URIN D/S- methenamine, sodium phosphate, monobasic, monohydrate, phenyl salicylate, methylene blue, and hyoscyamine sulfate tablet
Llorens Pharmaceutical International Division

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

URIN D/S

RX ONLY

Urinary antiseptic

NDC 54859-701-10

DESCRIPTION

Each tablet contains:
Methenamine.....81.6 mg
Sodium Biphosphate.....40.8 mg
Phenyl Salicylate.....36.2 mg
Methylene Blue.....10.8 mg
Hyoscyamine Sulfate.....0.12 mg

Inactive Ingredients: Carbopol 934P, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, dicalcium phosphate, polydextrose, hypromellose, D&C Red #27, titanium dioxide, FD&C Blue #2, triacetin, FD&C Red #40, macrogol, talc.

METHENAMINE. [100-97-0] 1,3,5,7-Tetraazatricyclo [3.3.1.-1 3,7] decane; hexamethylenetetramine; HMT; HMTA; hexamine; 1,3,5,7-tetraazaadamantane hexamethylenemine; Uritone; Urotropin. C6H12N4; mol wt 140.19; C 51.40%, H 8.63%, N 39.96%. 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.

SODIUM BIPHOSPHATE. [7558-80-7] Phosphoric acid sodium salt (1:1); Sodium biphosphate; sodium dihydrogen phosphate; acid sodium phosphate; monosodium orthophosphate; primary sodium phosphate; H2NaO4P; mol wt 119.98, H 1.68%, Na 19.16%, O 53.34%, P 25.82%. Monohydrate, white, odorless slightly deliquesce crystals or granules. At 100° C loses all its water; when ignited it converts to metaphosphate. It is freely soluble in water and practically insoluble in alcohol. The aqueous solution is acid. pH of 0.1 molar aqueous solution at 25° C: 4.5.

PHENYL SALICYLATE. [118-55-8] 2-Hydroxybenzoic acid phenyl ester; Salol. C13H10O3; mol wt 214.22, C 72.89%, H 4.71%, O 22.41%. Made by the action of phosphorus oxy-chloride on a mixture of phenol and salicylic acid. Phenyl Salicylate exists as white crystals with a melting point of 41°-43° C. It is very slightly soluble in water and freely soluble in alcohol.

METHYLENE BLUE. [61-73-4] 3,7-Bis(dimethylamino) phenothiazin-5-ium chloride; C.I. Basic Blue 9; methylthioninium chloride; tetramethylthionine chloride; 3,7-bis(dimethylamino) phenazathionium chloride. C16H18ClN3S; mol wt 319.85, C 60.08%, H 5.67%, Cl 11.08%, N 13.14%, S 10.03%. Methylene Blue (Methylthionine chloride) exists as dark green crystals. It is soluble in water and in chloroform; sparingly soluble in alcohol.

HYOSCYAMINE SULFATE. [620-61-1][3(S)-endo]-α-(Hydroxymethyl)-benzeneacetic acid 8-methyl-8-azabicyclo[3.2.1]oct-3-yl ester sulfate(2:1)(salt); 1αH,5αH-tropan-3α-ol(-)-tropate(ester) sulfate(2:1)(salt);3α-tropanyl S-(-)-tropate; l-tropic acid ester with tropine; l-tropine tropate. C34H48N2O10S. Hyoscyamine Sulfate is an alkaloid of belladonna. Exists as a white crystalline

powder. Its solutions are alkaline to litmus. Affected by light, it is slightly soluble in water; freely soluble in alcohol; sparingly soluble in ether.

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%-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 at a pH of 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 pH greater than 6.8.

SODIUM BIPHOSPHATE helps to maintain an acid pH in the urine necessary for the degradation of methenamine.

PHENYL SALICYLATE releases salicylate, a mild analgesic for pain.

