METHYLPHENIDATE HYDROCHLORIDE- methylphenidate hydrochloride tablet
METHYLPHENIDATE HYDROCHLORIDE- methylphenidate hydrochloride tablet, extended release
UCB Pharma, Inc.

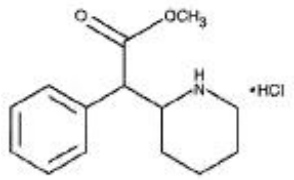
Methylphenidate Hydrochloride Tablets, USP
Methylphenidate Hydrochloride
Extended-Release Tablets, USP

CII

DESCRIPTION

Methylphenidate hydrochloride is a mild central nervous system (CNS) stimulant. Methylphenidate hydrochloride is available as 5, 10, and 20 mg tablets for oral administration. A 20 mg Extended-Release tablet for oral administration is also available.

Methylphenidate hydrochloride is methyl α-phenyl-2-piperidineacetate hydrochloride, and its structural formula is:



Methylphenidate hydrochloride is a white, odorless, fine crystalline powder. Its solutions are acid to litmus. It is freely soluble in water and in methanol, soluble in alcohol, and slightly soluble in chloroform and in acetone. Its chemical formula is $C_{14}H_{19}NO_2$•HCl, and its molecular weight is 269.77.

Inactive Ingredients: Methylphenidate hydrochloride tablets: lactose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate; 5 mg contains D&C Yellow #10; 10 mg contains FD&C Green #3, and 20 mg contains FD&C Yellow #6.

Methylphenidate hydrochloride extended-release tablets: cetyl alcohol, ethylcellulose, anhydrous lactose and magnesium stearate.

CLINICAL PHARMACOLOGY

Methylphenidate is a mild central nervous system stimulant.

The mode of action in man is not completely understood, but methylphenidate presumably activates the brain stem arousal system and cortex to produce its stimulant effect.

There is neither specific evidence which clearly establishes the mechanism whereby methylphenidate produces its mental and behavioral effects in children, nor conclusive evidence regarding how these effects relate to the condition of the central nervous system.

Methylphenidate hydrochloride in extended-release tablets is more slowly but as extensively absorbed as in the regular tablets. Bioavailability of the UCB methylphenidate hydrochloride extended-release tablet was compared to a sustained-release reference product and an immediate-release product. The extent of absorption for the three products was similar, and the rate of absorption of the two sustained-release products was not statistically different.
In another reported study with a brand of Methylphenidate HCl sustained-release, the time to peak rate in

children was reported as 4.7 hours (1.3 - 8.2 hours) for the sustained-release tablet dosage form and 1.9 hours (0.3 - 4.4 hours) for immediate release tablets. An average of 67% of a sustained-release tablet dosage form was excreted in children compared to 86% in adults.

In a clinical study involving adult subjects who received Extended-release (ER) tablets, plasma concentrations of methylphenidate hydrochloride's major metabolite appeared to be greater in females than in males. No gender differences were observed for methylphenidate hydrochloride's plasma concentration in the same subjects.

INDICATIONS AND USAGE

Attention Deficit Disorders, Narcolepsy

Attention Deficit Disorders (previously known as Minimal Brain Dysfunction in Children). Other terms being used to describe the behavioral syndrome below include: Hyperkinetic Child Syndrome, Minimal Brain Damage, Minimal Cerebral Dysfunction, Minor Cerebral Dysfunction.

Methylphenidate hydrochloride is indicated as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate-to-severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity. The diagnosis of this syndrome should not be made with finality when these symptoms are only of comparatively recent origin. Nonlocalizing (soft) neurological signs, learning disability, and abnormal EEG may or may not be present, and a diagnosis of central nervous system dysfunction may or may not be warranted.

Special Diagnostic Considerations

Specific etiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use not only of medical but of special psychological, educational, and social resources.

Characteristics commonly reported include: chronic history of short attention span, distractibility, emotional lability, impulsivity, and moderate-to-severe hyperactivity; minor neurological signs and abnormal EEG. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation of the child and not solely on the presence of one or more of these characteristics.

