

Stimulant and Related Medications: U.S. Food and Drug Administration-Approved Indications and Dosages for Use in Adults

The therapeutic dosing recommendations for stimulant and related medications are based on U.S. Food and Drug Administration (FDA)-approved product labeling. Nevertheless, the dosing regimen is adjusted according to a patient's individual response to pharmacotherapy. The FDA-approved dosages and indications for the use of stimulant and related medications in adults are provided in the table below. All medication doses listed are for oral administration. Information on the generic availability of the stimulant and related medications can be found by searching the Electronic Orange Book at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm> on the FDA website.



Stimulant and Related Medications: FDA-Approved Indications and Dosages for Use in Adults

| Medication | Indication | Dosing Information | Other Information | Generic Availability |
|---|--|--|--|----------------------|
| amphetamine mixed salts (Adderall®) ¹ | ADHD | Initial dose: 5 mg once or twice a day; Maximum dose: 40 mg per day | May increase daily dose by 5 mg at weekly intervals until optimal response is achieved. Only in rare cases will it be necessary to exceed a total of 40 mg per day. | Yes |
| amphetamine mixed salts (Adderall®) | narcolepsy | Initial dose: 10 mg per day; Usual dose: 5 mg to 60 mg per day in divided doses | May increase daily dose by 10 mg at weekly intervals until optimal response is achieved. | Yes |
| amphetamine mixed salts ER (Adderall XR®)* ² | ADHD | Recommended dose: 20 mg once a day | Patients switching from amphetamine mixed salts may take the same total daily dose once a day. | No |
| armodafinil (Nuvigil®) ³ | narcolepsy | Recommended dose: 150 mg or 250 mg once a day | Take as a single dose in the morning. | No |
| armodafinil (Nuvigil®) | obstructive sleep apnea, adjunct therapy | Recommended dose: 150 mg or 250 mg once a day | There is no consistent evidence that a 250 mg dose provides additional benefit. | No |
| armodafinil (Nuvigil®) | shift work sleep disorder | Recommended dose: 150 mg once a day | Take 1 hour prior to the start of a work shift. | No |
| atomoxetine (Strattera®) ⁴ | ADHD | Initial dose: 40 mg per day; Target dose: 80 mg per day; Maximum dose: 100 mg per day | May increase after 3 days to target dose. Dose may be further increased to 100 mg per day after 2 to 4 additional weeks; dose may be given once a day in the morning or twice a day, evenly divided, in the morning and late afternoon or early evening. | Yes |
| benzphetamine (Didrex®) ⁵ | exogenous obesity | Initial dose: 25 mg to 50 mg once a day; Suggested dose: 25 mg to 50 mg 1 to 3 times a day | Dose adjustments may be made by increasing the dose or frequency. Dose should be individualized depending on the response of the patient. | Yes |

Stimulant and Related Medications: FDA-Approved Indications and Dosages for Use in Adults (Cont.)

| Medication | Indication | Dosing Information | Other Information | Generic Availability |
|--|--------------------|---|---|----------------------|
| dexmethylphenidate ER (Focalin XR®)*6 | ADHD | Patients naive to methylphenidate: Initial dose: 10 mg once a day; Maximum dose: 40 mg once a day Patients currently taking methylphenidate: Initial dose: one-half the total daily dose of methylphenidate; Maximum dose: 40 mg once a day Patients currently taking dexmethylphenidate: Initial dose: the same total daily dose of dexmethylphenidate given once a day; Maximum dose: 40 mg once a day | May increase daily dose by 10 mg at weekly intervals. Take in the morning. | No |
| dextroamphetamine IR tablets ⁷ | narcolepsy | Initial dose: 10 mg per day; Usual dose: 5 mg to 60 mg per day in divided doses | May increase daily dose by 10 mg at weekly intervals until optimal response is achieved. | Yes |
| dextroamphetamine SR (Dexedrine® Spansule®) ⁸ | narcolepsy | Initial dose: 10 mg per day; Usual dose: 5 mg to 60 mg per day in divided doses | May increase daily dose by 10 mg at weekly intervals until optimal response is achieved. | Yes |
| lisdexamfetamine (Vyvanse®) ⁺⁹ | ADHD | Initial dose: 30 mg once a day; Maximum dose: 70 mg once a day | May increase daily dose by 10 mg or 20 mg at weekly intervals. Take in the morning. | No |
| methamphetamine (Desoxyn®) ¹⁰ | exogenous obesity | Dose: 5 mg one-half hour before each meal | Treatment should not exceed a few weeks in duration. | Yes |
| methylphenidate ER (Concerta®) ⁺¹¹ | ADHD | Initial dose: 18 mg or 36 mg once a day; Maximum dose: 72 mg once a day | Not FDA approved for use in patients over 65 years old. May increase daily dose by 18 mg at weekly intervals. Take in the morning. Consult prescribing information for converting from methylphenidate IR to Concerta®. | No |
| methylphenidate IR tablet (Ritalin®), chewable tablet and solution (Methylin™) ^{12, 13} | ADHD or narcolepsy | Average dose: 20 mg to 30 mg per day; Maximum dose: 60 mg per day | May increase daily dose by 5 mg or 10 mg at weekly intervals; preferably take 30 to 45 minutes before meals. | Yes |

