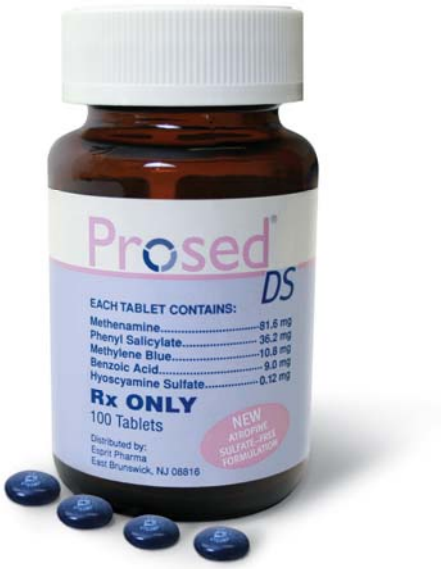
Prosed® DS
(Methenamine, Phenyl Salicylate, Methylene Blue, Benzoic Acid, Hyoscyamine Sulfate)

Now Available From Ferring Pharmaceuticals Inc.
Prosed® DS 100-Tablet Bottles

Description	NDC #	How Supplied
Prosed® DS	15456-805-03	Bottle of 100

- Brings soothing relief from the pain, burning, and spasm of:
  - Urinary tract infections
  - Urinary inflammatory diseases
  - Urinary diagnostic procedures
- Provides analgesic, antispasmodic, and antiseptic actions, unlike single-action agents
- Generally well tolerated
- Dosage: One tablet, 4 times daily
- No AB-rated equivalent:
  - Not substitutable
  - Atropine-free formulation
- Advise patients that their urine may turn blue-green as a result of methylene blue excretion
- Promoted nationally by a specialty sales force



The table below updates the NDC # for Prosed® DS, now available from Ferring Pharmaceuticals Inc.

Discontinued Prosed® NDC #	Active Prosed® DS NDC #
00076-0108-03	Bottle of 100 15456-805-03
00076-0909-90	
15456-0909-90	
00076-0805-03	

Please see full Prescribing Information at www.prosed.com.
To place an order for Prosed® DS, please contact your local wholesaler.

If you have any questions about Prosed® DS,
please call 1-888-FERRING (888-337-7464)
or visit www.ferringusa.com.

FERRING PHARMACEUTICALS

Prosed® DS

(Methenamine, Phenyl Salicylate, Methylene Blue, Benzoic Acid, Hyoscyamine Sulfate)

www.prosed.com

DESCRIPTION
PROSED®/DS is a dark blue, round, sugar coated tablet for oral administration. Each tablet contains: Methenamine 81.6 mg, Phenyl Salicylate 36.2 mg, Methylene Blue 10.8 mg, Benzoic Acid 9.0 mg and Hyoscyamine Sulfate 0.12 mg.
METHENAMINE (Hexamethylenetetramine) exists as colorless, lustrous crystals or white crystalline powder. Its solutions are alkaline to litmus. Freely soluble in water; soluble in alcohol and in chloroform.
PHENYL SALICYLATE (2-hydroxybenzoic acid phenyl ester) exists as white crystals with a melting point of 40-43°C. It is very slightly soluble in water and freely soluble in alcohol.
METHYLENE BLUE (methylthionine chloride) exists as dark green crystals. It is soluble in water and in chloroform; sparingly soluble in alcohol.
BENZOIC ACID (benzenecarboxylic acid) exists as white crystals, scales or needles. It has a slight odor and is slightly soluble in water; freely soluble in alcohol, in chloroform and in ether.
HYOSCYAMINE SULFATE (l-tropyl tropate) is an alkaloid of belladonna. It exists as a white crystalline powder. Its solutions are alkaline to litmus and affected by light. It is slightly soluble in water; freely soluble in alcohol; sparingly soluble in ether.

INACTIVE INGREDIENTS
PROSED®/DS tablets contain the inactive ingredients Calcium Sulfate, Carnauba Wax, Dicalcium Phosphate, FD&C Blue #2 Lake, FD&C Red #40 Lake, FD&C Yellow #6 Lake, Gelatin, Hypromellose, Kaolin, Magnesium Silicate, Magnesium Stearate, Microcrystalline Cellulose, Mineral Oil, Pharmaceutical Glaze, Polyethylene Glycol, Polyvinylpyrrolidone, Sugar and Titanium Dioxide.

