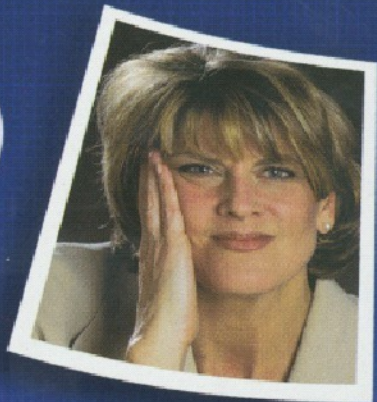


R<sub>x</sub> Only  
**Pamine<sup>®</sup>**  
**Forte 5 mg**  
(methscopolamine bromide)

**Dose Pack**

Antispasmodic  
Anticholinergic  
Therapy



**DO YOU  
SUFFER  
FROM**

- ABDOMINAL PAIN?**
- CRAMPING?**
- DIARRHEA?**
- BLOATING and GAS?**

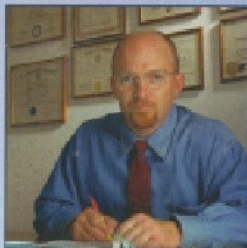
## Stop Suffering – Start Living Again

**If** you are suffering from abdominal pain and cramping, diarrhea, bloating and gas, it is often hard to maintain a normal lifestyle. Work attendance can suffer, leisure activities may be curtailed and vacations can become something to dread. However, you are not alone. Approximately 20% to 40% of all visits to



gastroenterologists are due to symptoms such as these. Now that you have sought medical attention, following your doctor's instructions can help you manage your symptoms and start living again!

As you follow your doctor's treatment regimen and advice, remember to monitor your symptoms and report any changes to your physician. Symptoms such as weight loss, black stools, rectal bleeding, awakening from sleep with pain or a need to move your bowels should be discussed with your doctor immediately.



## Why do I feel so much abdominal pain?

If you are suffering from an intestinal problem, the nerves and muscles in your bowel, or large intestine, may be hypersensitive. When you eat, or when you are under stress, the muscles of your bowel may cause painful spasms, which may result in cramping and diarrhea shortly after a meal or during times of high stress or anxiety.

## Can altering my diet help me feel better?

Certain foods can be associated with pain, diarrhea, bloating and gas.

## Foods that may sometimes trigger symptoms include but are not limited to:

- Dairy products (may be caused by an intolerance to lactose)
- Chocolate                      ■ Fatty foods
- Coffee/tea/caffeinated beverages
- Alcohol                         ■ Carbonated beverages
- Sorbitol\*-containing foods such as
  - Sugarless mints and chewing gum
  - Baked goods and baking mixes
  - Red and white wine

\* Sorbitol is found in many fruits, including cherries, plums, pears and peaches, and is a common sweetening agent in many "sugar-free" foods.

## What can I do to help control my symptoms?

Keep a diary of which foods cause the most problems. Knowing which foods trigger symptoms can help you modify your diet and may result in an improvement of your symptoms. You may want your doctor to check for lactose intolerance.

Lactose intolerance is an inability to break down lactose, the sugar found in milk and dairy products.



*It's wonderful to enjoy a day without worrying about a flare-up of pain and diarrhea*

This occurs when your intestine does not have lactase, the enzyme that digests lactose. Lactose intolerance may contribute to cramping, nausea, diarrhea, gas and abdominal rumblings.

The doctor can test your breath to determine if you are lactose intolerant. However, if you are curious, you might try this simple at-home test. First, avoid milk and all dairy products for several days. Then, drink two large glasses of skim or low-fat milk. If you develop abdominal discomfort or diarrhea within a few hours, it is likely that you are lactose intolerant. Make an appointment with your doctor for tests.



High-fiber foods have been associated with increased GI comfort. However, it is a good idea to increase fiber in your diet gradually, by adding one or two of the recommended foods listed below into your diet, and eating small portions of these items. It is important to increase fiber slowly since adding too much fiber too quickly can cause more gas and more abdominal discomfort. Always consult with your doctor before starting a high-fiber diet.

### High-fiber foods include:

- Apples
- Peaches



- Broccoli
- Carrots
- Prunes
- Kidney beans
- Brown rice
- Whole-grain cereals and breads



Doctors recommend that adults drink eight 8 oz. glasses of water a day. You may substitute juice or herbal tea, but it is a good idea to avoid soda, alcohol, coffee and caffeinated beverages.



