

Childhood Immunization Charts to Be Split in Two

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ATLANTA — Get ready to clear a bit more wall space in your office come January. Beginning in 2007-2008, the annual harmonized childhood and adolescent immunization schedule will be split in two, with a chart on one page devoted to children aged 0-6 years and another on a separate page for those aged 7-18.

The catch-up schedule also will be divided by age in the same way, but those two charts will appear on one page.

The Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention voted unanimously for the new format at its fall meeting. The American Academy of Pediatrics Committee on Infectious Disease supports it as well, AAP liaison Dr. Joseph A. Bocchini Jr. said in an interview.

"I think this is a significant improvement. As the vaccine schedule has become more complicated, the single table has become more difficult to interpret. Splitting it this way really improves the opportunity for the practitioner to determine what immunizations a patient needs at a particular age," said Dr. Bocchini, professor of pediatrics and chief of pediatric infectious disease at Louisiana State University, Shreveport.

The decisions about whether and how to split the schedule were based in part on results from focus group sessions involving 69 immunization providers, including pediatricians, family physicians, nurse practitioners, physician assistants, registered nurses, and licensed practical nurses. They came from private and public settings, and from urban, suburban, and rural areas. "We wanted to capture the real world out there," said Sarah J. Clark, associate director for research at the Child Health Evaluation and Research Unit at the University of Michigan in Ann Arbor, which conducted the focus group.

Overall, there was a general preference for two schedules rather than one. The group disagreed, however, on where to make the split. The majority who chose ages 0-6 and 7-18 did so primarily because it places the focus on preparing children for entering kindergarten or first grade.

However, some participants wanted the split at 0-10 years and 11-18 years, noting that if a clinician were only going to post one page, the younger age range chart would contain more information. And, noted Dr. Amy B. Middleman, the liaison to ACIP for the Society for Adolescent Medicine, "Clearly this makes the most sense and is the most visually appealing product. But I think we should consider a chart just for adolescents."

On the other hand, Dr. Bocchini pointed out, "I think this is a reasonable compromise. There are a number of things that need to be done before a child enters school, and so a break at age 6 ... fits very well."

The format of the catch-up chart proved to be a bit problematic for the focus group as well, primarily because of the confusion between the two different diphtheriatetanus-acellular pertussis vaccines (DTaP for infants and toddlers/Tdap for adolescents and adults). "At first glance, many providers liked the one-table version. Then they tried to figure out what to do with DTaP/Tdap, and couldn't do it. At that point, almost everyone preferred the twotable format," Ms. Clark said.

BRIEF SUMMARY: Consult the Full Prescribing Information for complete product information.

ADDERALL XR® CAPSULES

CII RX OnI

AMPHETAMINES HAVE A HIGH POTENTIAL FOR ABUSE. ADMINISTRATION OF AMPHETAMINES FOR PROLONGED

PERIODS OF TIME MAY LEAD TO DRUG DEPENDENCE. PARTICULAR ATTENTION SHOULD BE PAID TO THE POSSIBILITY

OF SUBJECTS OBITAINING AMPHETAMINES FOR NON-THERAPEUTIC USE OR DISTRIBUTION TO OTHERS AND THE DRUGS

SHOULD BE PRESCRIBED OR DISPENSED SPARINGLY.

MISUSE OF AMPHETAMINE MAY CAUSE SUDDEN DEATH AND SERIOUS CARDIOVASCULAR ADVERSE EVENTS

deaths, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD In the role of stimulants in these adult cases is also unknown, adults have a greater likelihood than children of having serious

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 bould also generally not be treated with stimulant forug (see COMTRAINDICATIONS). 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) [see ADVERSE EVENTS], 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 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

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e behavior or hostility is often observed in children and adolescents with ADHD, and has been reported in clinical
the postmarketing experience of some medications indicated for the treatment of ADHD. Although there is no
c evidence that stimulants cause aggressive behavior or hostility, patients beginning treatment for ADHD should be
for the appearance of or worsening of aggressive behavior or hostility.
Suppression of Growth
lillow-up of weight and height in children ages 7 to 10 years who were randomized to either methylphenidate or
zation treatment groups over 14 months, as well as in naturalistic subgroups of newly methylphenidate-treated and
cation treated children over 36 months (to the ages of 10 to 13 years), sugness; that consistently medicated children

Adherts with prior EEG abnormalities in about a state of seizures, the drug snound be about the presence of seizures.

Notes that the presence of seizures, the drug should be discontinued. Visual Disturbance Difficulties with accommodation and blurring of vision have been reported with stimulant treatment. PRECAUTIONS General: The least amount of amphetamine feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage. ADDERALL XRP' should be used with caution in patients who use other sympathominetic drugs. Ties: Amphetamines have been reported to exacerbate motor and phonic ties and Tourette's syndrome. Therefore, clinical evaluation for ties and Tourette's syndrome in children and their families should precede use of stimulant medicians. Information for Patients: Amphetamines may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or wholes. The patient should therefore be cautioned accordingly.

