

Brightside Specialty Pharmacy

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Patient Education for PROMETHAZINE-DM 6.25-15 MG/5ML



May cause photosensitive reactions Use sunscreen Not recommended for use in children < 2 yrs, unless directed Drink plenty of water to help loosen mucus Call doctor if no improvement in 7 days Avoid taking with other CNS depressant drugs or alcohol May cause drowsiness or dizziness Use caution driving. Measure dose accurately with dose-measuring device. Do not increase dose or frequency or use longer than directed.

Skin may be more prone to sunburn; Use sunscreen Unless MD directs, do not use in kids less than 2 Drink plenty of water to help loosen mucus Call doctor if you are not better in 7 days Avoid alcohol/other drugs that make you sleepy May make you drowsy or dizzy. Drive with caution Measure dose using a dosing spoon/cup/syringe. Do not increase dose or frequency or prolong use.

.....Education Section.....

IMPORTANT:

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

PROMETHAZINE/DEXTROMETHORPHAN - ORAL

(pro-METH-uh-zeen/dex-trow-meth-OR-fan)

WARNING:

Promethazine should not be used by children younger

than 2 years since it might cause serious (possibly fatal) slow/shallow breathing. This problem has occurred even with normal doses in this age group. The lowest effective dosage should be used, and other drugs that affect breathing should be avoided. Seek immediate medical attention in the unlikely event that slow/shallow breathing occurs. Promethazine should not be used by children with liver disease (including possible Reyes syndrome).

USES:

This combination medication is used to temporarily treat

runny nose, coughing, and sneezing caused by the common cold, allergies, hay fever, and other breathing illnesses. Promethazine is a phenothiazine that works like an antihistamine. It blocks the effects of a certain natural substance (histamine), which causes allergy symptoms. It also has a drying effect.

Dextromethorphan belongs to a class of drugs known as cough suppressants. It acts on a part of the brain (cough center) to reduce the need to cough.

This product is usually not used for ongoing cough from smoking or long-term breathing problems (such as chronic bronchitis, emphysema) unless directed by your doctor.

Cough-and-cold products have not been shown to be safe or effective in children younger than 6 years. Do not use this product to treat cold symptoms in children younger than 6 years

unless specifically directed by the doctor. Some products (such as long-acting tablets/capsules) are not recommended for use in children younger than 12 years. Ask your doctor or pharmacist for more details about using your product safely.

These products do not cure or shorten the length of the common cold and may cause serious side effects. To decrease the risk for serious side effects, carefully follow all dosage directions. Do not use this product to make a child sleepy. Do not give other cough-and-cold medication that might contain the same or similar ingredients (see also Drug Interactions section). Ask the doctor or pharmacist about other ways to relieve cough and cold symptoms (such as drinking enough fluids, using a humidifier or saline nose drops/spray).

HOW TO USE:

Take this medication by mouth as directed by your

doctor, with or without food, usually every 4-6 hours as needed. Since dosing recommendations may vary, carefully follow your doctor's directions for taking this medication.

The dosage is based on your age, medical condition, and response to treatment. Carefully measure the dose using a special measuring device/spoon. Do not use a household spoon because you may not get the correct dose.

Drink plenty of fluids while you are using this medication unless otherwise directed by your doctor. The fluid will help loosen the mucus in your lungs.

Improper use of this medication (abuse) may result in serious harm (such as brain damage, seizure, death). Do not increase your dose, take it more frequently, or use it for a longer time than directed.

Tell your doctor if your cough lasts, returns, or gets worse after 7 days or if it is accompanied by headache that doesn't go away, fever, severe sore throat, or rash.

SIDE EFFECTS:

Drowsiness, dizziness, blurred vision, nausea,

constipation, or dry mouth may occur. If any of these effects last or get worse, notify your doctor or pharmacist promptly.

To minimize dizziness and lightheadedness, get up slowly when rising from a sitting or lying position.

If you are very sleepy or have difficulty waking up after using this medication, stop taking this medication and talk to your doctor or pharmacist right away. Your dosage may need to be lower.

Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if you have any serious side effects, including: decreased coordination, difficulty urinating, shaking (tremor), mental/mood changes (such as nervousness, excitement, irritability, confusion, hallucinations), abnormal/uncontrolled movements (such as fixed upward stare, neck twisting, tongue movements), slow heartbeat, fainting.

Get medical help right away if you have any very serious side effects, including: slow/shallow breathing, seizures.

