Dexmethylphenidate extended-release capsules

MEDICATION GUIDE

What is this medicine?

DEXMETHYLPHENIDATE (dex meth ill FEN i date) is used to treat attention-deficit hyperactivity disorder. Federal law prohibits the transfer of this medicine to any person other than the person for whom it was prescribed. Do not share this medicine with anyone else.

This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.

How should I use this medicine?

Take this medicine by mouth with a glass of water. Follow the directions on the prescription label. Swallow whole. Do not crush, cut, or chew. The capsule may be opened and the dose gently sprinkled on a small amount (1 tablespoon) of cool applesauce. Do not sprinkle on warm applesauce or this may result in improper dosing. The sprinkles should not be crushed or chewed. Take immediately after sprinkling. Do not store for future use. Drink some fluids (water, milk or juice) after taking the sprinkles with applesauce. You can take this medicine with or without food. Take your doses at regular intervals. Do not take your medicine more often than directed.

A special MedGuide will be given to you by the pharmacist with each prescription and refill. Be sure to read this information carefully each time.

Talk to your pediatrician regarding the use of this medicine in children. While this medicine may be prescribed for children as young as 6 years for selected conditions, precautions do apply.

Overdosage: If you think you have taken too much of this medicine contact a poison control center or emergency room at once.

What if I miss a dose?

If you miss a dose, take it as soon as you can. If it is almost time for your next dose, take only that dose. Do not take double or extra doses.

What should I tell my health care provider before I take this medicine?

They need to know if you have any of these conditions:
- A history of alcohol or drug abuse
- Glaucoma
- Heart condition or recent history of a heart attack
- High blood pressure
- Liver disease
- Mental illness, including anxiety, bipolar disorder, depression, mania or schizophrenia
- Motor tics, family history or diagnosis of Tourette’s syndrome
- Overactive thyroid
- Seizures (convulsions) or an abnormal brain scan
- An unusual or allergic reaction to dexmethylphenidate, methylphenidate, other medicines, foods, dyes, or preservatives
- Pregnant or trying to get pregnant
- Breast-feeding

What may interact with this medicine?

Do not take this medicine with any of the following medications:
- Atomoxetine
- Lithium
- Medicines called MAO Inhibitors like Nardil, Parnate, Marplan, Eldepryl
- Other stimulant medicines like amphetamine, dextroamphetamine, dexmethylphenidate, methylphenidate and modafinil
- Procarbazine

This medicine may also interact with the following medications:
- Medicines for high blood pressure
- Other medicines for mental depression or anxiety
- Seizure or epilepsy medicine
• Warfarin

This list may not describe all possible interactions. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use. Also tell them if you smoke, drink alcohol, or use illegal drugs. Some items may interact with your medicine.

What side effects may I notice from receiving this medicine?

Side effects that you should report to your doctor or health care professional as soon as possible:
• Allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue
• Anxiety or severe nervousness
• Changes in mood or behavior
• Chest pain
• Fast, irregular heartbeat
• Fever, or hot, dry skin
• High blood pressure
• Males: prolonged or painful erection
• Uncontrollable head, mouth, neck, arm, or leg movements

Side effects that usually do not require medical attention (report to your doctor or health care professional if they continue or are bothersome):
• Headache
• Stomach upset
• Weight loss

This list may not describe all possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What should I watch for while using this medicine?

Visit your doctor or health care professional for regular checks on your progress. This prescription requires that you follow special procedures with your doctor and pharmacy. You will need to have a new written prescription from your doctor or health care professional every time you need a refill.

This medicine may affect your concentration, or hide signs of tiredness. Until you know how this drug affects you, do not drive, ride a bicycle, use machinery, or do anything that needs mental alertness. If you are having trouble sleeping, and this continues to be a regular and bothersome side effect, contact your health care provider to discuss your options.

Tell your doctor or health care professional if this medicine loses its effects, or if you feel you need to take more than the prescribed amount. Do not change the dosage without talking to your doctor or health care professional. Do not suddenly stop your medicine.

For males, contact your doctor or health care professional right away if you have an erection that lasts longer than 4 hours or if it becomes painful. This may be a sign of serious problem and must be treated right away to prevent permanent damage.

Decreased appetite is a common side effect when starting this medicine. Eating small, frequent meals or snacks can help. Talk to your doctor if you continue to have poor eating habits.

Height and weight growth of a child taking this medicine will be monitored closely.

Tell your doctor or healthcare professional right away if you notice unexplained wounds on your fingers and toes while taking this medicine. You should also tell your healthcare provider if you experience numbness or pain, changes in the skin color, or sensitivity to temperature in your fingers or toes.

Where should I keep my medicine?

Keep out of the reach of children. This medicine can be abused. Keep your medicine in a safe place to protect it from theft. Do not share this medicine with anyone. Selling or giving away this medicine is dangerous and against the law.

Store at room temperature between 15 and 30 degrees C (59 and 86 degrees F). Keep container tightly closed. Throw away any unused medicine after the expiration date.

NOTE: This sheet is a summary. It may not cover all possible information. If you have questions about this medicine, talk to your doctor, pharmacist, or health care provider.