## How should I keep track of my symptoms?

It is beneficial to keep a diary of your symptoms. Record how you feel and what you are doing at the time. Note what you eat (such as chocolate cake), drink (coffee or alcohol, for example) and any stress you may be experiencing. This record will help you and your physician manage your



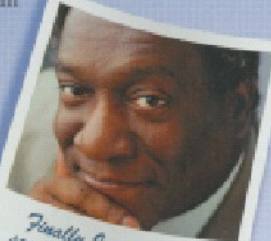
symptoms by recognizing what foods, beverages or situations may trigger your discomfort.

Generally, a large meal may trigger symptoms. Limit the size of your portions. Using a smaller plate, eating slowly and not going back for seconds may reduce your symptoms. Should you continue to experience cramping and diarrhea, six small meals per day rather than three regular to large size meals has been helpful for many patients.



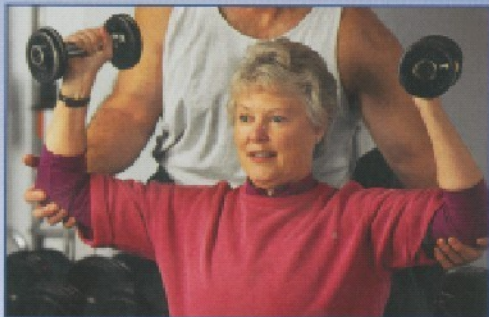
## Why do my symptoms get worse when I feel stressed?

A hypersensitive bowel can react to emotional stress. Stress reduction techniques such as meditation, yoga and exercise may help you manage the severity and frequency of your symptoms.



*Finally I can enjoy a social life without severe abdominal pain getting in the way.*

Exercise promotes a sense of well-being and also helps relieve stress. Choose walking, dancing, swimming or bike riding, but always check with your doctor before beginning an exercise regimen.



Rx Only  
**Pamine®  
Forte 5 mg**  
(methscopolamine bromide)

Your doctor may recommend **Pamine® Forte 5 mg** (methscopolamine bromide) to relieve your symptoms of:

**Dose Pack**

- ABDOMINAL PAIN
- CRAMPING
- DIARRHEA
- BLOATING and GAS

## How does Pamine® Forte 5 mg help my symptoms?

Pamine® Forte 5 mg is a prescription antispasmodic/anticholinergic that works as follows:

1. Relaxes the muscles of the bowel to help reduce muscle tightness and spasms to relieve pain
2. Relaxes muscles to help reduce bloating and feelings of fullness
3. Reduces intestinal contractions and the secretions in the bowel and may relieve loose bowels and diarrhea
4. Alleviates bowel urgency and lessens the number of bathroom visits



## How often do I take Pamine<sup>®</sup> Forte 5 mg?

Your doctor will tailor a dosage regimen to meet your needs. Knowing what triggers your symptoms and communicating this to your doctor will help both of you better control your symptoms.



## Summary of tips for reducing GI discomfort

1. Eat a balanced diet and avoid foods that trigger discomfort.
2. Keep a diary of your symptoms to help you learn which foods and drinks or stressors trigger your symptoms.
3. Try stress management techniques.
4. Exercise regularly.
5. Keep in touch with your doctor and follow his/her instructions.

## An example of a daily diary

### Sample Page

Fill out a section each time you suffer with symptoms, noting the information as shown in the following example.

This will help you to identify foods or situations that trigger your symptoms.

Symptoms	Date and Time	Recent Food and Drink	Stresses/Activities	Recent Exercise
Stomach pain and cramping	Monday: 8:30 a.m. to around noon	Corn flakes with milk	9:00 a.m. meeting at the office	Saturday morning at health club
Stomach ache and gas	Tuesday all evening	Fried chicken and brussels sprouts	Had to work late to finish a report	Missed opportunity to go to health club

## Your daily diary

Symptoms	Date and Time	Recent Food and Drink	Stresses/Activities	Recent Exercise

R<sub>x</sub> Only

# Pamine<sup>®</sup> Forte 5 mg

(methscopolamine bromide)

R<sub>x</sub> Only

# Pamine<sup>®</sup>

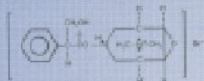
(methscopolamine bromide)

## 2.5 mg

**DESCRIPTION:** Pamine<sup>®</sup> 2.5 mg/Pamine<sup>®</sup> Forte 5 mg Tablets contain methscopolamine bromide, an anticholinergic, when used as an antispasmodic, or as an atropine substitute, powder. Methscopolamine bromide melts at about 220° C with decomposition. The drug is freely soluble in water, slightly soluble in alcohol, and practically insoluble in acetone and in benzene.