This medication may rarely cause a very serious condition called neuroleptic malignant syndrome (NMS). Get medical help right away if you have any of the following symptoms: fever, muscle stiffness/pain/tenderness/weakness, severe tiredness, severe confusion, sweating, fast/irregular heartbeat, dark urine, signs of kidney problems (such as change in the amount of urine).

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS:

See also Warning section.

Before taking this medication, tell your doctor or pharmacist if you are allergic to promethazine or to dextromethorphan; or to any other phenothiazines (such as prochlorperazine); or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: breathing problems (such as asthma, emphysema, sleep apnea), heart problems (such as slow/irregular heartbeat, chest pain), liver problems, difficulty urinating (such as due to an enlarged prostate), stomach/bowel problems (such as blockage, ulcer), high blood pressure, diabetes, a certain eye problem (glaucoma), seizures, blood/immune system problems (such as bone marrow depression).

This drug may make you dizzy or drowsy or blur your vision. Alcohol or marijuana (cannabis) can make you more dizzy or drowsy. Do not drive, use machinery, or do anything that needs

alertness or clear vision until you can do it safely. Children should be supervised during bicycle riding and other possibly hazardous activities to avoid injury. Limit alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis).

This medication may make you more sensitive to the sun. Limit your time in the sun. Avoid tanning booths and sunlamps. Use sunscreen and wear protective clothing when outdoors. Tell your doctor right away if you get sunburned or have skin blisters/redness.

Liquid forms of this medication may contain sugar, alcohol, or aspartame. Caution is advised if you have diabetes, liver disease, phenylketonuria (PKU), or any other condition that requires you to limit/avoid these substances in your diet. Ask your doctor or pharmacist about using this product safely.

Before having surgery or procedures such as X-rays with dye, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

Children may be more sensitive to the side effects of this drug, especially slowed breathing and uncontrolled movements (see also Warning section). Children may also experience excitability rather than drowsiness. Special caution should be taken in children with a family history of sudden infant death syndrome (SIDS), those who have a severe loss of fluid (dehydration), and those who are hard to wake up from sleep.

Older adults may be more sensitive to the side effects of this drug, especially drowsiness, confusion, constipation, or trouble urinating. Drowsiness and confusion can increase the risk of falling.

During pregnancy, this medication should be used only if clearly needed. Discuss the risks and benefits with your doctor.

It is unknown if this medication passes into breast milk. However, it may have undesirable effects on a nursing infant. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

Drug interactions may change how your

medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug include: diphenhydramine or other antihistamines applied to the skin (such as anti-itch cream, ointment, spray), metoclopramide, rolapitant.

Taking certain MAO inhibitors with this medication may cause a serious (possibly fatal) drug interaction. Avoid taking isocarboxazid, metaxalone, methylene blue, moclobemide, phenelzine, procarbazine, rasagiline, safinamide, selegiline, or tranylcypromine during treatment with this medication. Most MAO inhibitors should also not be taken for two weeks before treatment with this medication. Ask your doctor when to start or stop taking this medication.

The risk of serious side effects (such as slow/shallow breathing, severe drowsiness/dizziness) may be increased if this medication is taken with other products that may also cause

drowsiness or breathing problems. Tell your doctor or pharmacist if you are taking other products such as opioid pain or cough relievers (such as codeine, hydrocodone), alcohol, marijuana (cannabis), drugs for sleep or anxiety (such as alprazolam, lorazepam, zolpidem), muscle relaxants (such as carisoprodol, cyclobenzaprine), or other antihistamines (such as cetirizine, diphenhydramine).

Check the labels on all your medicines (such as allergy or cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about using those products safely.

Dextromethorphan is available in both prescription and nonprescription products. Check the labels of all your medications to make sure you are not taking more than one product containing dextromethorphan.

This product can affect the results of certain lab tests (such as urine pregnancy tests, skin allergy tests). Make sure laboratory personnel and all your doctors know you use this drug.

OVERDOSE:

If someone has overdosed and has serious symptoms such as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Symptoms of overdose may include: severe drowsiness, inability to wake up, slow/shallow breathing, slow heartbeat, hallucinations, seizures.

NOTES:

Do not share this medication with others.

This medication has been prescribed for your current condition only. Do not use it later for another condition unless told to do so by your doctor. A different medication may be necessary in those cases.

MISSED DOSE:

If you are prescribed this medication on a regular schedule and miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up.

STORAGE:

Store at room temperature away from light and moisture.

Do not store in the bathroom. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

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