Drug Interactions: Ambhetamines in the control of the patient to engage in potentially hazardous activities such as operating machinery or wholes. The control of the patient of the patient to engage in potentially hazardous activities such as operating machinery or wholes. The patient of the patient of the patient to engage in potentially hazardous activities such as operating machinery or wholes. The patient is allowed to the patient of the

approximately 2.4. 1.5, and 0.8 times, respectively, the maximum recommended human dose of 30 mg/day [child] on a mg/m² body surface area basis.

Amphetamine, in the enantiomer ratio present in ADDERALL® (immediate-release)(d- to 1- ratio of 3:1), was not clastogenic in the mouse bone marrow micronucleus test in wiva and was negative when tested in the E.coli component of the Ames test in witra of 1-Amphetamine (1:1 enantiomer ratio) has been reported to produce a positive response in the mouse bone marrow micronucleus test, and equivocal response in the Ames test, and negative responses in the in witra oister chromatid exchange and chromosomal aberration assays.

Amphetamine, in the enantiomer ratio present in ADDERALL® (immediate-release) (d- to 1- ratio of 3:1), did not adversely affect fertility or early embryonic development in the rat at doses of up to 20 mg/kg/day (approximately 5 times the maximum recommended human dose of 30 mg/day of 30 mg/day

e no adequate and well-controlled studies in pregnant women. There has been one report of severe congenital bony y, tracheo-esophageal fistula, and anal atresia (vater association) in a baby born to a woman who took dextreamphet-ilate with lovastain during the first trimester of pregnancy. Amphetamines should be used during pregnancy only if trial benefit justifies the potential risk to the fetus. Orgenic Effects: Infants born to mothers dependent on amphetamines have an increased risk of premature delivery and n veight. Also, these infants may experience symptoms of withdrawal as demonstrated by dysphoria, including and significant lassitude.

Nursing Mothers: Amphetamines are excreted in human milk. Mothers taking amphetamines should be advised to communism.

of age.

c Use: ADDERALL XR® has not been studied in the geriatric population.

Body System	Preferred Term	ADDERALL XR® (n=374)	Placebo (n=210)
General	Abdominal Pain (stomachache)	14%	10%
	Accidental Injury	3%	2%
	Asthenia (fatígue)	2%	0%
	Fever	5%	2%
	Infection	4%	2%
	Viral Infection	2%	0%
Digestive	Loss of Appetite	22%	2%
System	Diarrhea	2%	1%
	Dyspepsia	2%	1%
	Nausea	5%	3%
	Vomiting	7%	4%
Nervous System	Dizziness	2%	0%
	Emotional Lability	9%	2%
	Insomnia	17%	2%
	Nervousness	6%	2%
Metabolic/Nutritional	Weight Loss	4%	0%

Table 2 Adverse Events Reported by 5% or more of Adolescents Weighir ≤ 75 kg/165 lbs Receiving ADDERALL XR® with Higher Incidence Than Placebo in a 287 Patient Clinical Forced Weekly-Dose Titration Study*					
Body System	Preferred Term	ADDERALL XR® (n=233)	Placebo (n=54)		
General	Abdominal Pain (stomachache)	11%	2%		
Digestive System	Loss of Appetite b	36%	2%		
Nervous System	Insomnia ^b Nervousness	12% 6%	4% 6%ª		
Metabolic/Nutritional	Weight Loss b	9%	0%		

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Table 3 Adverse Events Reported by 5% or More of Adults Receiving ADDERALL XR® with Higher Incidence Than on Placebo in a 255 Patient Clinical Forced Weekly-Dose Titration Study*					
Body System	Preferred Term	ADDERALL XR® (n=191)	Placebo (n=64)		
General	Asthenia Headache	6% 26%	5% 13%		
Digestive System	Loss of Appetite Diarrhea Dry Mouth Nausea	33% 6% 35% 8%	3% 0% 5% 3%		
Nervous System	Agitation Anxiety Dizziness Insomnia	8% 8% 7% 27%	5% 5% 0% 13%		
Cardiovascular System	Tachycardia	6%	3%		
Metabolic/Nutritional	Weight Loss	11%	0%		
Urogenital System	Urinary Tract Infection	n 5%	0%		

Allergic: Urticaria, rash, hypersensitivity reactions including angioedema and anaphylaxis. Serious skin rashes, including Stevens Johnson Syndrome and toxic epidermal necrolysis have been reported.

Endocrine: Impotence, changes in libido

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