Drug treatment is not indicated for all children with this syndrome. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and/or primary psychiatric disorders, including psychosis. Appropriate educational placement is essential and psychosocial intervention is generally necessary. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the child's symptoms.

CONTRAINDICATIONS

Agitation

Methylphenidate is contraindicated in patients with marked anxiety, tension and agitation, since the drug may aggravate these symptoms.

Hypersensitivity to Methylphenidate

Methylphenidate is contraindicated in patients known to be hypersensitive to methylphenidate or other components of the product.

Glaucoma

Methylphenidate is contraindicated in patients with glaucoma.

Tics

Methylphenidate is contraindicated in patients with motor tics or with a family history or diagnosis of Tourette's syndrome (see ADVERSE REACTIONS).

Monoamine Oxidase Inhibitors

Methylphenidate is contraindicated during treatment with monoamine oxidase inhibitors, and also within a minimum of 14 days following discontinuation of a monoamine oxidase inhibitor (hypertensive crises may result).

Hypertension and Other Cardiovascular Conditions

Methylphenidate is contraindicated in patients with severe hypertension, angina pectoris, cardiac arrhythmias, heart failure, recent myocardial infarction, hyperthyroidism or thyrotoxicosis (see WARNINGS).

WARNINGS

Serious Cardiovascular Events

Sudden Death and Pre-existing Structural Cardiac Abnormalities or Other Serious Heart Problems

Children and Adolescents

Sudden death has been reported in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems. Although some serious heart problems alone carry an increased risk of sudden death, stimulant products generally should not be used in children or adolescents with known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that may place them at increased vulnerability to the sympathomimetic effects of a stimulant drug (see CONTRAINDICATIONS).

Adults

Sudden deaths, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD. Although the role of stimulants in these adult cases is also unknown, adults have a greater likelihood than children of having serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious cardiac problems. Adults with such abnormalities should also generally not be treated with stimulant drugs (see CONTRAINDICATIONS).

Hypertension and Other Cardiovascular Conditions

Stimulant medications cause a modest increase in average blood pressure (about 2-4 mmHg) and average heart rate (about 3-6 bpm), and individuals may have larger increases. While the mean changes alone would not be expected to have short-term consequences, all patients should be monitored for larger changes in heart rate and blood pressure. Caution is indicated in treating patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate, e.g., those with pre-existing hypertension, heart failure, recent myocardial infarction, or ventricular arrhythmia (see CONTRAINDICATIONS).

Assessing Cardiovascular Status in Patients being Treated with Stimulant Medications

Children, adolescents, or adults who are being considered for treatment with stimulant medications should have a careful history (including assessment for a family history of sudden death or ventricular arrhythmia) and physical exam to assess for the presence of cardiac disease, and should receive further cardiac evaluation if findings suggest such disease (e.g., electrocardiogram and echocardiogram). Patients who develop symptoms such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease during stimulant treatment should undergo a prompt cardiac evaluation.

Psychiatric Adverse Events

Pre-Existing Psychosis

Administration of stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder.

Bipolar Illness

Particular care should be taken in using stimulants to treat ADHD in patients with comorbid bipolar disorder because of concern for possible induction of a mixed/manic episode in such patients. Prior to initiating treatment with a stimulant, patients with comorbid depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression.

Emergence of New Psychotic or Manic Symptoms

Treatment emergent psychotic or manic symptoms, e.g., hallucinations, delusional thinking, or mania in children and adolescents without prior history of psychotic illness or mania can be caused by stimulants at usual doses. If such symptoms occur, consideration should be given to a possible causal role of the stimulant, and discontinuation of treatment may be appropriate. In a pooled analysis of multiple short-term, placebo-controlled studies, such symptoms occurred in about 0.1% (4 patients with events out of 3482 exposed to methylphenidate or amphetamine for several weeks at usual doses) of stimulant-treated patients compared to 0 in placebo-treated patients.

Aggression

Aggressive behavior or hostility is often observed in children and adolescents with ADHD, and has been reported in clinical trials and the postmarketing experience of some medications indicated for the treatment of ADHD. Although there is no systematic evidence that stimulants cause aggressive behavior or hostility, patients beginning treatment for ADHD should be monitored for the appearance of or worsening of aggressive behavior or hostility.

