

File information		Artwork Type [ PLEASE TICK ✓ ]		Sign / Stamp	
Product : T UPHADYL FORTE EXPECTORANT SAP No. : Version : RASUB/V1 Date : 16 May 2024		<input type="checkbox"/> Unit Box <input type="checkbox"/> Outer Box <input type="checkbox"/> Label		<input checked="" type="checkbox"/> Leaflet <input type="checkbox"/> Fix-A-Form <input type="checkbox"/> Others : _____	
<input type="checkbox"/> Aluminium Foil <input type="checkbox"/> Sachet		Document Category [ PLEASE TICK ✓ ]		Pharmacode / QR Code / Others	
<input checked="" type="checkbox"/> RA Submission Artwork <input type="checkbox"/> Internal Artwork Circulation <input type="checkbox"/> Others : _____		<input type="checkbox"/> NPRA Approval Copy <input type="checkbox"/> Previous Approved Artwork		<input type="checkbox"/> Approval Copy Artwork <input type="checkbox"/> Draft Artwork	
Remarks		Colour		N/A	
Font : Helvetica Regular ( Spacing - 6.5pt / Size - 7pt) Dimension : 148.5mm (w) x 210mm (h)		Black 100%			
Colours shown on this proof are to indicate correct colour separations.					

# UPHADYL forte

## EXPECTORANT

### RELIEVES CHESTY COUGH

#### DESCRIPTION

A brown, raspberry flavoured expectorant.  
Each 5ml contains  
Diphenhydramine HCl ..... 14 mg  
Ammonium Chloride ..... 135 mg

Preservatives: Methylparaben 0.1 % w/v

Route of Administration : Oral

#### ACTIONS AND MODE OR MECHANISMS OF ACTION

Antihistamine, expectorant, antitussive and for cold.

#### PHARMACODYNAMICS

The combination of Diphenhydramine Hydrochloride, an antihistamine and Ammonium Chloride, an expectorant, will provide rapid relief for cough which is associated with common cold influenza or allergic conditions. The menthol will give a soothing effect.

#### PHARMACOKINETICS

Diphenhydramine hydrochloride is well absorbed from the gastrointestinal tract. Peak plasma concentrations are achieved about 1 to 4 hours after oral doses. Diphenhydramine is widely distributed throughout the body including the CNS. Diphenhydramine is highly bound to plasma proteins. Metabolism is extensive. Diphenhydramine is excreted mainly in the urine as metabolites; little is excreted as unchanged drug. The elimination half-life has been reported to range from 2.4 to 9.3 hours.

Ammonium chloride is absorbed from the gastrointestinal tract. The ammonium ion is converted into urea in the liver, the anion thus liberated into the blood and extracellular fluid causes a metabolic acidosis and decreases the pH of the urine; this is followed by transient diuresis.

#### INDICATIONS

Uphadyl forte expectorant is indicated for the relief of chest congestion and coughs with thick phlegm. It clears nasal passages, liquefies and loosens stubborn phlegm and soothes tiresome coughing.

#### CONTRAINDICATIONS

Hypersensitivity to any of the ingredients.  
Patients receiving MAOIs.

#### SIDE EFFECTS/ADVERSE REACTIONS

The most common side effect is sedation. Other side effects include gastro intestinal disturbances such as nausea, vomiting, diarrhoea or constipation and epigastric pain.

It may produce headache, blurred vision, tinnitus, elation or depression, irritability, nightmare, anorexia, difficulty in micturition, dryness of the mouth, tightness of the chest and tingling, heaviness and weakness of the hands.

#### PRECAUTIONS/WARNINGS

UPHADYL may enhance the sedative effect of central depressants including alcohol, barbiturates, hypnotics, sedatives and tranquilisers. It may cause drowsiness and dulling of mental alertness. Patients undergoing treatment should not take charge of vehicles, other means of transport and machinery where loss of attention may lead to accidents.

When used for treatment of cough and cold:

- Not to be used in children less than 2 years of age.
- To be used with caution and doctor's/ pharmacists advice in children 2 to 6 years of age.

#### DRUG INTERACTION

Alcohol, tranquilizers, sedative-hypnotics and CNS depressants - increase CNS depression. MAO inhibitors - increases anticholinergic effects.

#### PREGNANCY AND LACTATION

##### Pregnancy

Reproduction studies in rats and rabbits given up to 5 times the human dose have shown no evidence of impaired fertility or harm to the fetus; use during pregnancy only if clearly needed.

##### Lactation

Contraindicated for use in nursing mothers due to the increased risk of antihistaminic side effects in newborns and infants.

#### DOSAGE

Unless otherwise prescribed by the physician:

Adults and children over 12 years:  
5 to 10 ml every 4 or 6 hours  
(not to exceed 60 ml in 24 hours).

Children 6 to 12 years:  
2.5 to 5 ml every 4 to 6 hours  
(not to exceed 30 ml in 24 hours).

Children 2 to 5 years:  
2.5 ml every 4 to 6 hours  
(not to exceed 20 ml in 24 hours).

Take medication with a full glass of water.  
Do not exceed the stated dose.

#### EFFECTS ON ABILITY TO DRIVE AND USE MACHINE

It may cause drowsiness and dulling of mental alertness. Patients undergoing treatment should not take charge of vehicles, other means of transport and machinery where loss of attention may lead to accidents.

#### OVERDOSAGE

In case of accidental overdosage, professional assistance must be considered or poison control centre should be contacted immediately.

#### PRESENTATION

60ml & 90ml

#### STORAGE CONDITIONS AND USER INSTRUCTIONS

Store in a dry place below 30°C.  
Protect from light.

Shake well before each dose.  
Keep out of reach of children.  
Jauhi daripada kanak-kanak.

Shelf life : Please refer to outer package.

#### Product Registration Holder: DUOPHARMA MANUFACTURING (BANGI) SDN. BHD.

Lot No. 2, 4, 6, 8 & 10, Jalan P/7,  
Section 13, Bangi Industrial Estate,  
43650 Bandar Baru Bangi, Selangor, Malaysia.

#### Manufacturer: DUOPHARMA MANUFACTURING (BANGI) SDN. BHD.

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210mm

148.5mm