The chemical name for methscopolamine bromide is 3-(3,4-diacetyloxyphenyl)-1,1,1-trifluoro-7,8-dihydro-7-oxo-5-phenylpropyl-2,4-dihydroxy-bromide, (7,8)-(±, 2S, 4S, 5S, 7R) and the molecular weight is 398.32.

The structural formula is represented below:



Pamine<sup>®</sup> 2.5 mg Tablets for oral administration contain 25 mg of methscopolamine bromide. Pamine<sup>®</sup> Forte 5 mg Tablets for oral administration contain 5 mg of methscopolamine bromide.

**Inactive ingredients:** microcrystalline cellulose, polyvinylpyrrolidone, magnesium stearate.

**Contains no latex.**

**CLINICAL PHARMACOLOGY:** Methscopolamine bromide is an anticholinergic agent which possesses most of the pharmacologic actions of the drug class. These include reduction in volume and force and content of gastric secretion, inhibition of gastrointestinal motility, inhibition of salivary secretion, dilation of the pupil and inhibition of accommodation with resulting blurring of vision. Large doses may result in tachycardia.

**PHARMACOKINETICS:** Methscopolamine bromide is a quaternary ammonium derivative of atropine. As a class, these agents are poorly and unevenly absorbed.<sup>1-3</sup> Total absorption of quaternary ammonium derivatives of the atropine is 50-80%. Rate of absorption is not available. Quaternary ammonium salts have limited absorption from intact skin, and cumulative concentration is poor.<sup>4</sup> Little is known of the fate and excretion of most of these agents.<sup>5</sup> Following oral administration, drug effects appear in about one hour and persist for 8 to 8 hours.<sup>6</sup> Methscopolamine bromide has limited ability to cross the blood-brain barrier.<sup>7-9</sup> The drug is excreted primarily in the urine and bile, or as unabsorbed drug in feces.<sup>10</sup> There is no data on the presence of methscopolamine in breast milk; traces of atropine have been found after administration of amipril.<sup>11</sup>

**INDICATIONS AND USAGE:** Adjunctive therapy for the treatment of peptic ulcer.

ANTICHOLINERGIC DRUGS HAS NOT BEEN SHOWN TO BE EFFECTIVE IN CONTRIBUTING TO THE HEALING OF PEPTIC ULCER, DECREASING THE RATE OF RECURRENCE, OR PREVENTING COMPLICATIONS.

**CONTRAINDICATIONS:** Glaucoma, obstructive uropathy (e.g., bladder neck obstruction due to prostatic hypertrophy), obstructive disease of the gastrointestinal tract (e.g., pylorospasm, stenosis), paralytic ileus, residual atony of the colon in operated patient, unstable cardiovascular system or acute hemorrhage, severe cardiac failure, renal impairment, concomitant administration with: myasthenia gravis.

**Pamine<sup>®</sup> 2.5 mg/Pamine<sup>®</sup> Forte 5 mg** is contraindicated in patients who are hypersensitive to methscopolamine bromide or related drugs.

**WARNINGS:** In the presence of high environmental temperature, heat prostration (heat and heat stroke due to decreased sweating) may occur with drug use.

Dizziness may be an early symptom of incomplete intestinal absorption, especially in patients with ileostomy or resection. In this instance treatment with this drug would be inappropriate and possibly harmful.

Methscopolamine bromide may produce drowsiness or blurred vision. The patient should be cautioned regarding activities requiring mental alertness such as operating a motor vehicle or other machinery or performing hazardous work while taking this drug. With overdosage, a curare-like action may occur, i.e., neuromuscular blockade leading to muscle weakness and possible paralysis.