METHYLENE BLUE possesses weak antiseptic properties. It is well absorbed by the gastrointestinal tract and rapidly reduced to leukomethylene blue which is stabilizied in some combination form in the urine. 75% is excreted unchanged.

HYOSCYAMINE SULFATE is a parasympatholytic which relaxes smooth muscles and thus produces an antispasmodic effect. It is well absorbed from the gastrointestinal tract and is rapidly distributed throughout the body tissues. Most is excreted in the urine within 12 hours, 13% to 50% being unchanged. Its biotransformation is hepatic. Its protein binding is moderate.

INDICATIONS AND USAGE

Indicated for the treatment of symptoms of irritative voiding. Indicated for the relief of local symptoms, such as inflammation, hypermotility, and pain, which accompany lower urinary tract infections. Indicated 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 when the following medical problems exist: cardiac disease (especially cardiac arrhythmias, congestive heart failure, coronary heart disease, and mitral stenosis); gastrointestinal tract obstructive disease; glaucoma; myasthenia gravis, acute urinary retention may be precipitated in obstructive uropathy (such as bladder neck obstruction due to prostatic hypertrophy).

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 belladonna alkaloids or salicylates may be intolerant of this medication also. Delay in gastric emptying could complicate the management of gastric ulcers.

Pregnancy Category C - Hyoscyamine Sulfate and Methenamine cross the placenta. Studies have not been done in animals or humans. It is not known whether Utira™-C Tablets cause fetal harm when

administered to a pregnant woman or can affect reproduction capacity. Utira™-C Tablets should be given to a pregnant woman only if clearly needed.

Breast-feeding - Problems in humans have not been documented, however, Methenamine and traces of Hyoscyamine Sulfate are excreted in breast milk. Accordingly, Utira™-C Tablets should be given to a nursing woman only if clearly needed.

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 usual doses of Hyoscyamine Sulfate with excitement, agitation, drowsiness, or confusion.

DRUG INTERACTIONS

Drug Interactions - because of this product's effect on gastrointestinal motility and gastric emptying, it may decrease the absorption of other oral medications during concurrent use such as: urinary alkalizers; 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 (may reduce absorption of hyoscyamine, concurrent use with antacids may cause urine to become alkaline, reducing 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); ketoconazole (patients should be advised to take this combination at least 2 hours after ketoconazole); monoamine oxidase (MAO) inhibitors (concurrent use 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 may become blue to blue-green and the feces may be discolored as a result of the excretion of the Methylene blue.

ADVERSE REACTIONS

Cardiovascular - rapid heartbeat, flushing

Central Nervous System - blurred vision, dizziness, drowsiness

Respiratory - shortness of breath or trouble breathing

Genitourinary - difficult micturition, acute urinary retention

Gastrointestinal - dry mouth, nausea and vomiting

DRUG ABUSE AND DEPENDENCE

A dependence on the use of URIN D/S has not been reported and due to the nature of its ingredients, abuse of URIN D/S 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 six years of age or younger.

HOW SUPPLIED

URIN D/S is a oval, purple tablet embossed with LLORENS on one side, available in bottles of 100 tablets NDC 54859-701-10 and professional sample bottles of 4 tablets NDC 54859-701-04.

