100 to 200 mg day, you will be required to stay in bed for the first few days.

Children
The initial dose is 1/4 mg/kg daily in 2 or 3 divided doses. The dose may be increased gradually until your child's symptoms are well controlled. The dose should not be more than 40 mg/day for a child less than 12 years of age.

If you or your child are too sedated during the day, a lower dose during the day can be given and a higher dose at night.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Overdose symptoms may include agitation, and confusion, drowsiness, dizziness, muscle stiffness or twitching, increased salivation, trouble swallowing, weakness, loss of balance or coordination, and fainting.

Missed Dose:
Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take extra medicine to make up the missed dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like other medications, METHOPRAZINE may cause some side effects. These side effects may be minor and temporary. However, some may be serious and need medical attention.

Side effects may include: sweating, urinary incontinence, dizziness, drowsiness, dry mouth, nasal congestion, nausea and vomiting, headache, sensitivity of the skin to the sun, menstrual changes, change in libido, swelling of the breasts and milk production in both men and women, weight changes and blurred vision.

If any of these affects you severely, tell your doctor.

Your doctor should check your body weight before starting METHOPRAZINE and continue to monitor it for as long as you are being treated.

Your doctor should take blood tests before starting METHOPRAZINE. They will monitor blood sugar, and the number of infection fighting white blood cells. Your doctor should continue to monitor your blood for as long as you are being treated.

If you have high levels of prolactin (measured with a blood test) and a condition called hypogonadism you may be at increased risk of breaking a bone due to osteoporosis. This occurs in both men and women.

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

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Unknown	**Allergic Reaction:** rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
	Neuroleptic Malignant Syndrome: any group of symptoms which may include high fever, sweating, stiff muscles, fast heartbeat, fast breathing and feeling confused, drowsy or agitated			✓
	Extrapyramidal Symptoms: muscle stiffness, body spasms, upward eye rolling, exaggeration of reflexes, drooling, difficulty moving how and when you want.			✓
	Fast or irregular heartbeat			✓
	Seizures or fits			✓

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

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek
	Long-lasting (greater than 4 hours in duration) and painful erection of penis			✓
	Tardive Dyskinesia: uncontrollable movements or twitches of the body, face, eyes or tongue, stretching the neck and body		✓	
	Low Blood Pressure: feeling of Lightheadedness or fainting especially when getting up from a lying or sitting position		✓	
	High Blood Pressure: headaches, vision disorders, nausea and vomiting		✓	
	Decreased sweating		✓	
	Jaundice: yellow colour to skin and eyes, dark urine		✓	
	Respiratory Infection: fever, flu-like symptoms, coughing, difficult or fast breathing		✓	
	New or worsening constipation		✓	
	Akathisia: a feeling of restlessness, inability to remain motionless		✓	
	Vision Changes: blurred vision, glaucoma or other eye disorder		✓	
	Increased Blood Sugar: frequent urination, thirst and hunger	✓		
	Inability to Urinate		✓	

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

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek
	Blood clots: swelling, pain and redness in an arm or leg that can be warm to touch. You may develop sudden chest pain, difficulty breathing and heart palpitations.		✓	

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

HOW TO STORE IT

Store at room temperature 15 to 30ºC. Protect from light. Keep blisters in carton.

Keep this and all medications out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

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1. Report online at www.healthcanada.gc.ca/medeffect
2. Call toll-free at 1-866-234-2345
3. Complete a Canada Vigilance Reporting Form and:
   - Fax toll-free to 1-866-678-6789, or
   - Mail to: Canada Vigilance Program
     Health Canada
     Postal Locator 0701E
     Ottawa, Ontario
     K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your doctor, pharmacist or other healthcare professional.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting the sponsor, AA-Pharma Inc. at:

1-866-469-1297

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