#### PRECAUTIONS

##### 1. General precautions

Use Pamine<sup>®</sup> 2.5 mg/Pamine<sup>®</sup> Forte 5 mg Tablets with caution in the elderly and in all patients with systemic neuropathy, prostatic or renal disease, or obstructive uropathy. Large doses may suppress reflexion activity in the event of producing a paralytic ileus and for this reason symptoms of aggrivated toxic megacolon,<sup>12</sup> a serious complication of the disease.

The drug also should be used with caution in patients having hypertension, coronary heart disease, congestive heart failure, tachycardia, tachyarrhythmia, hypernatremia, or prostatic hypertrophy.

##### 2. Information for patient (See statement under WARNINGS)

**3. Laboratory tests:** Progress of the peptic ulcer under treatment should be followed by upper gastrointestinal contrast radiology or endoscopy to insure healing. Stool tests for occult blood and blood hemoglobin or hematocrit values should be followed to rule out bleeding from the ulcer.

**4. Drug Interactions:** Additive anticholinergic effects may result from concurrent use with antipsychotics, tricyclic antidepressants, and other drugs with anticholinergic effects. Concurrent administration with antacids may interfere with the absorption of methscopolamine bromide.

**5. Contraception, sterility, impairment of fertility:** No long-term studies in animals have been performed to evaluate contraceptive potential.

##### 6. Pregnancy

**Teratogenic effects:** Pregnancy Category C. Animal reproduction studies have not been conducted with methscopolamine bromide. It also is not known whether methscopolamine bromide can cause fetal harm when administered to a pregnant woman or

can affect reproductive capacity. Methoxycarbonyl levamisole should be given to a pregnant woman only if clearly needed.

**2. Nursing mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when methoxycarbonyl levamisole is administered to a nursing woman. Anticancer drugs may suppress lactation.

**3. Pediatric use:** Safety and efficacy in children have not been established.

#### ADVERSE REACTIONS

The following adverse reactions have been observed, but there is not enough data to support an estimate of frequency.

**Cardiovascular:** Tachycardia, palpitation.

**Allergic:** Fever, allergic reactions or drug hypersensitivity including angioedema.

**CNS:** Headache, drowsiness, mental confusion, dizziness, ataxia.

**Special Senses:** Blurred vision, dilation of the pupil, mydriasis, increased visual evoked, loss of vision.

**Genit. Urinary:** Irritation and infection.

**Gastrointestinal:** Nausea, vomiting, constipation, ileated stool.

**Dermatologic:** Decreased sweating, ulcers, and other dermal manifestations.

**Musculoskeletal:** Myalgia, weakness, incoordination, myelomalacia, suppression of lactation.

**ORGAN RESERVE AND DEPENDENCE:** No evaluation.

**OVERDOSEAGE:** The symptoms of overdosage with **Pharmane<sup>®</sup> 3.3 mg Tablets** or **Pharmane<sup>®</sup> Forte 4 mg Tablets** progress from stimulation of the usual side effects to CNS stimulation from restlessness and excitement to psychotic behavior, circulatory changes (flushing, fall in blood pressure, circulatory failure), respiratory failure, paralysis, and coma.

Measures to be taken are: (1) induction of emesis and (2) injection of physostigmine 0.5 to 2 mg intravenously and repeated as necessary up to a total of 5 mg. Fever may be treated symptomatically (alcohol sponging, ice packs). Establishment of a degree of analgesia sufficient to manage pain may be managed with suitable intravenous analgesic given slowly intravenously or intrathecally (100-200 µg of a 2% solution) by spinal infusion. In the event of progression of the curare-like effect to paralysis of the respiratory tract, artificial respiration should be instituted and maintained until reflexive respiratory action returns.

The oral LD<sub>50</sub> in rats is 1,380 to 2,817 mg/kg. No data is available on the stability of methoxycarbonyl levamisole.

**DOSEAGE AND ADMINISTRATION:** The average dosage of **Pharmane<sup>®</sup> Tablets** is 2.5 mg one-half hour before meals and at bedtime. A starting dose of 12.5 mg daily will be clinically effective in most patients without the production of appreciable side effects.