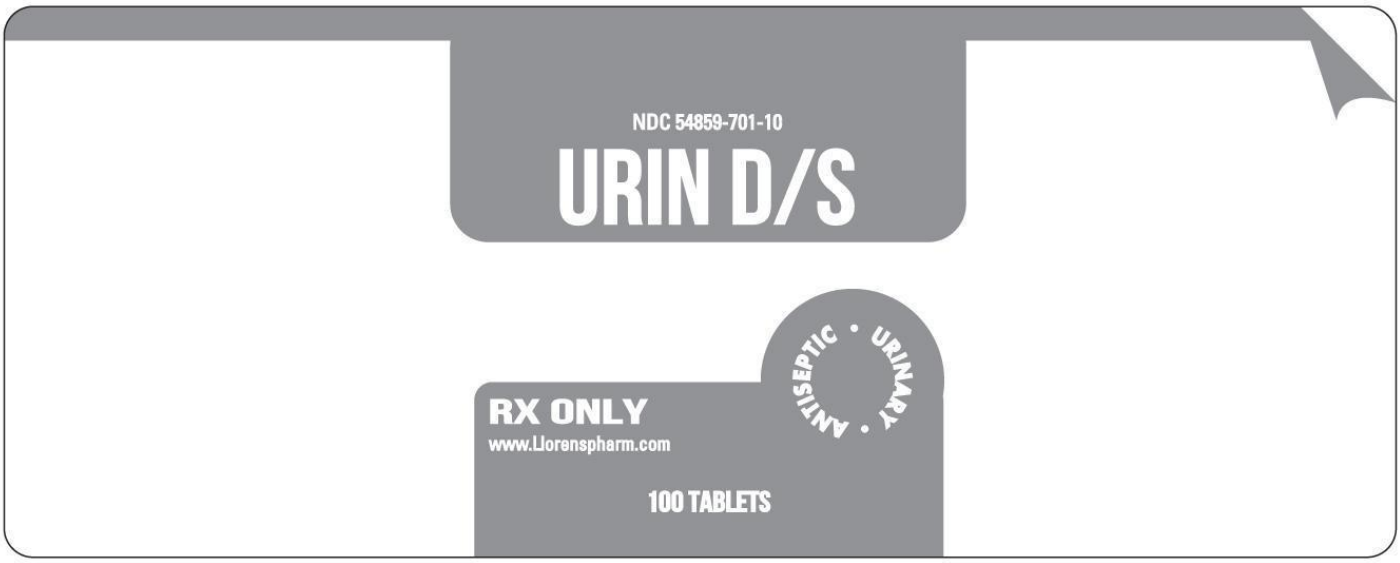
STORAGE

PHARMACIST: Preserve and dispense in tight-light resistant package as defined in the USP.

Store at controlled room temperature between 15-30 degrees C (59-86 degrees F)

Tamper evident by heat seal under cap. Do not use if there is evidence of tampering.

WARNING: Patient should be advised that urine may be colored blue while taking this medication



KEEP THIS AND ALL MEDICINES OUT OF THE REACH OF CHILDREN
Questions or comments? 1-866-595-5598

04/13

RX ONLY
www.Llorenspharm.com

100 TABLETS

MANUFACTURED FOR:
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PHARMACEUTICAL CORP.
International Division
Miami, FL 33166
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Sodium Biphosphate .....40.8 mg
Phenyl Salicylate .....36.2 mg
Methylene Blue.....10.8 mg
Hyoscyamine Sulfate.....0.12 mg

INACTIVE INGREDIENTS: Carbopol 934P, Magnesium Stearate, Microcrystalline Cellulose, Sodium Starch Glycolate, Dicalcium Phosphate, Polydextrose, Hypromellose, D&C Red #27, Titanium Dioxide, FD&C Blue #2, Triacetin, FD&C Red #40, Macrogol, Talc.

Methenamine. [100-97-0] 1,3,5,7-Tetraazatricyclo[3.3.1.1 3,7] decane; hexamethylenetetramine; HMT; HMTA; hexamine; 1,3,5,7-tetraazaadamantane; hexamethylenamine; Urtone; Urotropin. C6H12N4; mol wt 140.19, C 51.40%, H 8.63%, N 39.96%. 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.

Sodium Biphosphate. Sodium Biphosphate; sodium Dihydrogen phosphate; acid sodium phosphate; monosodium orthophosphate; primary sodium phosphosphate; [H2NaO4P-] mol wt 119.98. H 1.68%, Na 19.16%, O 53.34%, P 25.82%). Monohydrate.

