

**DADS/DSHS EXECUTIVE FORMULARY COMMITTEE MINUTES**  
**June 23, 2006**

The Executive Formulary Committee convened on Friday, June 23, 2006 in Room 240 - CO Building 2. The meeting was called to order by Dr. Ward, Interim Chair at 9:30 a.m.

Janet Adams, MSN, RN, CNS	√	Mike Maples	Absent
Rosha Chadwick, R.Ph.	Absent	Michael Woolsey	Absent
Jeanna Heidel, Pharm.D.	√	Jay Norwood, MSN, RN	Absent
J. Brett Hood, M.D.	√	Camille Hemlock, M.D.	√
Lisa Mican, Pharm.D.	√	Nina Muse, M.D.	Absent
Connie Millhollon, RN,	√	Steven P. Shon, M.D.	Absent
Victoria B. Morgan, M.D.	Absent	Vacant Center Position	
Ann L. Richards, Pharm.D.	√	Vacant Center Position	
Bernardo C. Tarin-Godoy, M.D.	√	Vacant Center Position	
Robert L. Ward, D.O.	√	Vacant State School Position	
Kenny Dudley	Absent	Vacant DADS Nursing Coordinator	
Scott Schalchlin	Absent		

**Guest Present: Sharon Tramonte, Pharm.D., San Antonio State School**

**Approval of Minutes of February 10, 2006**

On a motion of Dr. Tarin-Godoy, seconded by Dr. Heidel, the minutes of the February 10<sup>th</sup> meeting were approved as previously distributed.

**Adverse Drug Reaction Reports**

The Executive Formulary Committee received three adverse drug reaction reports. In the first case, a patient was receiving donepezil (Aricept®), lactulose (Chronulac®), amlodipine (Norvasc®), spironolactone (Aldactone®), vitamin B complex, zonisamide (Zonegran®), ranitidine (Zantac®), memantine (Namenda®), and olanzapine (Zyprexa®). The patient also has a history of multiple head trauma, hypertension, mild obesity, history of constipation, familial tremor, cirrhosis secondary to alcoholism and hepatitis C, anemia secondary to cirrhosis and GERD. Modafinil (Provigil®) was added to the patient's regimen in order to reduce sedation secondary to the olanzapine. Sertraline (Zoloft®) was also prescribed. The patient had elevated ammonia levels prior to the addition of modafinil. At this time the ammonia level was stable. The ammonia levels peaked about six weeks after this addition. The modafinil was discontinued, the lactulose dose was increased and the ammonia levels decreased.

In the second case, a 22-year-old male diagnosed with major depressive disorder with psychosis with a history of cocaine abuse had a seizure after receiving one dose of olanzapine (Zyprexa®). In this case, the patient was on risperidone (Risperdal®) and sertraline (Zoloft®). On January 14<sup>th</sup> at 3:44 p.m., the patient received a one-time 10 mg dose of olanzapine zydys for agitation/aggression. On January 15<sup>th</sup> at approximately 11 a.m., the patient had a grand mal seizure that lasted around 45 seconds.

An 18 year old male diagnosed with bipolar disorder was prescribed divalproex (Depakote®) ER which was titrated to 1,750 mg daily. Quetiapine (Seroquel®) and a nicotine patch were added. The patient had no known allergies prior to this admission. He developed a rash on the palms of his hands, neck and chest which was detected on January 28<sup>th</sup> around 8:50 a.m. By 11:50 a.m., the rash had spread to the arms and legs and was accompanied by itching. The divalproex was discontinued and the patient was administered diphenhydramine.

### **Psychotropic Audit Criteria**

The current Psychotropic Audit Criteria requires that a tardive dyskinesia evaluation be completed every six months for typical antipsychotics and every 12 months for atypical antipsychotics. These recommendations were based on the “Physical Health Monitoring of Patients with Schizophrenia” (Am J Psych 2004: 161:1334-1349). This article was based on the Mount Sinai Conference. The Texas Administrative Code Title 25, Part 1, Chapter 415, Subchapter A, Rule 415.10, Medication Monitoring, states that for medications known to cause movement disorder, the patient needs to be screened quarterly for abnormal involuntary movements. The TAC was finalized in August 2004 which is the same time that the article reporting the Mount Sinai Conference information was published. After discussing the issues, the Committee believed that the Mount Sinai Conference offers the best, evidence-based recommendations for monitoring tardive dyskinesia; therefore, on a motion of Dr. Tarin-Godoy, seconded by Dr. Mican, the Committee recommended that Dr. Muse be notified that the TAC needs to be updated to include the recommendations established by the Mount Sinai Conference.

The Psychotropic Audit Criteria for mesoridazine (Serentil®) and thioridazine (Mellaril®) does not require an EKG. However, the Drug Formulary Reserve Drug Category Guidelines for Use require the following:

- EKG prior to initiating therapy: 7-14 days after dose change; 7-14 days after other medication changes that could significantly alter the cardiac effects of thioridazine; every six months; and as clinically indicated.

On a motion of Dr. Mican, seconded by Ms. Millhollon, the recommendation to change the Psychotropic Audit Guidelines for mesoridazine and thioridazine to match the Drug Formulary reserve category requirements was approved.

The Psychotropic Audit Criteria requires an EKG before initiating treatment with ziprasidone (Geodon®) and subsequently if the patient demonstrates symptoms (e.g., syncope) associated with QT interval prolongation. The Mount Sinai Conference recommends that patients with the following risk factors: known heart disease, a personal history of syncope, a family history of sudden death at an early age (under age 40 years, especially if both parents had sudden death) or congenital prolonged QT syndrome have an EKG before treatment is initiated. A subsequent EKG is indicated if the patient presents with symptoms associated with a prolonged QT interval (e.g., syncope). On a motion of Dr. Tarin-Godoy, seconded by Dr. Heidel, the recommendation to change the EKG monitoring for ziprasidone to the recommendation by the Mount Sinai Conference was approved.

Currently the patient monitoring for the atypical antipsychotics criteria states: “Lipid screening [total cholesterol, low- and high-density lipoprotein (LDL and HDL), cholesterol, and triglycerides] – Every 2 years or more often if lipid levels are in the normal range, every 6 months if the LDL level is > 130 mg/dl.” It was suggested that the following be added to this statement: “If no lipid screening has been done within the last 2 years, then a lipid profile should be obtained within 30 days of initiation of the drug.” On a motion of Dr. Mican, seconded by Dr. Heidel, the recommendation to make this parameter more specific regarding the assessment of the patient’s lipid status was approved.

## **Psychotropic Dosing in Children and Adolescents**

Dr. Mican presented the “Psychotropic Medication Utilization Parameters for Foster Children” and the “Psychotropic Medication for Children and Adolescents” by the Los Angeles County Department of Mental Health Children and Family Services Bureau. Dr. Mican noted that the Drug Formulary includes suggested maximum dosage guidelines for psychotropic medications. For some drug categories, suggested geriatric maximum doses are also included. It was suggested that the Drug Formulary include dosage recommendations for children and adolescents for psychotropic medication. The Foster Children guidelines include a listing of maximum doses for children and adolescent. This document is well referenced and utilized many experts in this field of study for its development. Based on this, the Committee is considering using the doses recommended in this document as maximum doses in this population. In reviewing the Foster Children recommendations, it was noted that the guidelines were scheduled to be updated on an annual basis. Dr. Crismon, a participant in the development of the Foster Children Guidelines was contacted. He reported that the goal is to have the guidelines updated in the fall.