If the patient is experiencing symptoms such as dizziness, drowsiness or ataxia which demand prompt relief, the drug may be stopped on a daily dosage of 25 mg administered in doses of 5 mg one-half hour before meals and at bedtime. Every unpleasant side effect develops promptly. The daily dosage should be reduced. If neither symptomatic relief nor side effects appear, the daily dosage may be increased. Some patients have tolerated 50 mg daily with no unpleasant reactions.

Patients whose dosage has been reduced to eliminate or modify side effects often continue to show adequate response both subjectively in relief of symptoms and objectively as measured by antitumor effects.

The ultimate aim of therapy is to arrive at a dosage which provides maximal clinical effectiveness with a minimum of unpleasant side effects. Many patients report no side effects on a dosage which gives complete relief of symptoms. On the other hand, some patients have reported severe side effects without appreciable symptomatic relief. Such patients may be considered unresponsive to the therapy. Usually they have been or will prove to be clinically intolerant to other antitumor drugs. If methoxycarbonyl levamisole is to be used in a patient who gives a history of such intolerance, it should be started at a low dosage.

#### HOW SUPPLIED

**Pharmane<sup>®</sup> 3.3 mg Tablets** are available as white, round tablets, debossed with "Pharmane<sup>®</sup>" on one side, in the following package sizes: bottles of 100 (NDC 0982-0005-47).

**Pharmane<sup>®</sup> Forte 4 mg Tablets** are available as white, oval tablets, debossed with "Pharmane<sup>®</sup>" on one side, in the following package size: Dose Pack (30 tablets) of 10 (NDC 0982-0005-04).


Store at controlled room temperature 15°-30°C (59°-86°F).

**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**

#### REFERENCES

1. The Pharmacological Basis of Therapeutics, Gilman and Goodman, MacMillan Pub. Co., New York, 8th Ed., 1968.
2. American Hospital Formulary Service, American Society of Hospital Pharmacists, Bethesda, Maryland.
3. Dennis, R.P., Cooper, G., "Central and Peripheral Effects of Ethacrynic Chloride; Blocking Agents in Man," *Anesthesiology* 28:568-574 (1957).
4. Magnusson, L. and Olsson, E., "Arterial Complications after Parasympathetic Treatment of Bradycardia in a Coronary Care Unit," *Acta Med. Scand.* 190:489-498 (1971).
5. Neale, J.S., Jr., and Conley, H.K., "Rhythm Changes with Atropine and Methoxycarbonyl Levamisole," *Drugs*, *Pharmacol. Ther.* 1:123-130-135 (March 1973).

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**ASK YOUR DOCTOR ABOUT**

R<sub>x</sub> Only  
**Pamine<sup>®</sup>**  
**Forte 5 mg**  
(methscopolamine bromide)

**Dose Pack**

**Antispasmodic/Anticholinergic Therapy**

*This patient information booklet is provided as a service by*

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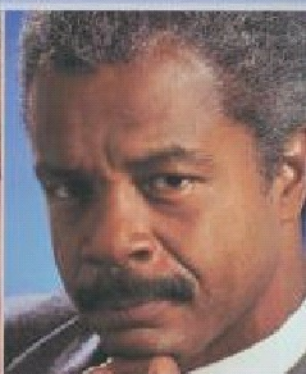
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*See full Prescribing Information on pages 20-23.*

PA 630

# Do Your Patients' Lives Revolve Around Gastrointestinal Motility Symptoms?



*"I wish I could just have a good time without constantly worrying about whether my pain and diarrhea will let me have a good day or not."*

*"At 35, I feel so isolated from the world. I find myself accepting invitations less and less because of my nearly uncontrollable diarrhea."*

*"Diarrhea and abdominal pain affect my life constantly. I can't count on regularly attending any of my activities."*

*"About three years ago, my life just fell apart. I started getting episodes of severe abdominal pain and bloating with diarrhea. Now, I miss several days of work each month, which is putting my job in jeopardy."*

**Help Your Patients Enjoy Life Again**

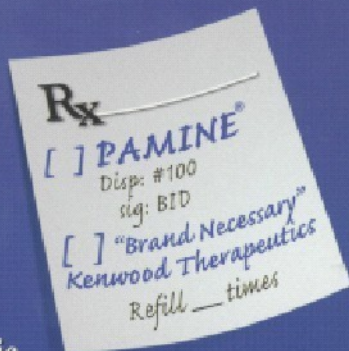
LACTOSE-FREE  
Rx Only •  
**Pamine**<sup>®</sup>  
(methscopolamine bromide)

