DEXMETHYLPHENIDATE CAPSULES

01/2020

6.2 Postmarketing Experience

5.7 Long-Term Suppression of Growth

• Maximum recommended daily dose: 30 mg in pediatric patients and 40 mg in adults (2.2)

5.6 Peripheral Vasculopathy, Including Raynaud’s Phenomenon

• Patients new to methylphenidate: Recommended starting dose is 5 mg once daily for

Boxed Warning 1/2019 [see Boxed Warning, Warnings have not been studied and are not recommended.

• Pediatric patients: Start with 5 mg orally once daily in the morning with or without food.

12.3 Pharmacokinetics

12.1 Mechanism of Action

9.3 Dependence

• Dexmethylphenidate Hydrochloride Extended-release Capsules. If improvement is not observed after appropriate dosage

capsule should be taken, and patients should not take anything less than one capsule per day.

Dexmethylphenidate Hydrochloride Extended-release Capsules and adjust dosage as needed.

5.2 Serious Cardiovascular Reactions

Dependence (9.2, 9.3)

• To prescribed, and monitor for signs of abuse and dependence while on therapy

needed (7.1).

Peripheral Vasculopathy, including Raynaud’s phenomenon: Signs and symptoms are usually intermittent and mild;

holidays or during discontinuation). Patients who develop abnormally sustained or frequent and painful erections should

products in both pediatric and adult patients. Priapism was not reported with drug initiation but developed after some time

Prolonged and painful erections, sometimes requiring surgical intervention, have been reported with methylphenidate

9.1 Controlled Substance

Dexmethylphenidate hydrochloride extended-release capsules have not been studied in the geriatric population.

6.2 Post-Marketing Experience

Examples

Intervention

Intervention

System Organ Class

System

38% 19%

System

Anxiety 5% 11% 11% 2%

Anorexia 5% 5% 7% 0%

Evaluated Avoid use of Dexmethylphenidate Hydrochloride Extended- 

Release Capsule on the day of surgery. 11/23/2016

Send IT for PATIENT COUNSELING INFORMATION and Mediation Guide.

Revised 3/18/2020

FULL PRESCRIPTIVE INFORMATION CONTENTS

2 Indication and Usage

3 Contraindications

4 Warnings and Precautions

5 Adverse Reactions

6 Full Precautions

7 Clinical Important Interactions with Dexmethylphenidate

Dexmethylphenidate hydrochloride extended-release capsules are a racemic mixture of the d- and l-enantiomers of methylphenidate. Methylphenidate is the d-isomer of the natural base, dextroamphetamine (dextroamphetamine sulfate) Use of dexmethylphenidate hydrochloride extended-release capsules as monotherapy or in combination with other drugs to treat attention-deficit/hyperactivity disorder, ADHD

5.4 Psychiatric Adverse Reactions

• In small clinical trials, the incidence of at least one adverse event (dyspepsia, headache, anxiety, and pharyngolaryngeal pain).

The following are discussed in more detail in other sections of the labeling:

including Raynaud’s phenomenon, were observed in post-marketing reports at different times and at therapeutic doses

with peripheral vasculopathy, including Raynaud’s phenomenon. Signs and symptoms are usually intermittent and mild;

in the long-term suppression of growth and weight loss after a period of time. Of the 212 pediatric patients treated with dexmethylphenidate hydrochloride extended-release capsules in the pivotal pediatric trials, 28% of patients had growth suppression (decrease in height or weight) by the end of the trial.

These highlights do not include all of the information needed to use dexmethylphenidate hydrochloride extended-release capsules safely and effectively. For complete information on dexmethylphenidate hydrochloride extended-release capsules, see Prescribing Information.
What is the most important information I should know about Dexmethylphenidate Hydrochloride Extended-Release Capsules? Dexmethylphenidate Hydrochloride Extended-Release Capsules should not be taken if you are allergic to any of the ingredients in Dexmethylphenidate Hydrochloride Extended-Release Capsules. See the end of this Medication Guide for a complete list of ingredients in Dexmethylphenidate Hydrochloride Extended-Release Capsules. Ask your health care provider if you are taking or plan to take any medicine that might interact with Dexmethylphenidate Hydrochloride Extended-Release Capsules. Your doctor should do a physical examination before you start taking the medication and 6-12 months after you start taking it. Your doctor will determine the dose of Dexmethylphenidate Hydrochloride Extended-Release Capsules that is right for you. The dose of Dexmethylphenidate Hydrochloride Extended-Release Capsules may need to be adjusted for multiple comparisons.

How should I store Dexmethylphenidate Hydrochloride Extended-Release Capsules? Store Dexmethylphenidate Hydrochloride Extended-Release Capsules in a safe place and in a tightly closed container at room temperature between 68° F to 77° F (20° C to 25° C). Dexmethylphenidate Hydrochloride Extended-Release Capsules may also be destroyed by a medicine take-back program at austere collection sites such as retail pharmacies, urgent care clinics, hospital pharmacies, and law enforcement locations.

What are the possible side effects of Dexmethylphenidate Hydrochloride Extended-Release Capsules? Tell your doctor if you or your child have any signs or symptoms of heart problems such as chest pain, shortness of breath, or fainting while taking Dexmethylphenidate Hydrochloride Extended-Release Capsules. Tell your doctor if you or your child have any symptoms that could be signs of a heart attack while taking Dexmethylphenidate Hydrochloride Extended-Release Capsules.

Common side effects include:
- dry mouth
- decreased appetite
- headache
- anxiety
- pharyngolaryngeal pain
- increased heart rate
- increased blood pressure
- agitation
- irritability
- nervousness
- insomnia
- dry eye
- constipation
- flatulence
- dyspepsia
- abdominal pain
- upper respiratory tract infection
- sinusitis
- otitis media
- acne
- nasopharyngitis
- sore throat
- upper respiratory infection
- sinusal congestion
- rhinitis

What should I watch for while taking Dexmethylphenidate Hydrochloride Extended-Release Capsules? See the end of this Medication Guide for a complete list of ingredients in Dexmethylphenidate Hydrochloride Extended-Release Capsules. If you or your child develop or worsen any of these symptoms while taking Dexmethylphenidate Hydrochloride Extended-Release Capsules, you should stop taking the medicine and call your doctor right away. You should also stop taking the medicine and call your doctor if your child or you have any other signs or symptoms that worry you.

General information about the safe and effective use of Dexmethylphenidate Hydrochloride Extended-Release Capsules.

What are the possible side effects of Dextromethorphan Hydrobromide? What is the most important information I should know about Dextromethorphan Hydrobromide? Dextromethorphan Hydrobromide may be used to treat cough and cold symptoms or other symptoms of respiratory illness (eg, allergy). tell your pharmacist that you are taking Dextromethorphan Hydrobromide or any other medicine.

Dextromethorphan Hydrobromide should not be taken with other medicines without telling the pharmacist. Tell each health care provider you visit about all your medications. And tell any doctor who treat you about all the medications, vitamins, and herbal supplements you use. One of the ingredients in Dextromethorphan Hydrobromide is propylene glycol. The propylene glycol can be absorbed through the skin and cause severe health problems, including organ failure, in the body. Call your pharmacist for medical advice about side effects. For Medication Guide, please visit www.medications.com.

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The Medication Guide has been approved by the U.S. Food and Drug Administration.