White, odorless, slightly deliquesce crystals or granules. At 100° loses all its water; when ignited it converts into metaphosphate. It is freely soluble in water and practically insoluble in alcohol. The aq soln is acid. PH of 0,1 molar aq soln at 25°: 4.5.

Phenyl Salicylate. [118-55-8] 2-Hydroxybenzoic acid phenyl ester; Salol. C13H10O3; mol wt 214.22. C 72.89%, H 4.70%, O 22.41%. Made by the action of phosphorus Oxy-chloride on a mixture of phenol and salicylic acid, Phenyl Salicylate 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. [61-73-4] 3,7-Bis(dimethylamino) phenothiazin-5-ium chloride; C.I. Basic Blue 9; methylthioninium chloride; tetramethylthionine chloride; 3,7-bis(dimethylamino) phenazathionium chloride. METHYLENE BLUE methylthionine chloride) exists as dark green crystals. It is soluble in water and in chloroform; sparingly soluble in alcohol.

Hyoscyamine Sulfate. [101-31-5] (3(s)-endo)-a-(Hydroxymethyl) benzeneacetic acid 8-methyl-8-azabicyclo[3,2,1]oct-3-yl ester; 1aH,5aH-tropan-3a-ol(-)-tropate (ester);3a-tropanS-(-)-tropate; 1-tropic acid ester with tropine;1-tropine tropate. Hyoscyamine Sulfate is an alkaloid of belladonna. Exists as a white crystalline powder. Its solutions are alkaline to litmus. Affected by light. It is slightly soluble in water; freely soluble in alcohol; sparingly soluble in ether.

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 pH greater than 6.8.

Sodium Biphosphate helps to maintain an acid pH in the urine necessary for the degradation of methenamine.

Phenyl Salicylate released salicylate, a mild analgesic for pain.

Methylene Blue possesses weak antiseptic properties. It is well absorbed in the gastrointestinal tract and is rapidly reduced to leukomethylene blue which is stabilized in some combination form in the urine. 75% is excreted unchanged.

Hyoscyamine Sulfate is a parasympatholytic which relaxes smooth muscles and thus produces an antispasmodic effect. It is well absorbed from the gastrointestinal tract and is rapidly distributed throughout body tissues. Most is excreted in the urine within 12 hours, 13% to 50% being unchanged. Its biotransformation is hepatic. Its protein binding is moderate.

INDICATIONS AND USAGE
Indicated for the treatment of symptoms of irritative voiding. Indicated for the relief of local symptoms, such as inflammation, hypermotility, and pain, which accompany lower urinary tract infections. Indicated for the relief of urinary tract symptoms caused by diagnostic procedures.

CONTRAINDICATIONS
Hypersensitivity to any of the ingredients. Risk benefit should be considered when the following medical problems exist: Cardiac disease (especially cardiac arrythmias, congestive heart failure, coronary heart disease, mitral stenosis); gastrointestinal tract obstructive disease; glaucoma; myasthenia gravis; acute urinary retention may be precipitated in obstructive uropathy (such as bladder neck obstruction due to prostatic hypertrophy). The use of MAOIs intended to treat psychiatric disorders with Urin D/S or within 14 days of stopping treatment with Urin D/S is contraindicated because of increased risk for serotonin syndrome. The use of Urin D/S within 14 days of stopping an MAOI intended to treat psychiatric disorders is also contraindicated.

WARNINGS
Serotonin Syndrome
Methylene blue is a potent monoamine oxidase inhibitor: Methylene blue has been demonstrated to be a potent monoamine oxidase inhibitor (MAOI) and may cause potentially fatal serotonin toxicity (serotonin syndrome) when combined with serotonin reuptake inhibitors (SRIs).

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 belladonna alkaloids or 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 Sulfate and Methenamine cross the placenta. Studies have not been done in animals or humans. It is not known whether URIN D/S™ tablets cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. URIN D/S tablets should be given to a pregnant woman only if clearly needed.