**First-Line Antispasmodic/Anticholinergic**

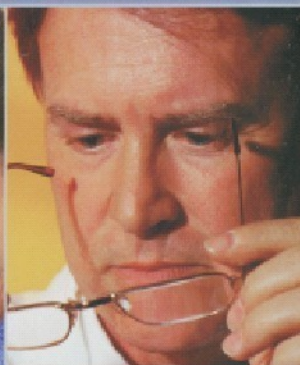
# Help Your Patients Regain Control of Their Lives

LACTOSE-FREE

Rx Only  
**Pamine**<sup>®</sup>  
(methscopolamine bromide)



First-Line Antispasmodic/Anticholinergic



*“Because of my diarrhea  
and cramps, I wouldn’t  
wish my life on anyone.”*

*“With pain, bloating  
and diarrhea,  
I feel like I have no  
control over my life.”*

*“I am hardly ever on time  
because I have to revisit  
the bathroom  
so many times.”*

*“I don’t even have fun  
anymore – I have had  
to curtail activities  
like golfing, tennis and  
vacations because my  
bowel is so unpredictable.”*

# Demonstrated Effective Relief of Painful Motility Symptoms

- INHIBITS DISCOMFORT CAUSED BY BLOATING, DIARRHEA AND CRAMPS, IMPROVING PATIENTS' CONTROL OF THEIR LIVES
- RELIEVES PAIN OF FUNCTIONAL GASTROINTESTINAL SYMPTOMS

In the **Pamine**<sup>®</sup> group, 63% of patients achieved a spasm-free experience or minimal spasms compared to 30% in the control group.

## Delivers Well-Tolerated Relief, Without Causing Additional Discomfort

- NOT LIKELY TO PRODUCE CNS SIDE EFFECTS SUCH AS
  - light-headedness
  - blurred vision
  - fatigue/drowsiness
  - dizziness
- LACTOSE-FREE TO MEET THE NEEDS OF LACTOSE-INTOLERANT PATIENTS

*“In clinical practice, antispasmodics and anticholinergic agents are best used on an as-needed basis up to 3 times per day for acute attacks of pain or before meals when postprandial symptoms are present.”*

**Control for the Physician –  
You Decide the Dosage**  
QD BID TID QID PRN

*You prescribe the optimal dosage for each patient based on the severity and frequency of symptoms.*

According to the **Pamine**<sup>®</sup> Prescribing Information

- “The average dosage of **Pamine**<sup>®</sup> Tablets is 2.5 mg one-half hour before meals and 2.5 to 5 mg at bedtime.”
- “Patients whose dosage has been reduced... often continue to show adequate response both subjectively in relief of symptoms and objectively...”

See each cover for full Prescribing Information.



# Do Your Patients' Lives Revolve Around Gastrointestinal Motility Symptoms?

Help Your Patients Regain  
Control of Their Lives

LACTOSE-FREE

Rx Only  
**Pamine**<sup>®</sup>  
(methscopolamine bromide)

DOES NOT CROSS THE BLOOD-BRAIN BARRIER

- No Significant CNS Effects
  - Unlike hyoscyanine sulfate, dicyclomine hydrochloride USP
- LACTOSE-FREE
- No added gastrointestinal problems
  - Unlike dicyclomine hydrochloride USP or glycopyrrolate USP

References: Open label study performed by Dr. R.P. Saunders at the prestigious Wolfson Unit for Endoscopy, St. Mark's Hospital in London, UK

**Pamine**<sup>®</sup> (methscopolamine bromide)

## CLINICAL PHARMACOLOGY

Methscopolamine bromide is an anticholinergic agent which possesses most of the pharmacologic actions of that drug class. These include reduction in volume and total acid content of gastric secretion, inhibition of gastrointestinal motility, inhibition of salivary secretion, dilation of the pupil and inhibition of accommodation with resulting blurring of vision. Large doses may result in mydriasis.