The Committee thought that the Foster Children Guidelines was an excellent resource and should be distributed to the field with the Committee’s endorsement.

On a motion of Dr. Tarin-Godoy, seconded by Dr. Heidel, it was recommended that the Foster Children Guidelines be distributed to the field and that the maximum dosages suggested in this document be added to the Drug Formulary as maximum doses for this population. In addition, it was recommended that feedback be obtained from the field regarding the use of these maximum doses in the children and adolescent population.

## **FDA Alerts**

The FDA has issued the following alerts that may have impact on our facilities.

For both the extended and immediate release forms of venlafaxine (Effexor®), warnings were issued for mydriasis and sustained hypertension. Patients with raised intraocular pressure or at risk of acute narrow-angle glaucoma (single-closure glaucoma) should be monitored. Cases of elevated blood pressure requiring immediate treatment have been reported in post marketing experience. Pre-existing hypertension should be controlled before treatment with venlafaxine.

For divalproex (Depakote®), hyperammonemia and encephalopathy associated with concomitant topiramate (Topamax®) use has been added as a precaution.

For telithromycin (Ketek®) an article in Annals of Internal Medicine reported three patients who experienced serious liver toxicity following the administration of telithromycin. The FDA is continuing to determine if labeling changes or other actions are warranted. As part of this, the FDA is continuing to work to better understand the frequency of liver-related adverse events reported for approved antibiotic, including telithromycin.

The FDA has published a Science Background Paper on Acute Phosphate Nephropathy and Renal Failure Associated with the Use of Oral Sodium Phosphate Bowel Cleansing Products. It noted that healthcare professionals should be aware that acute phosphate nephropathy, a type of acute renal failure, is a rare, but serious adverse event associated with the use of oral sodium phosphate (OSP) products for bowel cleansing.

Documented cases of acute phosphate nephropathy include 21 patients who used OSP solution (such as Fleet Phospho-soda and Fleet ACCU-PREP) and one patient who used OSP tablets (Visicol®). The recommended bowel cleansing doses of OSP solutions (two 45 ml doses taken 10-12 hours apart) and Visicol® (40 tablets) provide nearly identical amounts of sodium phosphate: about 60 grams of sodium phosphate per dose. No cases of acute phosphate nephropathy have been associated with OsmoPrep, an OSP tablet bowel preparation (containing 48 grams of sodium phosphate), approved in March 2006.

The Committee recommended that the information regarding the oral sodium phosphate bowel cleansing products be distributed to the field under a separate cover.

## Medicare D

Dr. Richards reported that we are currently receiving reimbursement for Medicare Part D patients. Data is being extrapolated from WORx and CARE and submitted through the switch company to the PDPs. We are still receiving many rejections that are being worked on. A Request For Proposal (RFP) is being developed to seek a third party to assist with the billing issues associated with Medicare Part D. The RFP should be released today. Mediware (the vendor for WORx™) is working on fixing the on-line adjudication (OLA) piece for their software. The revised version of their software should be released to their internal quality assurance department the first week of July.

## Non-Formulary Report Generated by WORx™

An Infomaker report for WORx has been written which obtains all the non-formulary new medication orders during a specific time frame for a specific facility. Currently, the Committee is dependent on each facility pharmacy to remember when a drug item is non-formulary, getting the form completed and then submitting it. With this new reporting capability, it should be easier to get facilities to run this report and then summarize the information on an Excel spreadsheet that has been set up as a template. Once a month, the spreadsheet can be emailed to Sally Smith to aggregate the data. This should increase reporting and provide a better understanding regarding the use of the non-formulary drugs. Each facility could develop a process to either incorporate this reporting system into their tracking of non-formulary drugs or could continue to use the current system in addition to this new reporting system.

## Non-Formulary Drug Justification Report

The Quarterly Non-Formulary Drug Justification Report was reviewed by facility, generic name and unit cost. Several of the requested items are for specific dosage strengths that are being considered for addition to the Formulary at this meeting.

## New Drug Applications

**(Please refer to Attachment A for the monographs and applications that were considered when determining action by the committee.)**

### **dexmethylphenidate (Focalin XR®) - discussed by Dr. Mican**

Dexmethylphenidate is the pharmacologically active *d*-threo enantiomer of racemic methylphenidate (Ritalin®). Dexmethylphenidate is thought to block the reuptake of norepinephrine and dopamine into the presynaptic neuron and increase the release of these monoamines into the extraneuronal space; however, the exact mode of therapeutic action in Attention Deficit Hyperactivity Disorder (ADHD) is not known. It is indicated for the treatment of ADHD in patients aged 6 years or older. Currently, only pharmacokinetic comparisons with methylphenidate have been conducted for dexmethylphenidate (Focalin XR®). Studies are not available to conclude if dexmethylphenidate (Focalin XR®) provides a superior drug profile in regard to safety, tolerability and efficacy with any formulation of methylphenidate. Dexmethylphenidate (Focalin XR®) is comparable in price to Concerta® which is on the Formulary and is also administered once a day.

**Following discussion, on motion of Dr. Mican, seconded by Dr. Heidel, the request to add dexmethylphenidate (Focalin XR®) to the formulary was denied.**

### **selegiline transdermal system (EMSAM®) - discussed by Dr. Mican**

Selegiline is an irreversible inhibitor of monoamine oxidase (MAO) A and B, with greater affinity for MAO-B. Selegiline is thought to exert its antidepressant effects by potentiating monoamine neurotransmission in the central nervous system (CNS). MAO-A and MAO-B play important roles in the catabolism of neurotransmitter amines such as norepinephrine, dopamine, and serotonin, as well as neuromodulators such as phenylethylamine in the CNS. Selegiline transdermal is indicated for the treatment of major depression disorder. The selegiline transdermal patch does not require a tyramine restricted diet at the 6 mg per day dose, whereas phenelzine (Nardil®) and

tranylcypromine (Parnate®) require tyramine restriction at all doses. The higher doses of the selegiline transdermal system requires tyramine restriction. Selegiline transdermal is currently the only antidepressant available in a transdermal system; however, along with this system comes the possibility of application site reactions (24-40%). Current formulary MAOIs are only available in tablet formulation. At this time, clinical studies are not available comparing the efficacy of selegiline transdermal vs. currently available MAOIs or other antidepressants. Drug-drug interactions are still a concern when using transdermal selegiline. Selegiline transdermal is approximately 4 times more expensive than the current formulary MAOIs.