Long-Term Suppression of Growth

Careful follow-up of weight and height in children ages 7 to 10 years who were randomized to either methylphenidate or non-medication treatment groups over 14 months, as well as in naturalistic subgroups of newly methylphenidate-treated and non-medication treated children over 36 months (to the ages of 10 to 13 years), suggests that consistently medicated children (i.e., treatment for 7 days per week throughout the year) have a temporary slowing in growth rate (on average, a total of about 2 cm less growth in height and 2.7 kg less growth in weight over 3 years), without evidence of growth rebound during this period of development. Published data are inadequate to determine whether chronic use of amphetamines may cause a similar suppression of growth, however, it is anticipated that they likely have this effect as well. Therefore, growth should be monitored during treatment with stimulants, and patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted.

Seizures

There is some clinical evidence that stimulants may lower the convulsive threshold in patients with

prior history of seizures, in patients with prior EEG abnormalities in absence of seizures, and, very rarely, in patients without a history of seizures and no prior EEG evidence of seizures. In the presence of seizures, the drug should be discontinued.

Visual Disturbance

Difficulties with accommodation and blurring of vision have been reported with stimulant treatment.

Drug Interactions

Methylphenidate may decrease the hypotensive effect of guanethidine. Use cautiously with pressor agents.

Human pharmacologic studies have shown that methylphenidate may inhibit the metabolism of coumarin anticoagulants, anticonvulsants (phenobarbital, diphenylhydantoin, primidone), phenylbutazone, and tricyclic drugs (imipramine, clomipramine, desipramine). Downward dosage adjustments of these drugs may be required when given concomitantly with methylphenidate.

Serious adverse events have been reported in concomitant use with clonidine, although no causality for the combination has been established. The safety of using methylphenidate in combination with clonidine or other centrally acting alpha-2-agonists has not been systematically evaluated.

Use in Children Under Six Years of Age

Methylphenidate should not be used in children under six years, since safety and efficacy in this age group have not been established.

Drug Dependence

Methylphenidate should be given cautiously to patients with a history of drug dependence or alcoholism.

Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during drug withdrawal from abusive use since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

PRECAUTIONS

Patients with an element of agitation may react adversely; discontinue therapy if necessary.

Periodic CBC, differential, and platelet counts are advised during prolonged therapy.

Drug treatment is not indicated in all cases of this behavioral syndrome and should be considered only in light of the complete history and evaluation of the child. The decision to prescribe methylphenidate should depend on the physician’s assessment of the chronicity and severity of the child’s symptoms and their appropriateness for his/her age. Prescription should not depend solely on the presence of one or more of the behavioral characteristics.

When these symptoms are associated with acute stress reactions, treatment with methylphenidate is usually not indicated.

Long-term effects of methylphenidate in children have not been well established.

Carcinogenesis, Mutagenesis, Impairment of Fertility

In a lifetime carcinogenicity study carried out in B6C3F1 mice, methylphenidate caused an increase in hepatocellular adenomas and, in males only, an increase in hepatoblastomas, at a daily dose of

approximately 60 mg/kg/day. This dose is approximately 30 times and 4 times the maximum recommended human dose on a mg/kg and mg/m^2 basis respectively.

Hepatoblastoma is a relatively rare rodent malignant tumor type. There was no increase in total malignant hepatic tumors. The mouse strain used is sensitive to the development of hepatic tumors, and the significance of these results to humans is unknown.

Methylphenidate did not cause any increases in tumors in a lifetime carcinogenicity study carried out in F344 rats; the highest dose used was approximately 45 mg/kg/day, which is approximately 22 times and 5 times the maximum recommended human dose on a mg/kg and mg/m^2 basis, respectively.

In a 24-week carcinogenicity study in the transgenic mouse strain p53+/-, which is sensitive to genotoxic carcinogens, there was no evidence of carcinogenicity. Male and female mice were fed diets containing the same concentration of methylphenidate as in the lifetime carcinogenicity study; the high-dose groups were exposed to 60-74 mg/kg/day of methylphenidate.

