

DHASEDYL SYRUP

PRODUCT NAME AND DESCRIPTION:

Dhasedyl syrup is a brown viscous mixture, with prune flavour. It contains:

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| Codeine Phosphate BP | 9.0 mg/5 ml |
| Promethazine HCl BP | 3.6 mg/5 ml |
| Ephedrine HCl BP | 6.0 mg/5 ml |

Excipients: Citric acid, Benzoic acid, sodium metabisulphite, sugar, liquid glucose, sodium citrate dihydrate, sodium saccharin, liquid caramel, ascorbic acid, prune flavor and purified water.

WHAT IS DHASEDYL SYRUP USED FOR?

Dhasedyl syrup contains:

Codeine: an opioid derivative/opiate agonist which has cough suppressant properties for relieving non-productive cough,

Promethazine: a sedating phenothiazine derivative antihistamine, which relieves symptoms of allergic condition and rhinitis.

Ephedrine: has sympathomimetic effect which is used for symptomatic relief of nasal congestion.

This formulation is used for temporary or short term (7 days) relief for cough and nasal congestion associated with upper respiratory symptoms due to allergy or the common cold. If symptoms persist consult the physician. Dosage should not be increased if cough fails to respond.

SPECIAL WARNING:

Caution is advised when codeine is used in patients with underlying respiratory conditions, including those with asthma and other chronic breathing problems.

Parents and caregivers of paediatric patients should be advised on the possible signs and symptoms of respiratory depression in their children, such as unusual sleepiness, confusion and difficult or noisy breathing, and to seek immediate attention if these are observed.

Nursing mothers should also be advised to exercise caution when taking codeine, since codeine's metabolite (morphine) may subsequently be found in the breast milk. If the infant shows signs of increased sleepiness, difficulty breastfeeding, breathing difficulties or limpness, immediate medical attention should be sought.

PRECAUTIONS

Prolonged use of codeine preparations carries the risk of dependence to the medicine.

Prolonged use of ephedrine may cause a lack of response to the medicine and a syndrome resembling an anxiety state.

Do not take this medicine if you are allergic to any of the ingredients (promethazine, codeine, ephedrine) in this product.

Do not take this medicine during pregnancy or breast feeding, before consulting your doctor or pharmacist.

Do not take this medicine after the expiry date stated on the label.

Do not take this medicine if you have liver disease, bronchial asthma, or receiving MAO (monoamine oxidase) inhibitors for conditions such as depression or Parkinson's disease.

Do not take this medicine if you are suffering from severe high blood pressure, severe coronary artery disease (heart disease caused by poor blood flow or narrowing of the blood vessels of the heart), other heart conditions, angle closure glaucoma, prostate hypertrophy, irregular heart rhythm, mental or behavioural disorder or thyrotoxicosis (a thyroid disease). Please check with your doctor if you have any of the above conditions.

Dhasedyl syrup may cause drowsiness. If affected, do not drive or operate machinery.

Dhasedyl syrup may cause your skin to be more sensitive to the sun especially if you have eczema or a tendency to rheumatism. You should protect your skin from exposure to strong sunlight.

If you are taking any other medications, going for a laboratory test or suffering from other medical conditions, consult your doctor or pharmacist before taking this medicine.

It is not intended for use in chronic or persistent cough e.g. cough that occurs with asthma or where cough is accompanied with excessive secretions or other symptoms (e.g., fever, rash, headache, nausea, vomiting), unless directed by a physician. To be used with caution in asthmatic/atopic children.

RECOMMENDED DOSAGE:

Extreme care should be taken in giving an accurate dose of medicine because overdoses have been reported to cause serious adverse events. It is highly recommended that a measuring spoon or syringe (which can be obtained from

the pharmacy) be used to administer doses.

To be administered orally.

Adults: 5 to 10ml 3 or 4 times a day.

Children and Adolescents: Codeine should not be used in children below 12 years old. In those 12 years old and above, codeine may be used for the treatment of unproductive cough which is not relieved by other anti-tussives alone. The lowest effective dose should be used for the shortest possible duration.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you are taking this medicine regularly and miss a dose, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for the dose that you have missed.

FOOD AND DRUG INTERACTIONS:

Avoid using alcohol, sleeping pills, medicines for reducing anxiety and tension or any other medicines that suppress breathing. Dhasedyl syrup may interact with MAOI, so please consult a doctor before using both medicines together.

SIDE EFFECTS:

A medicine may cause side effects in certain individuals. If you experience side effects and are concerned, you should seek advice from your doctor or pharmacist. Common side effects of Dhasedyl syrup include:

- Drowsiness
- Dry mouth
- Stomach upset
- Loss of appetite
- Nausea or vomiting
- Diarrhoea or constipation.
- Restlessness
- Dizziness
- Blurred vision
- Tinnitus (Ringing or buzzing in ears)
- Itch
- Nervousness, anxiety
- Tremors
- High blood pressure
- Palpitations (rapid heart beats)
- Insomnia

Less common but more serious side-effects include:

Fever, breathing difficulty, irregular heart beat, jaundice - yellow tinge to skin or eyes, tremors or convulsions, mental confusion or hallucinations, difficulty in micturition, muscular weakness, tachycardia, agitation and anxiety. Large doses may cause respiratory depression.

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

Symptoms of overdose include the following:

Over-excitement, shaky and unsteady movements, convulsions and/or tremors, restlessness, irritability, hallucinations, mental confusion, difficulty in breathing or slower breathing rate, drowsiness, muscular twitching, muscle weakness, rapid heartbeat, unconsciousness, coma, nausea and vomiting, chills, fever, nervousness, suicidal behaviour / delusions, blurred vision, involuntary rapid movement of the eyeball (nystagmus), difficulty in passing urine, high blood pressure may develop initially, followed later by low blood pressure.

If you experience any of the above symptoms or if you have taken more than the recommended dose, seek immediate medical attention.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

- 1) you experience common side effects that bother you and serious side effects that need urgent medical attention.
- 2) you have taken this medicine for 7-10 days in a row and your condition is not improving.
- 3) you have taken an overdose of the medicine.
- 4) you are currently using, just completed or about to start on any other medicines.

STORAGE CONDITION:

Store below 30°C in airtight container and protect from light. Keep out of the reach of children.

AVAILABILITY:

Dhasedyl Syrup is available in 120ml and 3.8L container.

Not all packs may be available locally.

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For further information, please consult your physician or pharmacist.

Manufactured by:
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