CLINICAL PHARMACOLOGY
METHENAMINE degrades in an acidic urine environment releasing formaldehyde which provides bactericidal or bacteriostatic action. It is well absorbed from the gastrointestinal tract. 70 to 90% reaches the urine unchanged at which point it is hydrolyzed if the urine is acidic. Within 24 hours it is almost completely (90%) excreted; of this amount at pH 5, approximately 20% is formaldehyde. Protein binding - some formaldehyde is bound to substances in the urine and surrounding tissues. Methenamine is freely distributed to body tissue and fluids but is not clinically significant as it does not hydrolyze at a pH greater than 6.8.
PHENYL SALICYLATE releases salicylate, a mild analgesic for pain.
METHYLENE BLUE possesses weak antiseptic properties. It is well absorbed by the gastrointestinal tract and is rapidly reduced to leukomethylene blue which is stabilized in some combination form in the urine. 75% is excreted unchanged.
BENZOIC ACID has a mild antibacterial and antifungal action. It also helps maintain an acid pH in the urine necessary for the degradation of methenamine.
HYOSCYAMINE SULFATE is a parasympatholytic drug which relaxes smooth muscles. Protein binding for hyoscyamine sulfate is moderate. Biotransformation for hyoscyamine sulfate is hepatic. It is well absorbed from the gastrointestinal tract. The majority of hyoscyamine sulfate is excreted unchanged.

INDICATIONS AND USAGE
PROSED®/DS is indicated for the relief of discomfort of the lower urinary tract caused by hypermotility resulting from inflammation or diagnostic procedures and in the treatment of cystitis, urethritis and trigonitis when caused by organisms which maintain or produce an acid urine and are susceptible to formaldehyde.

CONTRAINDICATIONS
Risk-benefit should be considered when the following medical problems exist: glaucoma, urinary bladder neck obstruction, pyloric or duodenal obstruction or cardiospasm. Hypersensitivity to any of the ingredients.

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

PRECAUTIONS
Cross sensitivity and/or related problems: Patients intolerant of other belladonna alkaloids or other salicylates may be intolerant of this medication also. Delay in gastric emptying could complicate the management of gastric ulcers.

Pregnancy/Reproduction (FDA Pregnancy Category C): Hyoscyamine and methenamine cross the placenta. Studies have not been done in either animals or humans. It is not known whether **PROSED®/DS** tablets can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. **PROSED®/DS** tablets should be given to a pregnant woman only if clearly needed.

Nursing mothers: Methenamine and traces of hyoscyamine are excreted in breast milk. Caution should be exercised when **PROSED®/DS** tablets are administered to a nursing mother.
Prolonged use: There have been no studies to establish the safety of prolonged use in humans. No known long-term animal studies have been performed to evaluate carcinogenic potential.

Pediatric: Infants and young children are especially susceptible to the toxic effect of the belladonna alkaloids.

Geriatric: Use with caution in elderly patients as they may respond to the usual doses of the belladonna alkaloids with excitement, agitation, drowsiness, or confusion.

Drug Interactions: As a result of hyoscyamine's effects on gastrointestinal motility and gastric emptying, absorption of other oral medications may be decreased during concurrent use with this combination medication.

Urinary alkalizers and thiazide diuretics: May cause the urine to become alkaline reducing the effectiveness of methenamine by inhibiting its conversion to formaldehyde.
Antimuscarinics: Concurrent use may intensify antimuscarinic effects of hyoscyamine because of secondary antimuscarinic activities of these medications.
Antacids/antidiarrheals: Concurrent use may reduce absorption of hyoscyamine resulting in decreased therapeutic effectiveness. Concurrent use with antacids 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.
Antimyasthenics: Concurrent use with hyoscyamine may further reduce intestinal motility, therefore, caution is recommended.
Ketoconazole and hyoscyamine may cause increased gastrointestinal pH. Concurrent administration with hyoscyamine may result in marked reduction in the absorption of ketoconazole. Patients should be advised to take this combination at least 2 hours after ketoconazole.
Monoamine oxidase (MAO) inhibitors: Concurrent use with hyoscyamine may intensify antimuscarinic side effects.
Opioid (narcotic) analgesics 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.

ADVERSE REACTIONS
Cardiovascular - rapid pulse, flushing
Central Nervous System - blurred vision, dizziness
Respiratory - shortness of breath or troubled breathing
Genitourinary - difficult micturition, acute urinary retention
Gastrointestinal - dry mouth, nausea/vomiting

DRUG ABUSE AND DEPENDENCE
A dependence on the use of **PROSED®/DS** has not been reported and due to the nature of its ingredients, abuse of **PROSED®/DS** 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 doses of diazepam to control excitement and seizures. Artificial respiration with oxygen if needed for respiratory depression. Adequate hydration. Symptomatic treatment as necessary.

DOSAGE AND ADMINISTRATION
Adults: One tablet orally 4 times per day followed by liberal fluid intake.
Older children: Dosage must be individualized by physician. Not recommended for use in children up to 12 years of age.

HOW SUPPLIED
Round, dark blue, sugar-coated tablets imprinted with "**PROSED®/DS**". Bottles of 100-NDC 15456-805-03 and Samples of 2-NDC 15456-805-02.

Rx Only

STORAGE
Store in a dry place between 15° and 30°C (59° to 86°F). Keep container tightly closed.

Medical Inquiries: 1-(888)-FERRING (1-(888)-337-7464) and www.prosed.com

FERRING PHARMACEUTICALS

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