**Following discussion, on motion of Dr. Mican, seconded by Dr. Tarin-Godoy, the request to add selegiline transdermal system (EMSAM®) to the formulary was denied.**

**Additional Dosage Strengths to the Formulary**

Dr. Richards presented a list of potential dosage strengths for consideration as additions to the Drug Formulary. See Attachment B. This list was obtained by reviewing the non-formulary items listed in WORx. Not all of the non-formulary items are included in this list. On a motion of Dr. Heidel, seconded by Ms. Millhollon, the dosage strengths were added to the Formulary.

**Pharmaceutical Waste**

Dr. Tramonte presented some literature on the best way to dispose of medication. Most pharmacies have a contract with a pharmaceutical return/waste company. However, the question arises as to how medication should be destroyed on the units. The Pharmacy Operating Instruction indicates that tablets or capsules can be destroyed by using the waste water system or by placement in the sharps container. Nationally, there have been reports of individuals going through sharps containers to obtain drugs that might have been placed there. Other drug formulations are suppose to be returned to the pharmacy for destruction and if these drugs were exposed to bodily fluids then these drugs must be placed in a resealable container (Ziploc bags). The Committee suggested that further research be completed to determine if there are better options to destroying pharmaceutical waste. Dr. Heidel, Dr. Richards and Dr. Tramonte will complete this task.

**Drug Formulary Sectional Review-**

- Immunological Agents**
- Intravenous Solutions and Additives**
- Nutritional Agents**

Dr. Tramonte provided the review of the immunological agents with her recommendations. Attachment C. The comparative cost index and dosage availability of these agents was reviewed (included in Attachment C).

Dr. Tramonte recommended that Hepatitis A Vaccine (Havrix®) be added to the Formulary. Currently, Vaqta® is on Formulary. On a motion of Dr. Tarin-Godoy, seconded by Dr. Hood, the recommendation to add Havrix® was approved.

Dr. Tramonte recommended the deletion of the following dosage strengths/formulations.

<b>Generic Name</b>	<b>Brand Name</b>	<b>Dosage forms to be deleted</b>	<b>Dosage forms still available</b>
Poliovirus vaccine, Inactivated	IPOL®	Injection, single dose	None
Rubella Virus Vaccine Live	Meruvax II ®	Injection, single dose	Measles, Mumps and Rubella Vaccine, Live (MMR II®)

On a motion of Dr. Tarin-Godoy, seconded by Dr. Hood, the recommendation to delete these products was approved. Feedback will be obtained from the field.

It was noted that mumps is being reported as occurring more frequently. The following is a summary of the key changes to the 1998 ACIP recommendations on mumps (May 17, 2006).

**Acceptable Presumptive Evidence of Immunity**

- Documentation of adequate vaccination is now 2 doses of a live mumps virus vaccine instead of 1 dose for:
  - ✓ School-aged children (i.e., grades K-12)
  - ✓ Adults at high risk (i.e., persons who work in health-care facilities, international travelers, and students at post-high school educational institutions).

**Routine Vaccination for Health-Care Workers**

- Persons born during or after 1957 without other evidence of immunity: 2 doses of live mumps virus vaccine
- Persons born before 1957 without other evidence of immunity; consider recommending 1 dose of a live mumps virus vaccine.

**For Outbreak Settings**

- Children aged 1-4 years and adults at low risk: if affected by the outbreak, consider a second dose (minimum interval between doses = 28 days) of live mumps virus vaccine.
- Health-care workers born before 1957 without other evidence of immunity: strongly consider recommending 2 doses of live mumps virus vaccine

The Committee discussed the recently approved vaccine for the prevention of cervical cancer, precancerous genital lesions and genital warts due to human papillomavirus (HPV) types 6, 11, 16 and 18. The vaccine is approved for use in females 9 – 26 years of age. Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine (Gardasil®) is given as three injections over a six month period. Immunization with Gardasil® is expected to prevent most cases of cervical cancer due to HPV types included in the vaccine. However, females are not protected if they have been infected with the HPV type(s) prior to vaccination, indicating the importance of immunization before potential exposure to the virus.

Dr. Tramonte provided the review of the intravenous solutions and additives with her recommendations. Attachment D. The comparative cost index and dosage availability of these agents was reviewed (included in Attachment D).

Dr. Tramonte recommended the deletion of the following dosage strengths/formulations.

Generic Name	Brand Name	Dosage forms to be deleted	Dosage forms still available
Dextran	Gentran®, LMD®, Macrodex®, Rheomacrodex®	High molecular weight: 6% Dextran 75 in D5W, 6% Dextran 75 in NS, 6% Dextran 70 in NS Low molecular weight: 10% Dextran 40 in D5W, 10% Dextran in NS	None

On a motion of Dr. Heidel, seconded by Dr. Tarin-Godoy, the recommendation to delete these products was approved. Feedback will be obtained from the field.

Dr. Tramonte also recommended the removal of the volumes from Water for Injection, Dextrose 50% in Water and Lactated Ringers. On a motion of Dr. Heidel, seconded by Dr. Tarin-Godoy, the recommendation to remove the volumes from these products was approved.

Dr. Tramonte provided the review of the nutritional agents with her recommendations. Attachment E. The comparative cost index and dosage availability of these agents was reviewed (included in Attachment E).

Dr. Tramonte recommended the addition of potassium phosphate (Neutra-Phos-K®) and calcium citrate/vitamin D combination.

Potassium phosphate (Neutra-Phos-K®) is indicated in the treatment and prevention of hypophosphatemia or hypokalemia. Phosphorus has a number of important functions in the biochemistry of the body. The bulk of phosphorus is located in the bones, where it plays a key role in osteoblastic and osteoclastic activities. Enzymatically catalyzed phosphate-transfer reactions are numerous and vital in the metabolism of carbohydrate, lipid and protein, and a proper concentration of the anion is primary importance in assuring an orderly biochemical sequence. In addition, phosphorus plays an important role in modifying steady-state tissue concentrations of calcium. Phosphate ions are important buffers of the intracellular fluid, and also play a primary role in the renal excretion of hydrogen ion. Oral administration of inorganic phosphates increases serum phosphate levels. Phosphates lower urinary calcium levels in idiopathic hypercalciuria. The contents of the packet should be emptied into 3 to 4 ounces of water. It should be taken with food to reduce the risk of diarrhea. Caution should be used to not confuse this product with K-Phos Neutral® (potassium phosphate plus sodium phosphate). Attachment F.

On a motion by Dr. Tarin-Godoy, seconded by Dr. Heidel, the recommendation to add potassium phosphate (Neutra-Phos-K®) to the formulary was approved. The Formulary CheckList was completed.

A monograph for calcium citrate with vitamin D was not completed as both items are on formulary. On a motion by Dr. Tarin-Godoy, seconded by Dr. Heidel, the recommendation to add calcium citrate with vitamin D to the formulary was approved.

Dr. Tramonte recommended that addition of the following dosage forms and strengths:

- Calcium carbonate/Vitamin D 600 mg/200 mg, 315 mg/200 mg
- Calcium citrate tablet: 315 mg, 950 mg
- Vitamin D tablet: 400 IU
- Potassium chloride SA capsule: 10 mEq
- Ascorbic acid tablet: 1,000 mg
- Vitamin D capsule: 0.25 mcg, 0.5 mcg

On a motion by Dr. Tarin-Godoy, seconded by Dr. Heidel, the recommendation to add these dosage strengths to the formulary was approved.