Breast-feeding – problems in humans have not been documented; however, Methenamine and traces of Hyoscyamine Sulfate are excreted in breast milk.

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 usual doses of Hyoscyamine Sulfate with excitement, agitation, drowsiness, or confusion.

Drug interactions – because of this product's effect on gastrointestinal motility and gastric emptying, it may decrease the absorption of other oral medications during concurrent use such as: urinary alkalizers; 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 Sulfate because of secondary antimuscarinic activities of these medications); antacids/anti-diarrheals (may reduce absorption of Hyoscyamine Sulfate, concurrent use with antacids may cause urine to become alkaline reducing effectiveness of Methenamine by inhibiting its conversion to formaldehyde) doses of these medications should be spaced 1 hour apart from doses of Hyoscyamine Sulfate; antimyasthenics (concurrent use with Hyoscyamine Sulfate may further reduce intestinal motility); ketoconazole (patients should be advised to take this combination at least 2 hours after ketoconazole); monoamine oxidase (MAO) inhibitors (concurrent use may intensify antimuscarinic side effects, opoid (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 may become blue-to-blue green and the feces may be discolored as a result of the excretion of Methylene blue. Methylene blue may interact with any drug that acts as a serotonin reuptake inhibitor (SRI) including, amongst others, selective serotonin reuptake inhibitors (SSRIs), sertonin and norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), norepinephrine-dopamine reuptake inhibitors (NDRIs), triptans and ergot alkaloids; such combinations may have the consequence of potentially fatal serotonin toxicity (serotonin syndrome). Methylene blue should not be co-administrated with any drug that acts as an SRI.

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

DRUG ABUSE AND DEPENDENCE
A dependence on the use of URIN D/S has not been reported and due to the nature of its ingredients, abuse of URIN D/S 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 6 years of age.

HOW SUPPLIED:
URIN D/S is an oval, purple tablet embossed with LLORENS on one side, available in bottles of 100 tablets NDC 54859-701-10 and professional sample bottles of 4 tablets NDC 54859-701-04.

Tamper evident by heat seal under cap. Do not use if there is evidence of tampering.

FOR DOSAGE AND FULL PRESCRIBING INFORMATION, SEE ATTACHED BOOKLET.

WARNING: Patient should be advised that urine may be colored blue while taking this medication.

PHARMACIST: Preserve and dispense in tight-light resistant package as defined in the USP.

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

MANUFACTURED FOR:
LLORENS
PHARMACEUTICAL CORP.
International Division
Miami, FL 33166
www.Llorenspharm.com

URIN D/S

methenamine, sodium phosphate, monobasic, monohydrate, phenyl salicylate, methylene blue, and hyoscyamine sulfate tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:54859-701
Route of Administration	ORAL		

Active Ingredient/Active Moiety		

Ingredient Name	Basis of Strength	Strength
Methenamine (UNII: J50OIX95QV) (Methenamine - UNII:J50OIX95QV)	Methenamine	81.6 mg
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN) (Sodium Cation - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE	40.8 mg
Phenyl Salicylate (UNII: 28A37T47QO) (Phenyl Salicylate - UNII:28A37T47QO)	Phenyl Salicylate	36.2 mg
Methylene Blue (UNII: T42P99266K) (METHYLENE BLUE CATION - UNII:ZMZ79891ZH)	Methylene Blue	10.8 mg
Hyoscyamine Sulfate (UNII: F2R8V82B84) (Hyoscyamine - UNII:PX44XO846X)	Hyoscyamine Sulfate	0.12 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
TRIACETIN (UNII: XHX3C3X673)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	purple (purple)	**Score**	no score
Shape	OVAL (Oval)	**Size**	13mm
Flavor		**Imprint Code**	LLORENS
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54859-701-10	100 in 1 BOTTLE		
2	NDC:54859-701-04	4 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		05/01/1999	

Labeler - Llorens Pharmaceutical International Division (037342305)