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## Levsin/SL advertisement.

[s.l.]: [s.n.], 1987

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# ONLY ONE

## ANTISPASMODIC

-  dissolves sublingually in *less than 2½ minutes\** for fast relief of IBS symptoms . . .
-  is mildly mint-flavored to enhance patient satisfaction . . .
-  and in 1 convenient tablet offers 3 convenient dosing methods: sublingual, oral, or chewable.

**LEVSIN<sup>®</sup>/SL**  
(hyoscyamine  
sulfate tablets USP) 0.125 mg

SCHWARZ  
P H A R M A

KREMERS URBAN COMPANY  
Milwaukee, WI 53201

\* Placebo study of volunteer subjects. Data on file.

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See next page for brief summary of prescribing information.

# LEVSIN® (hyoscyamine sulfate USP)

LEVSIN®/SL Tablets (hyoscyamine sulfate tablets USP) 0.125 mg  
LEVSIN® Tablets (hyoscyamine sulfate tablets USP) 0.125 mg  
LEVSIN® Drops (hyoscyamine sulfate oral solution USP) 0.125 mg/mL  
LEVSIN® Elixir (hyoscyamine sulfate elixir USP) 0.125 mg/5 mL  
LEVSIN® Injection (hyoscyamine sulfate injection USP) 0.5 mg/mL  
LEVSINEX™ TIMECAPS™ (hyoscyamine sulfate USP, 0.375 mg, timed-release)

The following is a brief summary. Before prescribing, see complete prescribing information in LEVSIN product labeling or PDR.

## INDICATIONS AND USAGE:

LEVSIN is effective as adjunctive therapy in the treatment of peptic ulcer. It can also be used to control gastric secretion, visceral spasm and hypermotility in spastic colitis, spastic bladder, cystitis, pylorospasm, and associated abdominal cramps. May be used in functional intestinal disorders to reduce symptoms such as those seen in mild dysenteries, diverticulitis, and acute enterocolitis. For use as adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and functional gastrointestinal disorders. Also as adjunctive therapy in the treatment of neurogenic bladder and neurogenic bowel disturbances including the splenic flexure syndrome and neurogenic colon. Also used in the treatment of infant colic (elixir and drops). LEVSIN is indicated along with morphine or other narcotics in the symptomatic relief of biliary and renal colic; as a "drying agent" in the relief of symptoms of acute rhinitis; in the therapy of parkinsonism to reduce rigidity and tremors and to control associated sialorrhea and hyperhidrosis. May be used in the therapy of poisoning by anticholinesterase agents.

Parenterally administered LEVSIN is also effective in reducing duodenal motility to facilitate the diagnostic radiologic procedure, hypotonic duodenography. LEVSIN may be used to reduce pain and hypersecretion in pancreatitis. LEVSIN may also be used in certain cases of partial heart block associated with vagal activity.

## IN ANESTHESIA:

LEVSIN Injection is indicated as a pre-operative antimuscarinic to reduce salivary, tracheobronchial, and pharyngeal secretions; to reduce the volume and acidity of gastric secretions, and to block cardiac vagal inhibitory reflexes during induction of anesthesia and intubation. LEVSIN protects against the peripheral muscarinic effects such as bradycardia and excessive secretions produced by halogenated hydrocarbons, and cholinergic agents such as physostigmine, neostigmine, and pyridostigmine given to reverse the actions of curariform agents.

## IN UROLOGY:

LEVSIN Injection may also be used intravenously to improve radiologic visibility of the kidneys.

## CONTRAINDICATIONS:

Glaucoma; obstructive uropathy (for example, bladder neck obstruction due to prostatic hypertrophy); obstructive disease of the gastrointestinal tract (as in achalasia, pyloroduodenal stenosis); paralytic ileus, intestinal atony of elderly or debilitated patients; unstable cardiovascular status in acute hemorrhage; severe ulcerative colitis; toxic megacolon complicating ulcerative colitis; myasthenia gravis.

## WARNINGS:

In the presence of high environmental temperature, heat prostration can occur with drug use (fever and heat stroke due to decreased sweating). Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance, treatment with this drug would be inappropriate and possibly harmful. Like other anticholinergic agents, LEVSIN may produce drowsiness or blurred vision. In this event, the patient should be warned not to engage in activities requiring mental alertness such as operating a motor vehicle or other machinery or to perform hazardous work while taking this drug.