Methylphenidate was not mutagenic in the *in vitro* Ames reverse mutation assay or in the *in vitro* mouse lymphoma cell forward mutation assay. Sister chromatid exchanges and chromosome aberrations were increased, indicative of a weak clastogenic response, in an *in vitro* assay in cultured Chinese Hamster Ovary (CHO) cells. Methylphenidate was negative *in vivo* in males and females in the mouse bone marrow micronucleus assay.

Methylphenidate did not impair fertility in male or female mice that were fed diets containing the drug in an 18-week Continuous Breeding study. The study was conducted at doses up to 160 mg/kg/day, approximately 80-fold and 8-fold the highest recommended dose on a mg/kg and mg/m^2 basis, respectively.

Pregnancy

Pregnancy Category C

In studies conducted in rats and rabbits, methylphenidate was administered orally at doses of up to 75 and 200 mg/kg/day, respectively, during the period of organogenesis. Teratogenic effects (increased incidence of fetal spina bifida) were observed in rabbits at the highest dose, which is approximately 40 times the maximum recommended human dose (MRHD) on a mg/m^2 basis. The no effect level for embryo-fetal development in rabbits was 60 mg/kg/day (11 times the MRHD on a mg/m^2 basis). There was no evidence of specific teratogenic activity in rats, although increased incidences of fetal skeletal variations were seen at the highest dose level (7 times the MRHD on a mg/m^2 basis), which was also maternally toxic. The no effect level for embryo-fetal development in rats was 25 mg/kg/day (2 times the MRHD on a mg/m^2 basis). When methylphenidate was administered to rats throughout pregnancy and lactation at doses of up to 45 mg/kg/day, offspring body weight gain was decreased at the highest dose (4 times the MRHD on a mg/m^2 basis), but no other effects on postnatal development were observed. The no effect level for pre- and postnatal development in rats was 15 mg/kg/day (equal to the MRHD on a mg/m^2 basis).

Adequate and well-controlled studies in pregnant women have not been conducted. Methylphenidate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

It is not known whether methylphenidate is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised if Methylphenidate Hydrochloride Tablets are administered to a nursing woman.

Pediatric Use

Long-term effects of methylphenidate in children have not been well established. Methylphenidate Hydrochloride Tablets should not be used in children under six years of age (see WARNINGS).

In a study conducted in young rats, methylphenidate was administered orally at doses of up to 100 mg/kg/day for 9 weeks, starting early in the postnatal period (Postnatal Day 7) and continuing through sexual maturity (Postnatal Week 10). When these animals were tested as adults (Postnatal Weeks 13-14), decreased spontaneous locomotor activity was observed in males and females previously treated with 50 mg/kg/day (approximately 6 times the maximum recommended human dose [MRHD] on a mg/m^2 basis) or greater, and a deficit in the acquisition of a specific learning task was seen in females exposed to the highest dose (12 times the MRHD on a mg/m^2 basis). The no effect level for juvenile neurobehavioral development in rats was 5 mg/kg/day (half the MRHD on a mg/m^2 basis). The clinical significance of the long-term behavioral effects observed in rats is unknown.

ADVERSE REACTIONS

Nervousness and insomnia are the most common adverse reactions but are usually controlled by reducing dosage and omitting the drug in the afternoon or evening. Other reactions include hypersensitivity (including skin rash, urticaria, fever, arthralgia, exfoliative dermatitis, erythema multiforme with histopathological findings of necrotizing vasculitis, and thrombocytopenic purpura); anorexia; nausea; dizziness; palpitations; headache; dyskinesia; drowsiness; blood pressure and pulse changes, both up and down; tachycardia; angina; cardiac arrhythmia; abdominal pain; weight loss during prolonged therapy. There have been rare reports of Tourette's syndrome. Toxic psychosis has been reported. Although a definite causal relationship has not been established, the following have been reported in patients taking this drug: instances of abnormal liver function, ranging from transaminase elevation to hepatic coma; isolated cases of cerebral arteritis and/or occlusion; leukopenia and/or anemia; transient depressed mood; a few instances of scalp hair loss. Very rare reports of neuroleptic malignant syndrome (NMS) have been received, and, in most of these, patients were concurrently receiving therapies associated with NMS. In a single report, a ten year old boy who had been taking methylphenidate for approximately 18 months experienced an NMS-like event within 45 minutes of ingesting his first dose of venlafaxine. It is uncertain whether this case represented a drug-drug interaction, a response to either drug alone, or some other cause.

