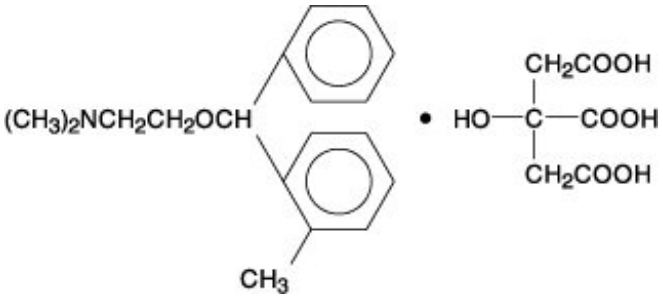
ORPHENADRINE CITRATE, ASPIRIN AND CAFFEINE- orphenadrine citrate, aspirin and caffeine tablet, multilayer
Rebel Distributors Corp

Orphenadrine Citrate, Aspirin and Caffeine Tablets

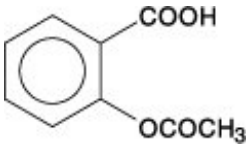
DESCRIPTION

Each tablet, for oral administration, contains Orphenadrine Citrate USP, 25 mg or 50 mg, Aspirin USP, 385 mg or 770 mg, Caffeine USP, 30 mg or 60 mg.

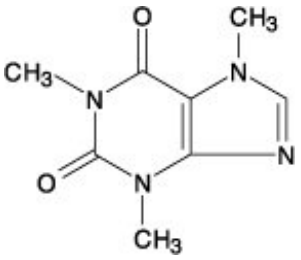
Orphenadrine citrate, *N*, *N*-Dimethyl-2-[(o-methyl-α-phenylbenzyl)oxy]ethylamine citrate (1:1), is a centrally acting (brain stem) compound. It occurs as a white, practically odorless, crystalline powder, having a bitter taste. Its molecular formula is $C_{18}H_{23}NO.C_6H_8O_7$ with a molecular weight of 461.51. The structural formula is shown below.



Aspirin, salicylic acid acetate, is a non-opiate analgesic, anti-inflammatory and antipyretic agent. It occurs as a white, crystalline tabular or needle like powder and is odorless or has a faint odor. Its molecular formula is $C_9H_8O_4$, with a molecular weight of 180.16. The structural formula is shown below.



Caffeine, 1,3,7-trimethylxanthine, is a central nervous system stimulant which occurs as a white powder or white glistening needles. It also has a bitter taste. Its molecular formula is $C_8H_{10}N_4O_2$, with a molecular weight of 194.19. The structural formula is shown below.



Each tablet contains the following inactive ingredients: colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C Blue No. 1, FD&C Yellow No. 10, anhydrous lactose, microcrystalline

cellulose, povidone, pregelatinized starch, stearic acid, and sodium lauryl sulfate.

CLINICAL PHARMACOLOGY

Orphenadrine citrate is a centrally acting (brain stem) compound which in animals selectively blocks facilitatory functions of the reticular formulation. 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 of Orphenadrine Citrate, Aspirin, and Caffeine 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 aspirin and caffeine has established them as safe agents. The addition of orphenadrine citrate does not alter the toxicity of aspirin 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 anticholinergic actions.

INDICATIONS AND USAGE

1. Symptomatic relief of mild to moderate pain of acute musculoskeletal disorders.
2. The orphenadrine component is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated 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, Aspirin, and Caffeine Tablets do not directly relax tense skeletal muscles in man.

CONTRAINDICATIONS

Because of the mild anti-cholinergic effect of orphenadrine, Orphenadrine Citrate, Aspirin, and Caffeine Tablets should not be used in patients with glaucoma, pyloric or duodenal obstruction, achalasia, prostatic hypertrophy, or obstructions at the bladder neck. Orphenadrine Citrate, Aspirin, and Caffeine Tablets are also contraindicated in patients with myasthenia gravis and in patients known to be sensitive to aspirin or caffeine.

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

WARNINGS

Reye’s Syndrome may develop in individuals who have chicken pox, influenza, or flu symptoms. Some studies suggest possible association between the development of Reye’s Syndrome and the use of medicines containing salicylate or aspirin. Orphenadrine Citrate, Aspirin, and Caffeine Tablets contain aspirin and therefore are not recommended for use in patients with chicken pox, influenza, or flu symptoms. Orphenadrine Citrate, Aspirin, 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.

Aspirin should be used with extreme caution in the presence of peptic ulcers and coagulation abnormalities.

Usage in Pregnancy

Since safety of the use of this preparation in pregnancy, during lactation, or in the child-bearing 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.

Usage in Children

The safe and effective use of this drug in children has not been established. Usage of this drug in children under 12 years of age is not recommended.

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, Aspirin, and Caffeine Tablets has not been established; therefore, if Orphenadrine Citrate, Aspirin, and Caffeine Tablets are prescribed for prolonged use, periodic monitoring of blood, urine and liver function values is recommended.

