Hyophen®

A dependence on the use of DRUG ABUSE AND DEPENDENCE:

Patients should be advised that the urine and/or stools may become blue to blue-green as a result of the excretion of methylene blue. These drugs may precipitate with formaldehyde in the urine increasing the danger of crystalluria.

Sulfonamides: Opioid (narcotic) analgesics may result in increased risk of severe constipation. Concurrent use with hyoscyamine may intensify antimuscarinic side effects. Monoamine oxidase (MAO) inhibitors: Reduction in the absorption of ketoconazole. Patients should be advised to take this combination at least 2 hours after ketoconazole. Ketoconazole and hyoscyamine may cause increased gastrointestinal pH. Concurrent administration with hyoscyamine may result in marked inhibition of its conversion to formaldehyde. Urinary alkalizers and thiazide diuretics: May cause the urine to become alkaline reducing the effectiveness of methenamine by inhibiting its conversion to formaldehyde. Antimyasthenics: Concurrent use with hyoscyamine may further reduce intestinal motility, therefore, caution is recommended. Concurrent use may reduce absorption of hyoscyamine resulting in decreased therapeutic effectiveness. Antacid/antidiarrheals: Concurrent use may reduce absorption of hyoscyamine resulting in decreased therapeutic effectiveness. Anticholinergic agents may cause urine to become alkaline reducing the effectiveness of methenamine by inhibiting its conversion to formaldehyde. Doses of these medications should be spaced 1 hour apart from doses of hyoscyamine. Antitartrazines: Concurrent use with hyoscyamine may result in decreased therapeutic effectiveness. Concomitant use may result in marked reduction in the absorption of ketoconazole. Patients should be advised to take this combination at least 2 hours after ketoconazole. Antimycotic (fungicidal) agents may result in increased risk of severe constipation.

Sulfonamides: These drugs may precipitate with formaldehyde in the urine increasing the danger of crystalluria. Patients should be advised that the urine and/or stools may become blue to blue-green as a result of the excretion of methylene blue.

**DRUG ABUSE AND DEPENDENCE:**

A dependence on the use of Hyophen® tablets has not been reported and due to the nature of its ingredients, abuse of Hyophen® tablets is not expected.

**OVERDOSAGE:**

Emesis or gastric lavage. Slow intravenous administration of physostigmine in doses of 1 to 4 mg (0.5 to 1 mg in children), repeated as needed in one to two hours to reverse severe antimuscarinic symptoms. Administration of small does of diazepam to control excitement and seizures. Artificial respiration with oxygen if needed for respiratory depression. Adequate hydration. Symptomatic treatment as necessary.

If overdose is suspected, contact your local Poison Control Center or emergency room immediately. US residents can contact the US National Poison Hotline at 1-800-222-1222.

**DOSE AND ADMINISTRATION:**

**Adults:** One tablet orally 4 times per day followed by liberal fluid intake.

**Older Children:** Dosages must be individualized by physician. Not recommended for use in children six years of age or younger.

**HOW SUPPLIED:**

Hyophen® tablets are blue tablets imprinted with “SAT” on one side and “901” on opposite side. NDC 0076-0901-01, Bottle of 100 Tablets and NDC 0076-0901-02, Carton of 20 individually pouched tablets.

**STORAGE:**

Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure.

Store at controlled room temperature 20°-25° C (68°-77° F).

Keep in a cool, dry place.

Keep container tightly closed.

Keep this and all drugs out of reach of children.

**INDICATIONS:**

Hyophen® (methenamine 81.6 mg, benzoic acid 9.0 mg, phenyl salicylate 36.2 mg, methylene blue 10.8 mg, and hyoscyamine sulfate 0.12 mg) is indicated for the treatment of symptoms of irritative voiding, the relief of local symptoms (e.g., inflammation, hypermotility, pain) which accompany lower urinary tract infections, and for the relief of urinary tract symptoms caused by diagnostic procedures.

**CONTRAINDICATIONS:** Hypersensitivity to any of the ingredients is possible.

Risk benefits should be carefully considered with certain medical conditions: cardiac disease (especially cardiac arrhythmias, congestive heart failure, coronary heart disease, and mitral stenosis); gastrointestinal obstructive disease; glaucoma; myasthenia gravis; acute urinary retention may be precipitated in obstructive uropathy (such as bladder neck obstruction due to prostatic hypertrophy).

Please see additional Important Safety Information inside and accompanying full Prescribing Information.
Combination Treatment

For the relief of pain, burning and spasm of the lower urinary tract caused by:

- Lower urinary tract infections and inflammation
- Interstitial cystitis (IC)
- Painful bladder syndrome (PBS)
- Pre and Post diagnostic procedures

Triple-action relief

- Analgesic action (phenyl salicylate) to relieve pain and burning
- Antispasmodic action (hyoscyamine sulfate) to reduce frequency and urgency through smooth muscle relaxation
- Antiseptic action* (methenamine, methylene blue, benzoic acid) to help inhibit growth of bacteria and fungus

*Hyophen does not replace antibiotic therapy prescribed by your doctor

Dosing and Usage†

- Dose: One tablet four times daily
- Generally well tolerated

†Please see Precautions in full Prescribing Information regarding cross sensitivity and/or related problems, pregnancy/reproduction, breast feeding, prolonged use, pediatric use, and geriatric use.

Important Safety Information (Con’t)

WARNINGS: Do not exceed recommended dosage. If rapid pulse, dizziness or blurring of vision occurs, discontinue use immediately.

PRECAUTIONS: Hyophen should be used with caution in:

- patients who are intolerant of belladonna alkaloids or salicylates.
- patients with gastric ulcers. Delay in gastric emptying could complicate management.
- pregnant women. It is not known whether Hyophen causes fetal harm or can affect reproductive capacity. Only use if clearly needed.

ADVERSE REACTIONS: Adverse reactions associated with Hyophen include: rapid heartbeat, flushing, blurred vision, dizziness, drowsiness, difficult micturition, acute urinary retention, dry mouth, nausea, vomiting, and shortness of breath or trouble breathing. Serious allergic reactions to this drug are rare. Patients should be instructed to seek immediate medical attention if they experience symptoms of a serious allergic reaction, including itching, rash, severe dizziness, swelling or trouble breathing. This medication can cause urine and sometimes stools to turn blue-green. This effect is harmless and will subside after medication is stopped, however, patients should be advised.

Please see accompanying full Prescribing Information for additional information including Drug Interactions.