## PHARMACOKINETICS

Methscopolamine bromide is a quaternary ammonium derivative of atropine. As a class, these agents are poorly and irregularly absorbed.<sup>1</sup> Total absorption of quaternary ammonium derivatives of the atropine is 10-20%. Rate of absorption is not feasible. Quaternary ammonium salts have limited absorption from intact skin and conjunctival penetration is poor. Little is known of the fate and excretion of most of these agents.<sup>2</sup> Following oral administration, drug effects appear in about one hour and persist for 4 to 6 hours.<sup>3</sup> Methscopolamine bromide has limited ability to cross the blood-brain barrier.<sup>4</sup> The drug is excreted primarily in the urine and bile, or as an adsorbed drug in feces.<sup>5</sup> There is no data on the presence of methscopolamine in breast milk, traces of atropine have been found after administration of atropine.<sup>6</sup>

## INDICATIONS AND USAGE

Indicative therapy for the treatment of peptic ulcer.

METHSCOPOLAMINE BROMIDE HAS NOT BEEN SHOWN TO BE EFFECTIVE IN CONTRIBUTING TO THE HEALING OF PEPTIC ULCER, DECREASING THE RATE OF RECURRENCE OR PREVENTING COMPLICATIONS.

## CONTRAINDICATIONS

Glaucoma; obstructive uropathy (e.g., bladder neck obstruction due to prostatic hypertrophy); obstructive disease of the gastrointestinal tract (e.g., pyloroduodenal stenosis); paralytic ileus; intestinal obstruction of the elderly or debilitated patient; unstable cardiovascular status (acute hemorrhage; severe circulatory deficit; basic metabolism compensating obstructive cardiac dysfunction); glaucoma. PAMINE<sup>®</sup> is contraindicated in patients who are hypersensitive to methscopolamine bromide or related drugs.

## WARNINGS

In the presence of high environmental temperature, heat prostration (fever and heat stroke due to decreased sweating) can occur with drug use. Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In the instance treated with this drug would be inappropriate and possibly harmful. Methscopolamine bromide may produce drowsiness or blurred vision. The patient should be cautioned regarding activities requiring mental alertness such as operating a motor vehicle or other machinery or performing hazardous work while taking this drug. With overdosage, a curare-like action may occur, i.e., neuromuscular blockade leading to muscular weakness and possible paralysis.

## PRECAUTIONS

### 1. General precautions

Use PAMINE<sup>®</sup> tablets with caution in the elderly and in all patients with autonomic neuropathy, hepatic or renal disease, or abnormal cardiac rhythm. Large doses may suppress vital functions to the point of producing a paralytic ileus and, for this reason, prochlorperazine or prochlorperazine, a serious complication of the disease. The drug also should be used with caution in patients having hyperthyroidism, coronary heart disease, congestive heart failure, tachyarrhythmia, tachycardia, hypertension, or prostatic hypertrophy.

### 2. Information for patient

See statement under WARNINGS.

### 3. Laboratory tests

Progress of the peptic ulcer under treatment should be followed by upper gastrointestinal contrast radiology or endoscopy to insure healing. Stool tests for occult blood and blood hemoglobin or hemoglobin values should be followed to rule out bleeding from the ulcer.

### 4. Drug interactions

Active anticholinergic effects may result from concurrent use with antipsychotics, tricyclic antidepressants, and other drugs with anticholinergic effects. Concurrent administration with beta-blockers may interfere with the absorption of methscopolamine bromide.

### 5. Carcinogenesis, mutagenesis, impairment of fertility

No long-term studies in animals have been performed to evaluate carcinogenic potential.

### 6. Pregnancy

#### Teratogenic effects

Pregnancy Category C: Animal reproduction studies have not been conducted with methscopolamine bromide. It is also not known whether methscopolamine bromide can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Methscopolamine bromide should be given to a pregnant woman only if clearly needed.

### 7. Nursing mothers

It is not known whether the drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when methscopolamine bromide is administered to a nursing woman. Anticholinergic drugs may suppress lactation.

### 8. Pediatric use

Safety and efficacy in children have not been established.