Dr. Tramonte also recommended the following:

- Add potassium chloride to this section in addition to the IV solutions and additives section
- Add sodium chloride to this section in addition to the IV solutions and additive section

On a motion by Dr. Tarin-Godoy, seconded by Dr. Heidel, these recommendations were approved.

### **Sectional Review for October 2006**

The respiratory and ophthalmic agents will be reviewed at the next meeting.

### **Pharmacy Board Complaint**

It was reported that one of the facility pharmacies had a complaint filed with the Texas State Board of Pharmacy. The patient called the Board of Pharmacy and complained that he was being prescribed too many medications. This particular patient was a transfer from another state facility. The Board of Pharmacy did investigate this case. The Board noted that the patient had multiple drug interactions and focused on whether or not the Pharmacy notified the

prescriber about the drug interactions. However, different databases rated the drug interactions at different levels of significance. The facility had documented this. Pharmacies need to be aware of these issues.

### **Next Meeting Date**

The next meeting was scheduled for October 13, 2006.

### **Adjourn**

There being no further business, the meeting was adjourned at 2:05 p.m.



Approved: \_\_\_\_\_  
Robert Ward, D.O., Chairman

### **Attachments**

- Attachment A – New Drug Applications
- Attachment B – Dosage Strengths Recommended for Addition
- Attachment C – Immunological Agents Class Review & Cost Review and Alphabetical Listing
- Attachment D – Intravenous Solutions and Additives Class Review & Cost Review and Alphabetical Listing
- Attachment E – Nutritional Agents Class Review & Cost Review and Alphabetical Listing
- Attachment F – Potassium phosphate (Neutra-Phos-K®) Monograph

Minutes Prepared by:  
Ann L. Richards, Pharm.D., BCPP

**Dexmethylphenidate Extended-Release  
(Focalin XR<sup>®</sup>)**

**Classification:** Central Nervous System Stimulant

**Pharmacology:**

Dexmethylphenidate is the pharmacologically active *d*-threo enantiomer of racemic methylphenidate (Ritalin<sup>®</sup>). Dexmethylphenidate is thought to block the reuptake of norepinephrine and dopamine into the presynaptic neuron and increase the release of these monoamines into the extraneuronal space; however, the exact mode of therapeutic action in Attention Deficit Hyperactivity Disorder (ADHD) is not known.

**Pharmacokinetics:**

**Absorption:** Dexmethylphenidate produces a bi-modal pharmacokinetic profile that displays a peak at approximately 1.5 hours (typical range 1-4 hours) and a second peak at approximately 6.5 hours (typical range 4.5-7 hours) after administration. Each capsule contains half immediate-release beads and half enteric-coated, delayed-release beads.

**Distribution:** The plasma protein binding of dexmethylphenidate is not known; however, racemic methylphenidate is 12-15 % bound to plasma proteins. The volume of distribution for dexmethylphenidate is  $2.65 \pm 1.11$  L/kg.

**Metabolism:** Dexmethylphenidate is primarily metabolized by de-esterification to d-ritalinic acid, which has no pharmacologic activity.

**Elimination:** The elimination half-life of dexmethylphenidate is variable with a mean of 3 hours (typical range 2-4.5 hours). Children tend to have a slightly shorter elimination half-life ranging from 2-3 hours.

**Indications:**

Indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients aged 6 years and older

**Dosage:**

Recommended starting dose for patients not currently taking racemic methylphenidate, dexmethylphenidate, or patients who are on stimulants other than methylphenidate is 5 mg once daily for pediatric patients and 10 mg once daily for adults. Dosage adjustments may be made at weekly intervals in 5 mg increments in pediatric patients and 10 mg increments in adults (maximum recommended dose is 20 mg per day). Extended release capsule may be opened and beads may be sprinkled on applesauce if necessary.

For patients currently using methylphenidate, the recommended starting dose of dexmethylphenidate XR is one half the total daily dose of racemic methylphenidate. Patients currently taking dexmethylphenidate immediate release can be converted to the extended release by using the same total daily dose of dexmethylphenidate given once daily.

**Contraindications:**

Patients with hypersensitivity to methylphenidate or other ingredients in the product  
Patients with marked anxiety, tension, and/or agitation  
Patients with glaucoma  
Patients with motor tics and those with a family history or diagnosis of Tourette's syndrome  
Patients treated with MAOIs (concurrent or within preceding 14 days)  
Patients with structural cardiac abnormalities, cardiomyopathy, serious arrhythmias, or other serious cardiac problems

**Precautions:**

Pregnancy Category C  
Patients with hypertension, heart failure, recent myocardial infarction, coronary artery disease, or other cardiac conditions  
Patients with pre-existing psychosis  
Patients with bipolar disorder  
Patients with a seizure disorder or history of seizures  
Patients with history of drug dependence or alcoholism

**Interactions:**

Coadministration of antacids or acid suppressants may alter the release of dexamethylphenidate because the modified release component is pH dependent  
Dexamethylphenidate should not be used in patients treated with a monoamine oxidase inhibitor (MAOI) currently or within the preceding two weeks due to the risk of hypertensive crisis  
Possible increase in blood pressure with concomitant pressor agents  
Methylphenidate use may decrease the effectiveness of antihypertensives  
Methylphenidate has been reported to inhibit coumarin anticoagulants, anticonvulsants, and tricyclic agents.

**Adverse Reactions:**

Focalin XR® has demonstrated similar bioavailability to the immediate-release formulation and has, therefore, demonstrated a similar CNS-stimulant side-effect profile. Possible significant side effects include dry mouth, dyspepsia, decreased appetite, headache, anxiety, pharyngolaryngeal pain and dizziness. Increases in blood pressure and pulse may also be seen and appear to be dose dependent.

**Costs and Monitoring:**

Focalin XR® strengths 5, 10, 20 mg – all strengths \$2.63 per capsule, QD dosing

**Price Comparison:**

Focalin® 5mg \$0.69 and 10mg \$0.99, BID dosing  
Concerta® 18mg \$2.68, 27mg \$2.74, 36mg \$2.83, 54mg \$3.08, QD dosing  
Methylphenidate 5mg \$0.11, 10mg \$0.12, 20mg \$0.24, BID-TID dosing

**Schedule CII**

In patients with cardiac disease or findings suggesting cardiac disease an EKG is recommended. Height and weight in children and adolescents. Periodic CBC with differential and platelet count is recommended during prolonged therapy.

**Product Identification:**

Capsule (extended release): 5 mg, 10 mg, 20 mg

**Efficacy:**

The efficacy of Focalin XR® for the treatment of ADHD was demonstrated in 103 pediatric patients (ages 6-12, n=86; ages 13-17, n=17) in two randomized, double-blind, placebo-controlled studies.<sup>1</sup> Patients received flexible dose Focalin XR® (5-30 mg/day) or placebo once daily for 7 weeks. There was a statistically significant treatment effect favoring Focalin XR® vs. placebo.