Psychosis has been reported in sensitive individuals given anticholinergic drugs. CNS signs and symptoms include confusion, disorientation, short term memory loss, hallucinations, dysarthria, ataxia, coma, euphoria, decreased anxiety, fatigue, insomnia, agitation and mannerisms, and inappropriate affect. These CNS signs and symptoms usually resolve within 12-48 hours after discontinuation of the drug.

The 10 mL multiple-dose vial of LEVSIN Injection contains sodium metabisulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

## PRECAUTIONS:

### General:

Use with caution in patients with: autonomic neuropathy, hyperthyroidism, coronary heart disease, congestive heart failure, cardiac arrhythmias, and hypertension and renal disease. Investigate any tachycardia before giving any anticholinergic drug since they may increase the heart rate. Use with caution in patients with hiatal hernia associated with reflux esophagitis.

### Information for Patients:

LEVSIN may cause drowsiness, dizziness or blurred vision; patients should observe caution before driving, using machinery or performing other tasks requiring mental alertness.

Use of LEVSIN may decrease sweating resulting in heat prostration, fever or heat stroke; febrile patients or those who may be exposed to elevated environmental temperatures should use caution.

### Drug Interactions:

Additive adverse effects resulting from cholinergic blockade may occur when LEVSIN is administered concomitantly with other antimuscarinics, amantadine, haloperidol, phenothiazines, monoamine oxidase (MAO) inhibitors, tricyclic antidepressants or some antihistamines.

Antacids may interfere with the absorption of LEVSIN. Administer LEVSIN before meals; antacids after meals.

### Carcinogenesis, Mutagenesis, Impairment of Fertility:

No long-term studies in animals have been performed to determine the carcinogenic, mutagenic or impairment of fertility potential of LEVSIN; however, over 30 years of marketing experience shows no demonstrable evidence of a problem.

### Pregnancy—Pregnancy Category C:

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

### Nursing Mothers:

LEVSIN is excreted in human milk. Caution should be exercised when LEVSIN is administered to a nursing woman.

## ADVERSE REACTIONS:

Not all of the following adverse reactions have been reported with hyoscyamine sulfate. The following adverse reactions have been reported for pharmacologically similar drugs with anticholinergic/antispasmodic action. Adverse reactions may include dryness of the mouth; urinary hesitancy and retention; blurred vision; tachycardia; palpitations; mydriasis; cycloplegia; increased ocular tension; loss of taste; headache; nervousness; drowsiness; weakness; dizziness; insomnia; nausea; vomiting; impotence; suppression of lactation; constipation; bloated feeling; allergic reactions or drug idiosyncrasies; urticaria and other dermal manifestations; ataxia; speech disturbance; some degree of mental confusion and/or excitement (especially in elderly persons); and decreased sweating.

## OVERDOSAGE:

The signs and symptoms of overdose are headache, nausea, vomiting, blurred vision, dilated pupils, hot dry skin, dizziness, dryness of the mouth, difficulty in swallowing, and CNS stimulation. Measures to be taken are immediate lavage of the stomach and 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 (tepid water sponge baths, hypothermic blanket). Excitement to a degree which demands attention may be managed with sodium thiopental 2% solution given slowly intravenously or chloral hydrate (100-200 mL 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.

In rats, the LD<sub>50</sub> for hyoscyamine is 375 mg/kg. LEVSIN is dialyzable.

## HOW SUPPLIED:

LEVSIN	dosage strength	package size	NDC
SL Tablets	0.125 mg	100's	0091-3532-01
	0.125 mg	500's	0091-3532-05
Tablets	0.125 mg	100's	0091-3531-01
	0.125 mg	500's	0091-3531-05
Drops	0.125 mg/mL	15 mL	0091-4538-15
Elixir	0.125 mg/5 mL	Pint	0091-4532-16
Injection	0.5 mg/mL	5/1 mL	0091-1536-05
	0.5 mg/mL	10 mL	0091-1536-10
LEVSINEX TIMECAPS	0.375 mg	100's	0091-3537-01

**CAUTION:** Federal law prohibits dispensing without a prescription.

**SCHWARZ**  
P H A R M A

KREMERS URBAN COMPANY  
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