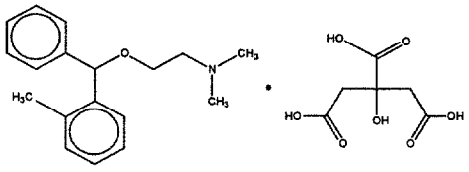
LACHMAN CONSULTANT SERVICES, INC.
Westbury, NY 11590

ATTACHMENT C

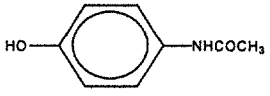
Orphenadrine Citrate, Acetaminophen and Caffeine Tablets
25 mg/385 mg/30 mg
and
50 mg/770 mg/60 mg

DESCRIPTION:
Orphenadrine citrate is the citrate salt of orphenadrine (Ethanamine, *N,N*-dimethyl-2-[(2-methylphenyl) phenylmethoxy]-citrate). It occurs as a white, crystalline powder having a bitter taste. It is practically odorless; sparingly soluble in water, slightly soluble in alcohol. It has the following structural formula:



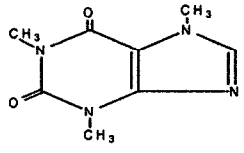
$C_{18}H_{23}NO \cdot C_6H_8O_7$ MW = 461.50

Acetaminophen (4'-hydroxyacetanilide), a slightly bitter, white, odorless, crystalline powder, is a non-opiate, non-salicylate analgesic and antipyretic. It has the following structural formula:



$C_8H_9NO_2$ MW = 151.16

Caffeine (1,3,7-trimethylxanthine), a bitter, white powder or white-glistening needles, is a central nervous system stimulant. It has the following structural formula:



$C_8H_{10}N_4O_2$ MW = 194.19

Each Orphenadrine Citrate, Acetaminophen and Caffeine Tablet contains:

Orphenadrine Citrate	25 mg	50 mg
Acetaminophen	385 mg	770 mg
Caffeine	30 mg	30 mg

Inactive Ingredients:
In accordance with good pharmaceutical practice and the provisions of USP 26 <1091> this section of the labeling will indicate the therapeutically inactive ingredients contained in this dosage form once established.

ACTIONS:
Orphenadrine citrate is a centrally acting (brain stem) compound which in animals selectively blocks facilitatory functions of the reticular formation. Orphenadrine does not produce myoneural block, nor does it affect crossed extensor reflexes. Orphenadrine prevents nicotine-induced convulsions but not those produced by strychnine.

Chronic administration to dogs and rats has revealed no drug-related toxicity. No blood or urine changes were observed, nor were there any macroscopic or microscopic pathological changes detected. Extensive experience with combinations containing acetaminophen and caffeine has established them as safe agents. The addition of orphenidrine should not alter the toxicity of acetaminophen and caffeine.

The mode of therapeutic action of orphenadrine has not been clearly identified, but may be related to its analgesic properties. Orphenadrine citrate also possesses anti-cholinergic actions.

INDICATIONS:
Symptomatic relief of mild to moderate pain of acute musculoskeletal disorders.

The orphenadrine component is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort with acute painful musculoskeletal conditions. The mode of action of orphenadrine has not been clearly identified, but may be related to its analgesic properties. Orphenadrine citrate, acetaminophen and caffeine tablets do not directly relax tense skeletal muscles in man.

CONTRAINDICATIONS:
Because of the mild anticholinergic effects of orphenadrine, this product should not be used in patients with glaucoma, pyloric or duodenal obstruction, achalasia, prostatic hypertrophy or obstructions of the bladder neck. Orphenadrine Citrate, acetaminophen and caffeine tablets are also contraindicated in patients with myasthenia gravis and in patients known to be sensitive to acetaminophen and caffeine.

The drug is contraindicated in patients who have demonstrated a previous hypersensitivity to the drug.

WARNINGS:
Orphenadrine citrate, acetaminophen and caffeine tablets may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle; ambulatory patients should therefore be cautioned accordingly.

Use with Other Acetaminophen-containing Products
Due to the potential for acetaminophen hepatotoxicity at doses higher than the recommended dose, orphenadrine citrate, acetaminophen and caffeine should not be used concomitantly with other acetaminophen-containing products.

Pregnancy:
Since safety of the use of this preparation in pregnancy, during lactation, or in the childbearing age has not been established, use of the drug in such patients requires that the potential benefits of the drug be weighed against its possible hazard to the mother and child.

Pediatric Use:
Safety and effectiveness in pediatric patients have not been established.

PRECAUTIONS:
Confusion, anxiety and tremors have been reported in a few patients receiving propoxyphene and orphenadrine concomitantly. As these symptoms may be simply due to an additive effect, reduction of dosage and/or discontinuation of one or both agents is recommended in such cases.

Safety of continuous long term therapy with orphenadrine citrate, acetaminophen and caffeine tablets has not been established; therefore, if orphenadrine citrate, acetaminophen and caffeine tablets is prescribed for prolonged use, periodic monitoring of blood, urine and liver function values is recommended.

ADVERSE REACTIONS:
Side effects of orphenadrine citrate, acetaminophen and caffeine tablets are those seen with acetaminophen and caffeine or those usually associated with mild anticholinergic agents. These may include tachycardia, palpitation, urinary hesitancy or retention, dry mouth, blurred vision, dilatation of the pupil, increased intraocular tension, weakness, nausea, vomiting, headache, dizziness, constipation, drowsiness, and rarely, urticaria and other dermatoses. Infrequently, an elderly patient may experience some degree of confusion. Mild central excitation and occasional hallucinations may be observed. These mild side effects can usually be eliminated by reduction in dosage. One case of aplastic anemia associated with the use of an orphenadrine citrate containing product has been reported. No causal relationship has been established. Some patients may experience transient episodes of light-headedness, dizziness or syncope.

DOSAGE AND ADMINISTRATION:
Orphenadrine citrate, acetaminophen and caffeine tablets, 25 mg/385 mg/30 mg:
Adults 1 to 2 tablets 3 to 4 times daily.

Orphenadrine citrate, acetaminophen and caffeine tablets, 50 mg/770 mg/60 mg:
Adults ½ to 1 tablet 3 to 4 times daily.

HOW SUPPLIED:
Orphenadrine citrate, acetaminophen and caffeine tablets are supplied as follows:

Dosage Form: Tablets
Shape, Color, and Scoring: To be determined.
Packaging: To be determined

Store at controlled room temperature, 15°C to 30°C (59° F to 86°F). [See USP].

Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).

Rx only

Manufactured by:
Manufacturer

Code 000000 Rev. 10/30/03