The efficacy of Focalin XR® for the treatment of ADHD in 221 adults (ages 18-60) was demonstrated in a 5-week randomized, double-blind, placebo-controlled study.<sup>1</sup> Patients were randomized to receive a fixed dose of 20mg, 30mg, or 40mg of Focalin XR® or placebo once daily (initiated at 10mg per day and titrated at 10mg per week increments). All three doses of Focalin XR® were significantly better than placebo with no obvious increase in efficacy with increasing dose.

To date safety and efficacy comparisons between Focalin XR® and methylphenidate (Ritalin) have not been conducted. Dexmethylphenidate and methylphenidate have been studied vs. placebo; however, the study was not designed to compare the two active components.<sup>2</sup> Patients in this study received dexmethylphenidate, methylphenidate, or placebo for 4 weeks. The primary efficacy variable was change from baseline to the final study visit in the Teacher Swanson, Nolan, and Pelham (SNAP) rating scale. Both treatment groups showed significant improvement in scores and the effect size was large for both active agents (effect size=1.0 for both). Parent SNAP ratings and Math Tests showed significant improvement at 3pm with both agents; whereas, only the dexmethylphenidate showed significant improvement at 6pm. Both the dexmethylphenidate and methylphenidate groups had significantly higher responder rates based on CG-I scores than placebo.

**Conclusions:**

Currently, only pharmacokinetic comparisons with methylphenidate have been conducted for Focalin XR®. Studies are not available to conclude if Focalin XR® provides a superior drug profile in regard to safety, tolerability and efficacy with any formulation of methylphenidate. One study comparing Focalin® to methylphenidate suggests similar efficacy and safety, and perhaps longer duration of action during the afternoon than methylphenidate with twice daily dosing of both agents.<sup>2</sup> Methylphenidate may be administered three times a day, but this dosing schedule was not studied in the trial. Focalin XR® is comparable in price to Concerta® which is currently available on the formulary and is also administered once daily. Focalin XR® is \$0.65 to \$1.25 more expensive per day than Focalin® for daily doses of 20mg and 10mg respectively. Focalin XR® is \$2.15 to \$2.39 (5-11x) more expensive per day than equivalent doses of generic methylphenidate 40mg and 20mg respectively.

**Recommendation:**

Not recommended for addition to the formulary.

**References:**

Focalin XR® Package Insert. Novartis. East Hanover, New Jersey. May 2005.

Wigal S, Swanson JM, Feifel D, Sangal RB, Elia J, Casat CD, et al. A double-blind, placebo-controlled trial of dexamethylphenidate hydrochloride and d,l,threo-methylphenidate hydrochloride in children with attention-deficit/hyperactivity disorder. *J Am. Acad. Child Adolesc. Psychiatry* 2004;43(11):1406-1414.

Prepared by:  
Steve Helm and Suzanne Fry  
Pharm.D. Interns

Lisa M. Mican, Pharm.D., BCPP  
Clinical Pharmacologist  
Austin State Hospital  
June 2006

## Dosage Strengths Recommended for Addition

Drug Name	Addition	Already on
Acetaminophen	Capsule: 500 mg	Liquid: 160 mg/5 ml Suppository, rectal: 120 mg, 125 mg, 325 mg, 650 mg Tablet: 325 mg, 500 mg Tablet, chewable: 80 mg
Acyclovir	Cream: 5%	Capsule: 200 mg Powder for Injection: 500 mg, 1000 mg Ointment, topical 5% [50 mg/g]: 3 gm, 15 gm Suspension, oral: 200 mg/5 ml Tablets: 400 mg, 800 mg
Adapalene	Cream: 0.1%	Gel, topical: 0.1%
Alprazolam	Tablet, sustained release: 3 mg	Tablet: 0.25 mg, 0.5 mg, 1 mg, 2 mg Tablet, sustained release: 0.5 mg, 1 mg, 2 mg
Aluminum Hydroxide	Capsule: 400 mg	Suspension, oral: 320 mg/5 ml; 600 mg/5 ml Tablet: 300 mg, 400 mg, 500 mg, 600 mg
Amoxicillin/Clavulanate	Suspension: 400/57 mg per 5 ml, 600/42.9 mg per 5 ml Tablet, extended release: 1000 mg	Tablet: 200 mg, 250 mg, 400 mg, 500 mg, 875 mg Tablet, chewable: 125 mg, 250 mg
Aripiprazole	Tablet: 2 mg	Solution, oral: 1 mg/ml Tablet: 5 mg, 10 mg, 15 mg, 20 mg, 30 mg
Ascorbic acid	Tablet: 1,000 mg	Solution, oral: 100 mg/ml Tablet: 250 mg, 500 mg Tablet, Chewable: 250 mg, 500 mg

<b>Drug Name</b>	<b>Addition</b>	<b>Already on</b>
Aspirin	Tablet, enteric coated: 162 mg	Suppository, rectal: 300 mg, 600 mg Tablet: 325 mg Tablet, buffered: 325 mg with buffering agents Tablet, chewable: 81 mg Tablet, enteric coated: 81 mg, 325 mg, 500 mg, 650 mg
Benzoyl peroxide	Wash, topical: 2.5%, 4%, 5%, 10% Pads: 9%	Bar: 5% Cream, topical: 10% Gel, topical: 2.5%, 5%, 10% Liquid, topical: 5%, 10% Lotion: 10%
Calcium carbonate/vitamin D	Tablet: 600 mg/Vitamin D 200 IU	Tablet: calcium 250 mg / Vitamin D 125 IU, calcium 500 mg / Vitamin D 125 IU,
Ciprofloxacin	Ointment, ophthalmic: 0.3%	Injection: 200 mg, 400 mg Solution, ophthalmic:0.3% Suspension, oral: 5 gm/100 ml, 10 gm/100 ml Tablet: 100 mg, 250 mg, 500 mg, 750 mg
Clozapine	Tablet: 50 mg, 200 mg	Tablet: 25 mg, 100 mg Tablet, oral disintegrating: 25 mg, 100 mg
Desmopressin	Injection: 4 mcg/ml	Solution, nasal: 100 mcg/ml, 1.5 mg/ml Tablet: 0.1 mg, 0.2 mg
Donepezil	Tablet, oral disintegrating: 5 mg, 10 mg	Tablet: 5 mg, 10 mg
Fentanyl	Patch: 12 mcg/hr Lozenge: 200 mcg, 400 mcg, 600 mcg, 800 mcg	Patch: 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr

<b>Drug Name</b>	<b>Addition</b>	<b>Already on</b>
Guaifenesin	Tablet: 400 mg	Caplet, sustained release: 600 mg Liquid, oral: 100 mg/5 ml, 200 mg/5 ml Tablet: 100 mg, 200 mg Tablet, sustained release: 600 mg
Heparin	Injection: 10 units/ml, 5,000 units/ml	Injection: 100 units/ml, 1,000 units/ml, 10,000 units/ml, 20,000 units/ml
Ibuprofen	Tablet, chewable: 100 mg	Suspension, oral: 40 mg/ml, 100 mg/5 ml Tablet: 200 mg, 400 mg, 600 mg, 800 mg
Levetiracetam	Tablet: 100 mg, 1000 mg	Solution, oral: 100 mg/ml Tablet: 250 mg, 500 mg, 750 mg
Mesalamine	Suppository: 1,000 mg	Capsule, controlled release: 250 mg Suppository: 500 mg Suspension, rectal: 4 gm/60 ml Tablet, delayed release: 400 mg
Quetiapine	Tablet: 50 mg, 400 mg	Tablet: 25 mg, 100 mg, 200 mg, 300 mg`
Risperidone	Tablet, oral disintegrating: 3 mg, 4 mg	Injection, long acting: 25 mg/2 ml, 37.5 mg/2 ml, 50 mg/2 ml Solution, oral: 1 mg/ml Tablet: 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg Tablet, oral disintegrating: 0.5 mg, 1 mg, 2 mg

<b>Drug Name</b>	<b>Addition</b>	<b>Already on</b>
Sulfacetamide	Gel: 10%	Lotion: 10% Ointment, ophthalmic: 10% Solution, ophthalmic: 10%
Verapamil	Capsule, sustained release: 100 mg	Capsule, sustained release: 120 mg, 180 mg, 240 mg, 360 mg Injection: 2.5 mg/ml Tablet: 40 mg, 80 mg, 120 mg Tablet, sustained release: 120 mg, 180 mg, 240 mg
Vitamin A	Capsule: 8,000 units	Capsule: 10,000 units, 25,000 units, 50,000 units Injection: 50,000 units/ml Tablet: 5,000 units
Vitamin A & D	Cream	Ointment

**Memorandum**

To: Executive Formulary Committee 

From: Sharon M. Tramonte, Pharm.D.

Through: Ann L. Richards, Pharm.D.

Subject: Class Review – Immunological Agents

Date: 21 June 2006

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Upon review, the following is a synopsis of recommended changes to the DSHS/DADS Formulary.

Recommended for addition:

- ◆ Other dosage forms & strengths of agents already on formulary  
Hepatitis A vaccine (Havrix)

Recommended for deletion:

- ◆ Poliovirus Vaccine, Inactivated (IPOL)
- ◆ Rubella Virus Vaccine Live (Meruvax II)

Immunological Agents

Immune Serums

Hepatitis B Immune Globulin (HBIG)                      \$\$\$\$\$\$

Bacterial Vaccines

Pneumococcal Vaccine, Polyvalent (Pneumovax)                      \$\$\$\$\$

### Viral Vaccines

Hepatitis A Vaccine (Vaqta)	\$\$\$\$\$\$
Hepatitis B Virus Vaccine, Recombinant (Recombivax HB, Engerix-B)	\$\$\$\$\$\$
Influenza Virus Vaccine (Fluzone, Fluviron)	\$\$
Measles, Mumps and Rubella Virus Vaccine, Live (MMR II)	\$\$\$\$\$\$
Poliovirus Vaccine, Inactivated (IPOL)	\$\$\$\$
Rubella Virus Vaccine Live (Meruvax II)	\$\$\$\$
Varicella Virus Vaccine, Live (Varivax)	\$\$\$\$\$\$

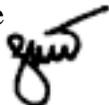
### Toxoids

Diphtheria & Tetanus Toxoids Adsorbed (DT)	\$\$\$\$
Diphtheria & Tetanus Toxoids Adsorbed for Adult Use (Td)	\$\$\$

### In-Vivo Diagnostic Biologicals

Tuberculin, Purified Protein Derivative (P.P.D.)	\$\$ - \$\$\$\$\$\$
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**Memorandum**

To: Executive Formulary Committee  
From: Sharon M. Tramonte, Pharm.D.   
Through: Ann L. Richards, Pharm.D.  
Subject: Class Review – Intravenous Solutions & Additives  
Date: 22 June 2006

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Upon review, the following is a synopsis of recommended changes to the DSHS/DADS Formulary.

Recommended for deletion:

- ♦ Dextran

Other Recommendations:

- ◆ Remove volumes from Water for Injection, Dextrose 50% in Water and Lactated Ringers Intravenous Solutions and Additives

#### Intravenous Solutions

Amino Acid Injection (Aminosyn)	\$\$\$\$ - \$\$\$\$\$\$
Dextran (Gentran, LMD, Macrodex, Rheomacrodex)	\$\$\$\$\$ - \$\$\$\$\$\$
Dextrose/Sodium Chloride Intravenous Solution	\$\$\$\$
Dextrose 5% in 0.2% Sodium Chloride	
Dextrose 5% in 0.45% Sodium Chloride	
Dextrose 5% in 0.9% Sodium Chloride	
Dextrose 5% in Water	\$ - \$\$
Dextrose 5% in Ringer's Lactate	\$
Dextrose 5% with Multiple Electrolytes (D5 E75, Baxter)	\$\$\$
Dextrose 5%/Sodium Chloride/Potassium Chloride Intravenous Solution	\$\$\$\$\$\$ - \$\$\$\$\$\$
Dextrose 5%/Sodium Chloride 0.2%/Potassium Chloride	
Dextrose 5%/Sodium Chloride 0.45%/Potassium Chloride	
Dextrose 5%/Sodium Chloride 0.9%/Potassium Chloride	
Dextrose 50% in Water	\$\$\$\$ - \$\$\$\$\$
Ringer's Lactate Solution (Hartmann's Solution)	\$\$
Sodium Chloride Intravenous Solution	\$\$\$\$ - \$\$\$\$\$
Sodium Chloride 0.2	\$ - \$\$\$
Sodium Chloride 0.45	
Sodium Chloride 0.9%	
Water for Injection	\$\$ - \$\$\$\$

#### Electrolyte Replacement Additives

Calcium Gluconate	\$\$
Magnesium Sulfate	\$ - \$
Potassium Chloride	\$ - \$\$
Sodium Bicarbonate	\$ - \$\$
Sodium Chloride	\$ - \$\$
Sodium Lactate	\$\$\$\$
Zinc Sulfate	\$ - \$\$

#### Amino Acid Injection (Aminosyn)

Infusion: 3.5%, 5%, 7%, 8.5%, 10%, 15%

Calcium Gluconate [9% elemental calcium]

Injection: 10% [100 mg/mL]

Tablet: 500 mg, 650 mg, 975 mg, 1 g

Dextran (Gentran, LMD, Macrodex, Rheomacrodex)

High molecular weight: 6% Dextran 75 in D5W, 6% Dextran 75 in NS, 6% Dextran 70 in NS