In children, loss of appetite, abdominal pain, weight loss during prolonged therapy, insomnia, and tachycardia may occur more frequently; however, any of the other adverse reactions listed above may also occur.

Postmarketing Experience

In addition to the adverse events listed above, the following have been reported in patients receiving methylphenidate worldwide. The list is alphabetized: abnormal behavior, aggression, anxiety, cardiac arrest, depression, fixed drug eruption, hyperactivity, irritability, sudden death, suicidal behavior (including completed suicide), and thrombocytopenia. Data are insufficient to support an estimation of incidence or establish causation.

DOSAGE AND ADMINISTRATION

Dosage should be individualized according to the needs and responses of the patient.

Adults

Tablets

Administer in divided doses 2 or 3 times daily, preferably 30 to 45 minutes before meals. Average dosage is 20 to 30 mg daily. Some patients may require 40 to 60 mg daily. In others, 10 to 15 mg daily will be adequate. Patients who are unable to sleep if medication is taken late in the day should take the last dose before 6 p.m.

Extended-Release Tablets

Methylphenidate hydrochloride extended-release tablets have a duration of action of approximately 8 hours. Therefore, the extended-release tablets may be used in place of the immediate-release tablets when the 8-hour dosage of methylphenidate hydrochloride extended-release tablets corresponds to the titrated 8-hour dosage of the immediate-release tablets. Methylphenidate hydrochloride extended-release tablets must be swallowed whole and never crushed or chewed.

Children (6 years and over)

Methylphenidate hydrochloride tablets should be initiated in small doses, with gradual weekly increments. Daily dosage above 60 mg is not recommended.

If improvement is not observed after appropriate dosage adjustment over a one-month period, the drug should be discontinued.

Tablets

Start with 5 mg twice daily (before breakfast and lunch) with gradual increments of 5 to 10 mg weekly.

Extended-Release Tablets

Methylphenidate hydrochloride extended-release tablets have a duration of action of approximately 8 hours. Therefore, the extended-release tablets may be used in place of the immediate-release tablets when the 8-hour dosage of methylphenidate hydrochloride extended-release tablets corresponds to the titrated 8-hour dosage of the immediate-release tablets. Methylphenidate hydrochloride extended-release tablets must be swallowed whole and never crushed or chewed.

If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage, or, if necessary, discontinue the drug.

Methylphenidate should be periodically discontinued to assess the child’s condition. Improvement may be sustained when the drug is either temporarily or permanently discontinued.

Drug treatment should not and need not be indefinite and usually may be discontinued after puberty.

OVERDOSAGE

Signs and symptoms of acute overdosage, resulting principally from overstimulation of the central nervous system and from excessive sympathomimetic effects, may include the following: vomiting, agitation, tremors, hyperreflexia, muscle twitching, convulsions (may be followed by coma), euphoria, confusion, hallucinations, delirium, sweating, flushing, headache, hyperpyrexia, tachycardia, palpitations, cardiac arrhythmias, hypertension, mydriasis, and dryness of mucous membranes.

Consult with a Certified Poison Control Center regarding treatment for up-to-date guidance and advice.

Treatment consists of appropriate supportive measures. The patient must be protected against self-injury and against external stimuli that would aggravate overstimulation already present. Gastric contents may be evacuated by gastric lavage. In the presence of severe intoxication, use a carefully titrated dosage of a *short-acting* barbiturate *before* performing gastric lavage. Other measures to detoxify the gut include administration of activated charcoal and a cathartic.

Intensive care must be provided to maintain adequate circulation and respiratory exchange; external cooling procedures may be required for hyperpyrexia.

Efficacy of peritoneal dialysis or extracorporeal hemodialysis for methylphenidate overdosage has not been established.