ADVERSE REACTIONS

Side effects of Orphenadrine Citrate, Aspirin, and Caffeine Tablets are those seen with aspirin and caffeine or those usually associated with mild anticholinergic agents. These may include tachycardia, palpitation, urinary hesitancy or retention, dry mouth, blurred vision, dilation 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 Orphenadrine Citrate, Aspirin, and Caffeine Tablets has been reported. No causal relationship has been established. Rare G.I. hemorrhage due to aspirin content may be associated with the administration of Orphenadrine Citrate, Aspirin, and Caffeine Tablets. Some patients may experience transient episodes of lightheadedness, dizziness or syncope.

DOSAGE AND ADMINISTRATION

Orphenadrine Citrate, Aspirin, and Caffeine Tablets, 25 mg/385 mg/30 mg: Adults 1 to 2 tablets 3 to 4 times daily.

Orphenadrine Citrate, Aspirin, and Caffeine Tablets, 50 mg/770 mg/60 mg: Adults 1/2 to 1 tablet 3 to 4 times daily.

HOW SUPPLIED

Orphenadrine Citrate, Aspirin, and Caffeine Tablets, 50 mg/770 mg/60 mg are scored, capsule-shaped, layered tablets colored white and green, imprinted SZ 491 and are supplied as:

NDC 21695-726-30 bottles of 30

NDC 21695-726-45 bottles of 45

Storage

Store at 20°-25°C (68°-77° F) (see USP Controlled Room Temperature).

Protect from moisture.

Sandoz Inc.

Princeton, NJ 08540

Repackaged by:

Rebel Distributors Corp

Thousand Oaks, CA 91320

50 mg/770 mg/60 mg Label

Orphenadrine

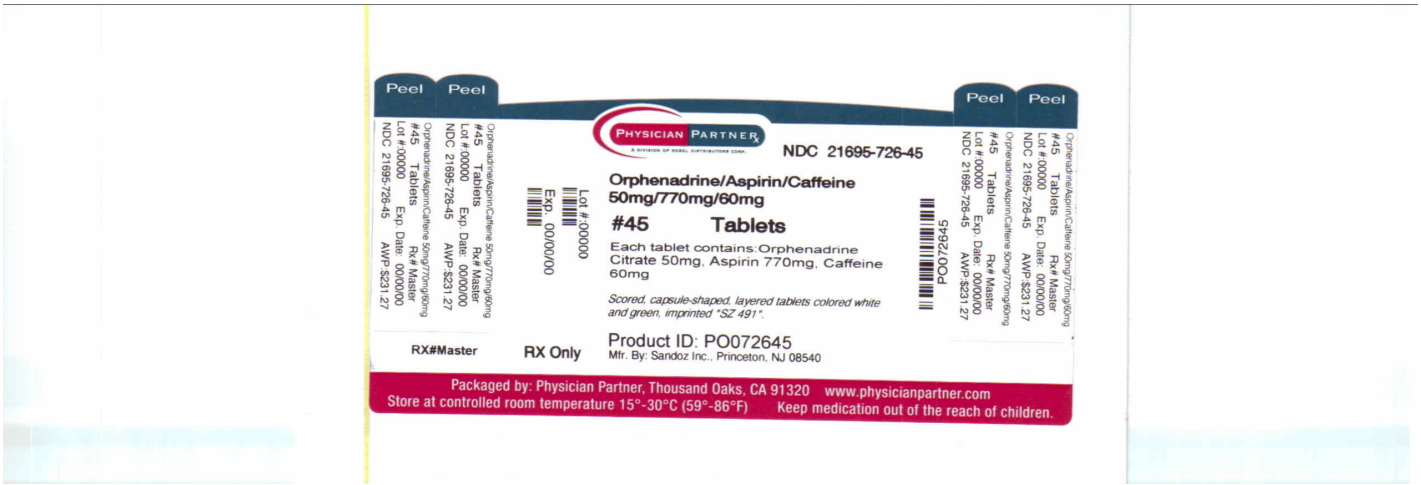
Citrate, Aspirin,

and Caffeine

Tablets

50 mg/770 mg/60 mg

Rx only



ORPHENADRINE CITRATE, ASPIRIN AND CAFFEINE

orphenadrine citrate, aspirin and caffeine tablet, multilayer

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:21695-726(NDC:0185-0714)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ORPHENADRINE CITRATE (UNII: X0A40N8I4S) (ORPHENADRINE - UNII:AL805O9OG9)	ORPHENADRINE CITRATE	50 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	770 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	60 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	WHITE, GREEN	**Score**	no score
Shape	CAPSULE	**Size**	2mm
Flavor		**Imprint Code**	SZ491
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-726-30	30 in 1 BOTTLE		
2	NDC:21695-726-45	45 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074654	12/31/1996	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 10/2010 Rebel Distributors Corp