Low molecular weight: 10% Dextran 40 in D5W, 10% Dextran 40 in NS

Dextrose/Sodium Chloride Intravenous Solution

Dextrose 5% in 0.2% Sodium Chloride

Dextrose 5% in 0.45% Sodium Chloride

Dextrose 5% in 0.9% Sodium Chloride

Dextrose 5%/Sodium Chloride/Potassium Chloride Intravenous Solution

Dextrose 5%/Sodium Chloride 0.2%/Potassium Chloride

Infusion with Potassium Chloride: 10 mEq, 20 mEq

Dextrose 5%/Sodium Chloride 0.45%/Potassium Chloride

Infusion with Potassium Chloride: 10 mEq, 20 mEq, 40 mEq

Dextrose 5%/Sodium Chloride 0.9%/Potassium Chloride

Infusion with Potassium Chloride: 20 mEq, 40 mEq

Dextrose 5% in Water

Infusion

Dextrose 5% in Ringer's Lactate

Infusion

Dextrose 5% with Multiple Electrolytes (D5 E75, Baxter)

Infusion

Dextrose 50% in Water

Infusion: 500 mL, 1000 mL, 2000 mL

Syringe: 50 mL

Vials: 50 mL

Magnesium Sulfate (Epsom Salt)

Granules: ~40 mEq magnesium/5 g

Injection: 100 mg/mL, 125 mg/mL, 250 mg/mL, 500 mg/mL

## Potassium Chloride

Capsules: 8 mEq, 10 mEq

Crystals for oral suspension, extended release: 20 mEq/packet

Liquid, oral: 10% [20 mEq/15 mL], 15% [30 mEq/15 mL], 20% [40 mEq/15 mL]

Powder for oral suspension (per packet): 15 mEq, 20 mEq, 25 mEq

Injection, concentrate: 2 mEq/mL

Tablet, controlled release (microencapsulated): 750 mg [10 mEq], 1500 mg [20 mEq]

Tablet, controlled release (wax matrix): 500 mg [6.7 mEq], 600 mg [8 mEq], 750 mg [10 mEq]

## Ringer's Lactate Solution (Hartmann's Solution)

Infusion: 150 mL, 250 mL, 500 mL, 1000 mL

## Sodium Bicarbonate

Injection: 4.2% [5 mEq/10 mL], 8.4% [10 mEq/10 mL]

## Sodium Chloride

Drops, nasal: 0.9%

Infusion: 0.2%, 0.45%, 0.9%, 3%, 5%, 20%, 23.4%

Injection, bacteriostatic: 0.9%

Injection, for admixtures: 50 mEq, 100 mEq, 635 mEq

Ointment, ophthalmic: 5%

Solution, irrigation: 0.45%, 0.9%

Solution, nasal: 0.4%, 0.6%, 0.65%

Solution, nebulizing: 0.9%

Solution, ophthalmic: 2%, 5%

Tablet: 650 mg, 1 g

Tablet, enteric coated: 1 g

Tablet, slow release: 600 mg

## Sodium Chloride Intravenous Solution

Sodium Chloride 0.2

Sodium Chloride 0.45%

Sodium Chloride 0.9%

## Sodium Lactate

Injection: Sodium 167 mEq/Lactate 168 mEq per liter

## Water for Injection

Infusion: 5 mL, 250 mL, 500 mL, 1000 mL, 2000 mL, 3000 mL

## Zinc Sulfate

Capsule: 220 mg [50 mg zinc]

Injection: 1 mg/mL, 5 mg/mL

**Memorandum**

To: Executive Formulary Committee

From: Sharon M. Tramonte, Pharm.D. 

Through: Ann L. Richards, Pharm.D.

Subject: Class Review – Nutritionals 2006

Date: 22 June 2006

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Upon review, the following is a synopsis of recommended changes to the DSHS/DADS Formulary.

Recommended for addition:

- ◆ Potassium Phosphate (Neutra-phos-K®)
- ◆ Calcium citrate/Vitamin D
- ◆ Other dosage forms & strengths of agents already on formulary
  - Calcium carbonate/Vitamin D tablet: 600 mg/200 mg, 315 mg/200 mg
  - Calcium citrate tablet: 315 mg, 950 mg
  - Vitamin D tablet: 400 IU
  - Potassium chloride SA capsule: 10 mEq
  - Ascorbic acid tablet: 1,000 mg
  - Vitamin D tablet: 400 IU
  - Vitamin D capsule: 0.25 mcg, 0.5 mcg

Other Recommendations:

- ◆ Add Potassium chloride to this section in addition to the IV solutions and additives section
- ◆ Add Sodium chloride to this section in addition to the IV solutions and additives section

## Nutritional Agents

### Vitamins

Ascorbic Acid (Vitamin C)	\$ - \$
Cyanocobalamin (Vitamin B12)	\$ - \$\$\$\$\$\$\$
Folic Acid (Folvite)	\$ - \$\$\$\$
Leucovorin (Wellcovorin)	\$\$ - \$\$\$\$
Niacin/Nicotinamide (Nicobid)	\$
Phytonadione (Vitamin K1, Mephyton, Konakion)	\$\$ - \$\$\$
Pyridoxine (Vitamin B6)	\$ - \$\$
Thiamine (Vitamin B1)	\$ - \$
Vitamin A (Aquasol A)	\$ - \$\$\$\$\$\$\$
Vitamin D (Ergocalciferol, Calciferol, Drisdol)	\$
Vitamin E (Aquasol E)	\$ - \$\$\$\$\$\$\$

### Minerals Trace Elements and Electrolytes

Calcium Carbonate (Os-Cal, Titalac) - 40% elemental calcium	\$
Calcium Citrate (Citracal)	\$
Calcium Glubionate (Neo-Calglucon) - 6% elemental calcium	\$ - \$\$
Calcium Gluconate - 9% elemental calcium	\$\$
Ferrous Fumarate/Docusate Sodium (Ferro-Sequels) - 33% elemental iron	\$\$
Ferrous Sulfate (Feosol, Fer-In-Sol) -20% elemental iron	\$
Zinc Sulfate	\$ - \$\$

### Combination Products

Calcium Carbonate/Vitamin D (Oscal + D)	\$
Multivitamin (Unicap, Hexavitamins)	\$ - \$
Multivitamin/Minerals	\$ - \$
Multivitamins, Pediatric (Poly-Vi-Sol)	\$\$
Multivitamins, Prenatal (Filibon)	\$
Vitamin B Complex/Vitamin C (Stresscaps, Allbee with C)	\$
Vitamin B Complex/Vitamin C/Zinc	\$

### Ascorbic Acid (Vitamin C)

Solution, oral: 100 mg/mL

Tablet: 250 mg, 500 mg

Tablet, chewable: 250 mg, 500 mg

Calcium Carbonate (Os-Cal, Titalac) [40% elemental calcium]

Liquid, oral: 500 mg/5 mL, 1000 mg/5 mL

Tablet: 600 mg, 1250 mg, 1500 mg

Tablet, chewable: 350 mg, 500 mg, 550 mg, 750 mg, 850 mg, 1000 mg

Calcium Carbonate/Vitamin D (Oscal + D)

Tablet: Calcium 250 mg/Vitamin D 125 IU, Calcium 500 mg/Vitamin D 125 IU

Calcium Citrate (Citracal) [21% elemental calcium]

Tablet: 200 mg, 250 mg

Calcium Glubionate (Neo-Calglucon) [6% elemental calcium]