HOW SUPPLIED

Methylphenidate Hydrochloride Tablets, USP are supplied as follows:

5 mg: round, yellow, uncoated, unscored, (debossed **531** and **MD**).

bottles of 100 NDC 0781-8840-01

10 mg: round, pale blue/green, uncoated, scored, (debossed **530** and **MD**).

bottles of 100 NDC 0781-8841-01

20 mg: round, orange, uncoated, scored, (debossed **532** and **MD**).

bottles of 100 NDC 0781-8842-01

Extended-Release, 20 mg: round, white, uncoated, unscored, (debossed **562** and **MD**).

bottles of 100 NDC 0781-8843-01

NOTE: Extended-release tablets are color-additive free.

Pharmacist

Dispense in a tight container as defined in the USP with a child-resistant closure.

Store at 20° -25°C (68° -77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature]. Protect from moisture.

Manufactured by
UCB Manufacturing, Inc.
Rochester, NY 14623 for
Sandoz Inc.
Broomfield, CO 80020

Rev. 3E 06/2006
4000391

METHYLPHENIDATE HYDROCHLORIDE

methylphenidate hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	0781-8840
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
methylphenidate hydrochloride (UNII: 4B3SC438HI) (methylphenidate - UNII:207ZZ9QZ49)		5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
lactose ()	
magnesium stearate (UNII: 70097M6I30)	
microcrystalline cellulose ()	
sodium starch glycolate ()	
D & C Yellow No. 10 ()	

Product Characteristics			
Color	YELLOW (YELLOW)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	6mm
Flavor		**Imprint Code**	531;MD
Contains			
Coating	false	**Symbol**	false

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0781-8840-01	100 in 1 BOTTLE, PLASTIC		

METHYLPHENIDATE HYDROCHLORIDE

methylphenidate hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	0781-8841
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
methylphenidate hydrochloride (UNII: 4B3SC438HI) (methylphenidate - UNII:207ZZ9QZ49)		10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
lactose ()	
magnesium stearate (UNII: 70097M6I30)	
microcrystalline cellulose ()	
sodium starch glycolate ()	
FD & C Green No. 3 ()	

Product Characteristics			
Color	BLUE (pale blue/green) , GREEN (pale blue/green)	**Score**	2 pieces
Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	530;MD
Contains			
Coating	false	**Symbol**	false

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:0781-8841-01	100 in 1 BOTTLE, PLASTIC		

METHYLPHENIDATE HYDROCHLORIDE

methylphenidate hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	0781-8842
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
methylphenidate hydrochloride (UNII: 4B3SC438HI) (methylphenidate - UNII:207ZZ9QZ49)		20 mg

Inactive Ingredients	
Ingredient Name	**Strength**
lactose ()	
magnesium stearate (UNII: 70097M6I30)	
microcrystalline cellulose ()	
sodium starch glycolate ()	
FD & C Yellow No. 6 ()	

Product Characteristics			
Color	ORANGE (ORANGE)	**Score**	2 pieces
Shape	ROUND (ROUND)	**Size**	8mm
Flavor		**Imprint Code**	532;MD
Contains			
Coating	false	**Symbol**	false

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0781-8842-01	100 in 1 BOTTLE, PLASTIC		

METHYLPHENIDATE HYDROCHLORIDE

methylphenidate hydrochloride tablet, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	0781-8843
Route of Administration	ORAL	**DEA Schedule**	CII

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
methylphenidate hydrochloride (UNII: 4B3SC438HI) (methylphenidate - UNII:207ZZ9QZ49)		20 mg

Inactive Ingredients	
Ingredient Name	**Strength**
cetyl alcohol (UNII: 936JST6JCN)	
ethylcellulose ()	
anhydrous lactose ()	
magnesium stearate (UNII: 70097M6I30)	

Product Characteristics			
Color	WHITE (WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	562;MD
Contains			
Coating	false	**Symbol**	false

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0781-8843-01	100 in 1 BOTTLE, PLASTIC		

Labeler - UCB Pharma, Inc.

Revised: 9/2006 UCB Pharma, Inc.