Stimulant and Related Medications: FDA-Approved Indications and Dosages for Use in Adults (Cont.)

| Medication | Indication | Dosing Information | Other Information | Generic Availability |
|---|--|--|---|----------------------|
| methylphenidate ER (Metadate ER [®] , Methylin [™] ER, Ritalin-SR [®]) ^{†14, 15} | ADHD or narcolepsy | Dose: the 8-hour dosage should correspond to the titrated 8-hour dosage of the methylphenidate IR formulation | Methylphenidate ER (Ritalin-SR [®]) tablets have a duration of action of approximately 8 hours. | Yes |
| modafinil (Provigil [®]) ¹⁶ | narcolepsy or obstructive sleep apnea, adjunct therapy | Recommended dose: 200 mg once a day | Doses up to 400 mg once a day have been used. There is no consistent evidence that doses above 200 mg provide additional benefit. Take in the morning. | No |
| modafinil (Provigil [®]) | shift work sleep disorder | Recommended dose: 200 mg once a day | Doses up to 400 mg once a day have been used. There is no consistent evidence that doses above 200 mg provide additional benefit. Take 1 hour prior to the start of a work shift. | No |

ER = extended-release IR = immediate-release SR = sustained-release ADHD = attention-deficit/hyperactivity disorder

* Capsules may be swallowed whole or may be opened and the contents sprinkled on applesauce.

† Tablets or capsules must be swallowed whole. Do not chew, crush or divide.

‡ Capsules may be swallowed whole or may be opened and dissolved in a glass of water.

References

¹ Adderall[®] (amphetamine mixed salts) prescribing information. (2007, June 7). Retrieved July 27, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2007/011522s040lbl.pdf

² Adderall XR[®] (amphetamine mixed salts ER) prescribing information. (2010, November 12). Retrieved July 7, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021303s020s022lbl.pdf

³ Nuvigil[®] (armodafinil) prescribing information. (2010, October 21). Retrieved July 21, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021875s005s008s015lbl.pdf

⁴ Strattera[®] (atomoxetine) prescribing information. (2011, March 7). Retrieved July 7, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021411s035lbl.pdf

⁵ Didrex[®] (benzphetamine) prescribing information. (2009, August). Retrieved November 22, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/012427s026lbl.pdf

⁶ Focalin XR[®] (dexamethylphenidate) prescribing information. (2011, April 21). Retrieved July 7, 2011, from <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=45863>

⁷ Dextroamphetamine prescribing information. (2008, February). Retrieved August 5, 2011, from <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=6980>

⁸ Dexedrine[®] Spansule[®] (dextroamphetamine SR) prescribing information. (2008, May 23). Retrieved July 7, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2008/017078s044lbl.pdf

⁹ Vyvanse[®] (lisdexamfetamine) prescribing information. (2011, March 16). Retrieved July 7, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/021977s012lbl.pdf

¹⁰ Desoxyn[®] (methamphetamine) prescribing information. (2007, May 11). Retrieved July 7, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2007/005378s026lbl.pdf

¹¹ Concerta[®] (methylphenidate ER) prescribing information. (2010, November 23). Retrieved July 7, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021121s026s027lbl.pdf

¹² Ritalin[®] and Ritalin-SR[®] (methylphenidate and methylphenidate ER) prescribing information. (2010, December 9). Retrieved July 27, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/018029s043lbl.pdf

¹³ Methylin™ (methylphenidate) prescribing information. (2010, October 18). Retrieved July 8, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021419s004lbl.pdf

¹⁴ Metadate ER® (methylphenidate ER) prescribing information. (1999, October 20). Retrieved July 25, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/anda/99/40306_Metadate_Prntlbl.pdf

¹⁵ Ritalin® and Ritalin-SR® (methylphenidate and methylphenidate ER) prescribing information. (2010, December 9). Retrieved July 27, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/018029s043lbl.pdf

¹⁶ Provigil® (modafinil) prescribing information. (2010, October 21). Retrieved July 7, 2011, from http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020717s030s034s036lbl.pdf

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