Syrup: 1.8 g/5 mL

Calcium Gluconate [9% elemental calcium]

Injection: 10% [100 mg/mL]

Tablet: 500 mg, 650 mg, 975 mg, 1g

Cyanocobalamin (Vitamin B12)

Injection: 1000 mcg/mL

Tablet: 100 mcg, 250 mcg, 500 mcg, 1000 mcg

Ferrous Fumarate/Docusate Sodium (Ferro-Sequels)[contains 33% elemental iron]

Tablet, timed released: Ferrous fumarate 150 mg [50 mg]/Docusate Sodium 100 mg

Ferrous Sulfate (Feosol, Fer-In-Sol) [contains 20% elemental iron]

Elixir with 5% alcohol: 220 mg/5 mL [18 mg/5 mL]

Tablet: 300 mg [60 mg], 325 mg [65 mg]

Folic Acid (Folvite)

Tablet: 0.4 mg, 0.8 mg, 1 mg

Leucovorin (Wellcovorin)

Injection: 3 mg/mL

Powder for injection: 25 mg, 50 mg, 100 mg, 350 mg

Tablet: 5 mg, 10 mg, 15 mg, 25 mg

Multivitamin (Unicap, Hexavitamins)

Liquid, oral: each solution contains a minimum of USDA requirements

Tablet: each tablet contains a minimum of USDA requirements

Tablet, chew: each tablet contains a minimum of USDA requirements

Multivitamin, Prenatal (Filibon)

Tablet: each tablet contains a minimum of USDA requirements

### Multivitamin/Minerals

Liquid, oral: each solution contains a minimum of USDA requirements

Tablet: each tablet contains a minimum of USDA requirements

Tablet, chew: each tablet contains a minimum of USDA requirements

### Multivitamins, Pediatric (Poly-Vi-Sol)

Liquid, oral: each solution contains a minimum of USDA requirements

### Niacin/Nicotinamide (Nicobid)

Capsule, extended release: 250 mg, 500 mg

Tablet: 50 mg, 100 mg, 250 mg, 500 mg

Tablet, extended release: 250 mg, 500 mg, 750 mg, 1000 mg

### Phytonadione (Vitamin K1, Mephyton, Konakion)

Injection, aqueous colloidal: 2 mg/mL, 10 mg/mL

Injection, aqueous (IM only): 2 mg/mL, 10 mg/mL

Tablet: 5 mg

### Pyridoxine (Vitamin B6)

Injection: 100 mg/mL

Tablet: 25 mg, 50 mg, 100 mg

### Thiamine (Vitamin B1)

Injection: 100 mg/mL, 200 mg/mL

Tablet: 50 mg, 100 mg, 250 mg, 500 mg

### Vitamin A (Aquasol A)

Capsule: 10,000 units, 25,000 units, 50,000 units

Injection: 50,000 units/mL

Tablet: 5000 units

### Vitamin B Complex/Vitamin C (Stresscaps, Allbee with C)

Capsule: each capsule contains a minimum of USDA requirements

Tablet: each tablet contains a minimum of USDA requirements

### Vitamin B Complex/Vitamin C/Zinc

Tablet: each tablet contains a minimum of USDA requirements

### Vitamin D (Ergocalciferol, Calciferol, Drisdol)

Capsule: 50,000 IU

Drops, oral: 200 IU/drop

Vitamin E (Aquasol E)

Capsule: 100 units, 200 units, 400 units, 1000 units

Tablet: 200 units, 400 units

Zinc Sulfate

Capsule: 220 mg [50 mg zinc]

Injection: 1 mg/mL, 5 mg/mL

**Potassium Phosphate  
(Neutra-Phos-K®)**

Classification: Nutritionals; Minerals, Trace Elements & Electrolytes

Description: Do not administer the capsules whole. Sound-alike/look-alike issues: Neutra-Phos-K® may be confused with K-Phos Neutral® (Potassium Phosphate + Sodium Phosphate)

**Pharmacology:**

Phosphorus has a number of important functions in the biochemistry of the body. The bulk of the phosphorus is located in the bones, where it plays a key role in osteoblastic and osteoclastic activities. Enzymatically catalyzed phosphate-transfer reactions are numerous and vital in the metabolism of carbohydrate, lipid and protein, and a proper concentration of the anion is primary importance in assuring an orderly biochemical sequence in addition, phosphorus plays an important role in modifying steady-state tissue concentrations of calcium. Phosphate ions are important buffers of the intracellular fluid, and also play a primary role in the renal excretion of hydrogen ion.

Oral administration of inorganic phosphates increases serum phosphate levels. Phosphates lower urinary calcium levels in idiopathic hypercalciuria.

Pharmacokinetics: In general, in adults, about two thirds of the ingested phosphate is absorbed from the bowel, most of which is rapidly excreted into the urine.

Indications: Used in the treatment and prevention of hypophosphatemia or hypokalemia.

Dosage: Normal requirements of phosphorus in the adult are 800 mg.

It is difficult to provide concrete guidelines for the treatment of severe hypophosphatemia because the extent of total body deficits and response to therapy are difficult to predict.

Aggressive doses of phosphate may result in a transient serum elevation followed by redistribution into intracellular compartments or bone tissue. It is recommended that repletion of severe hypophosphatemia (<1 mg/dL in adults) be done intravenously because large doses of oral phosphate may cause diarrhea and intestinal absorption may be unreliable.

Empty the contents of the packet into 3 to 4 ounces of water. Take with food to reduce the risk of diarrhea.

**Contraindications and Precautions:**

Pregnancy category: C

Contraindicated in hyperphosphatemia, hyperkalemia, hypocalcemia, hypomagnesemia and renal failure

Use with caution in patients with renal insufficiency, cardiac disease or metabolic alkalosis

**Interactions:**

Increased effects of potassium phosphate are seen with potassium-sparing diuretics, salt substitutes or ACE inhibitors. Potassium phosphate can increase the effect of digitalis.

Aluminum and magnesium-containing antacids or Sucralfate can act as phosphate binders.

Food drug interactions: avoid administering with oxalate (berries, nuts, chocolate, beans, celery, tomato) or phytate-containing foods (bran, whole wheat).

**Adverse Reactions:**

The most common adverse reactions (>10%) are gastrointestinal: diarrhea, nausea, stomach pain, flatulence and vomiting. Less common reactions (1% to 10%) include: bradycardia, hyperkalemia, muscle weakness and dyspnea. Rare reactions (<1%) include: acute renal failure, arrhythmia, chest pain, edema, mental confusion or paresthesia.

**Costs and Monitoring:**

Monitoring should include serum potassium, calcium, phosphate and sodium levels.

Costs vary by dosage required. Each packet costs approximately \$ 0.45.

**Product Identification:**

Powder for oral solution [packet]: contains 250 mg elemental phosphorus and 556 mg potassium.

Recommendation: Add to formulary

**References:**

Potassium Phosphate Monograph. APhA Drug Information Handbook. Lexi-Comp, Inc. Hudson Ohio. 2002-2003.

**Prepared by:**

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21 June 2006