

DHASEDYL DM SYRUP

PRODUCT NAME AND DESCRIPTION:

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

Dextromethorphan Hydrobromide	10.0mg/5ml
Promethazine Hydrochloride	3.6 mg/5 ml
Ephedrine Hydrochloride	6.0 mg/5 ml

And Sodium Benzoate 0.1%w/v as preservative.

Excipients : Citric acid monohydrate , Sodium Benzoate, Sodium Metabisulphate, Granulated Fine White Sugar, Sodium Citrate Dihydrate, Sodium Saccharin, Liquid Caramel (SRC 3212), Prune HC 3995, Propylene Glycol, Glycerin, Disodium EDTA, Purified Water

WHAT IS DHASEDYL DM SYRUP USED FOR?

Dhasedyl DM syrup contains:

Dextromethorphan: an opioid derivative and cough suppressant 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 of symptoms of cough and cold. If symptoms persist, consult the physician. Dosage should not be increased if cough fails to respond.

WARNINGS:

Dhasedyl DM contains promethazine hydrochloride. It should not be used in paediatric patients less than 2 years of age because of the potential for fatal respiratory depression.

Dhasedyl DM syrup is to be used with caution in children 2 years and older.

Not for use in patients suffering from severe high blood pressure and severe coronary artery disease (heart disease caused by poor blood flow or narrowing of the blood vessels of the heart).

PRECAUTIONS

Do not take this medicine if you are allergic to any of the ingredients (promethazine, dextromethorphan, 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. Dhasedyl DM syrup is to be used with caution in patients with narrow-angle glaucoma, high blood pressure, heart conditions, prostate hypertrophy, irregular heart rhythm, mental or behaviour disorder and thyrotoxicosis (a thyroid disease).

Dhasedyl DM syrup may cause drowsiness. If affected, do not drive or operate machinery. Dhasedyl DM 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. Prolonged use of ephedrine may cause a lack of response to the medicine and a syndrome resembling an anxiety state.

RECOMMENDED DOSAGE:

Dhasedyl DM contains promethazine hydrochloride. It should not be used in the pediatric patients less than 2 years of age because of the potential for fatal respiratory depression.

Dhasedyl DM syrup is to be used with caution in children 2 years and older.

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.

Children 2-6 years: 2.5ml 3 times a day.

Children 6-12 years: 2.5 to 5ml 3 times a day.

PHARMACODE
AREA

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

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 DM syrup may interact with MAOI, so please consult a doctor before using both medicines together.

SIDE EFFECTS:

Any 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 DM 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. Protect from light. Keep out of the reach of children.

AVAILABILITY:

Dhasedyl DM Syrup is available in 120ml amber glass bottle and 3.8 litres high density polyethylene container.

DATE OF REVISION: May 2021

Manufactured by:
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