## ADVERSE REACTIONS

The following adverse reactions have been observed, but there is not enough data to support an estimate of frequency: Cardiovascular: Tachycardia, palpitation. Allergic: Severe allergic reaction or drug hypersensitivity including anaphylaxis. CNS: Headaches, nervousness, mental confusion, drowsiness, dizziness. Special Senses: Blurred vision, dilation of the pupil, cycloplegia, increased lacrimation, loss of taste. Renal: Urinary hesitancy and retention. Gastrointestinal: Nausea, vomiting, constipation, coated tongue. Dermatologic: Decreased sweating, urticaria and other allergic manifestations. Miscellaneous: Xerostomia, weakness, incontinence, incontinence, suppression of lactation.

## DRUG ABUSE AND DEPENDENCE

Not applicable.

## OVERDOSAGE

The symptoms of overdosage with PAMINE<sup>®</sup> Tablets progress from intensification of the usual side effects to CNS disturbances (from restlessness and excitement to psychotic behavior), respiratory changes (flushing, fall in blood pressure, circulatory failure), respiratory failure, paralysis, and coma. Measures to be taken are: 1) Induction of emesis and 2) injection of physostigmine 0.5 to 2 mg intravenously and repeated as necessary up to a total of 3 mg. Fever may be treated symptomatically (alcohol sponging, ice packs). Excitement of a degree which demands attention may be managed with sodium thiosulfate 2% solution given orally intravenously or diluted hydrolytic (100-200 mg) of a 2% solution by rectal infusion. In the event of progression of the curare-like effect to paralysis of the respiratory muscles, artificial respiration should be instituted and maintained until effective respiratory action returns. The oral LD<sub>50</sub> in rats is 1.382 to 2.617 mg/kg. No data is available on the dialyzability of methscopolamine bromide.

## DOSAGE AND ADMINISTRATION

The average dosage of PAMINE<sup>®</sup> Tablets is 2 to 6 mg orally four before meals and 2.5 to 6 mg at bedtime. A starting dose of 12.5 mg daily will be clinically effective in most patients without the production of noticeable side effects. Patients whose dosage has been reduced to eliminate or modify side effects often continue to show adequate response both subjectively in relief of symptoms and objectively as measured by anticholinergic effects. If the patient is having severe symptoms which demand prompt relief, the drug may be started on a daily dosage of 20 mg, administered in doses of 5 mg one-half hour before meals and at bedtime. If very unpleasant side effects develop promptly, the daily dosage should be reduced. If neither symptomatic relief nor side effects appear after the daily dosage may be increased. Some patients have tolerated 30 mg daily with no unpleasant reactions. The ultimate aim of therapy is to arrive at a dosage which provides maximal clinical effectiveness with a minimum of unpleasant side effects. Many patients require side effects on a dosage which gives complete relief of symptoms. On the other hand, some patients have reported severe side effects without appreciable symptomatic relief. Such patients may be considered unresponsive to this therapy. Usually, they have been or will prove to be primarily intolerant to other anticholinergic drugs. If methscopolamine bromide is to be used in a patient who gives a history of such intolerance, it should be started at a low dosage.

## HOW SUPPLIED

PAMINE<sup>®</sup> Tablets 2.5 mg are available as white, round tablets in the following package sizes: Bottles of 100 (NDC 0482-0081-01). Store at controlled room temperature 15°-30°C (59°-86°F).

## REFERENCES

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## Rx Only

Manufactured by:

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## Pamine<sup>®</sup> Rx Only (methscopolamine bromide)

The discomforts of bloating, diarrhea, cramps and other related GI problems caused by hypermotility (increased muscular activity in the GI tract) is, in fact, a fairly common condition. Statistics show that as many as 20% - 30% of the general population experience these symptoms on a regular basis.

**Pamine<sup>®</sup>** helps relieve the pain associated with bloating, diarrhea, and cramps by *slowing the motion* of the GI tract. Safe, effective, and time-tested, Pamine<sup>®</sup> reduces the amount of acid in your stomach, thereby reducing the pain associated with excessive stomach acid. And, unlike some anticholinergics/antispasmodics that contain substances that cross the blood-brain barrier and enter the Central Nervous System (CNS), Pamine<sup>®</sup> has not been shown to penetrate the blood-brain barrier and has no significant CNS effects. Using Pamine<sup>®</sup>, therefore, genuinely minimizes the risk of significant central effects such as light-headedness or fatigue.



Cost effective, too! **Pamine<sup>®</sup>** is a wise choice for the safe and effective relief of on-going GI tract discomforts

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