DEXTROMETHORPHAN HBr
PHENYLPROPANOLAMINE HCl
PARACETAMOL

TUSERAN® FORTE

15 mg / 25 mg / 325 mg Capsule
Antitussive / Nasal Decongestant / Analgesic - Antipyretic

FORMULATION

Each capsule contains:
Dextromethorphan Hydrobromide, USP ……15 mg
Phenylpropanolamine Hydrochloride ……..…..…25 mg
Paracetamol…..…….……....325 mg

PRODUCT DESCRIPTION

Dextromethorphan HBr + Phenylpropanolamine HCl + Paracetamol (Tuseran® Forte) is a hard gelatin capsule with gray opaque cap, printed with "Medichem" logo and yellow opaque body printed with "TUSERAN FORTE"

WHAT IS IN THE MEDICINES?

This medicine contains dextromethorphan HBr, phenylpropanolamine HCl and paracetamol.
Dextromethorphan HBr, an antitussive, suppresses the area in the brain that causes coughing.
Phenylpropanolamine HCl, a nasal decongestant, clears obstructed air passages and nasal sinuses due to congestion making breathing easier. It also reduces postnasal drip.
Paracetamol is an effective fever reducer and pain reliever.

STRENGTH OF THE MEDICINE

See Formulation

WHAT IS THIS MEDICINE USED FOR?

This medicine is used for the relief of cough, clogged nose, postnasal drip, headache, body aches, and fever associated with the common cold, allergic rhinitis, sinusitis, flu, and other minor respiratory tract infections. It also helps decongest sinus openings and passages.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Adults and Children 12 years and older: Orally, 1 capsule every 6 hours, or as recommended by a doctor.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

- If you are allergic to any ingredient of the product
- If you have high blood pressure or severe heart disease unless recommended by a doctor
- If you have anemia, kidney or liver disease unless recommended by a doctor
- If you are pregnant or breastfeeding

UNDESIRABLE EFFECTS

Adverse effects with dextromethorphan are rare and include nausea, vomiting, stomach discomfort, constipation, dizziness, drowsiness, excitation, and mental confusion.

Hypersensitivity reactions have also been reported.

Phenylpropanolamine HCl may cause sudden, persistent, severe headache, nervousness, restlessness, insomnia/sleep disturbance, dizziness, anxiety (feeling of uneasiness), confusion, high blood pressure, palpitation, chest tightness, tremor, agitation, irritability, aggressiveness (particularly in young children), nausea, and blurred vision.

Paracetamol, when taken within the recommended dose and duration of treatment, has low incidence of side effects. Skin rashes, hypersensitivity reactions, changes in the number of white blood cells and platelets, and minor stomach and intestinal disturbances have been reported. Rare cases of serious skin reactions (i.e., Stevens-Johnson syndrome, toxic epidermal necrolysis, and acute generalized exanthematous pustulosis) have also been reported.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

Do not use this product together with sympathomimetic agents (e.g., epinephrine) and general anesthetics (e.g., halothane) because of the possibility for increased toxicity.

Concurrent administration with monoamine oxidase (MAO) inhibitors (e.g., selegiline, moclobemide) and tricyclic antidepressants (e.g., amitriptyline, imipramine) may result in hypertensive crisis (sudden, severe increase in blood pressure that can lead to stroke).

Combined use of phenylpropanolamine and caffeine may produce an additive increase in blood pressure. Severe, life threatening, and occasionally fatal hypertensive reactions have been reported.

Dextromethorphan is primarily metabolized by the cytochrome P450 isoenzyme CYP2D6. There is a possibility of interaction with inhibitors of this enzyme, including amiodarone, haloperidol, propafenone, quinidine, selective serotonin reuptake inhibitors (SSRIs), and thioridazine. Symptoms of dextromethorphan toxicity have been reported when used together with amiodarone and quinidine.

Additive central nervous system (CNS) depression may occur when dextromethorphan is taken together with alcohol, antihistamines, psychotropics and other CNS depressants.

Paracetamol, when used together with warfarin (a blood-thinning medicine), may cause an increase in the International Normalized Ratio (INR), which may serve as a sign of increased risk for bleeding. Paracetamol increases the anticoagulation effect of warfarin.

Medicines which stimulate the enzymes responsible for the metabolic activation of paracetamol such as medicines for convulsion (e.g., phenobarbital, phenytoin) may increase susceptibility to the harmful effects to the liver.

The absorption of paracetamol may be accelerated by metoclopramide or domperidone and reduced by cholestyramine.

Tell your doctor about other medicines you are taking (i.e., other medicines for cough, cold, allergy, pain, or fever, especially other paracetamol-containing products).

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you miss a dose, just take the next dose if still needed for the condition being treated, and the subsequent doses at the recommended time or schedule (i.e., every 6 hours).

Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?

Keep the product out of reach and sight of children.
Store at temperatures not exceeding 30°C.

SIGNS AND SYMPTOMS OF OVERDOSAGE

Dextromethorphan HBr
Acute overdosage of dextromethorphan may cause nausea, vomiting, drowsiness, dizziness, excitation, confusion, psychosis, CNS depression, stupor (decreased mental alertness), blurred vision, nystagmus (involuntary and rapid movement of the eyeball), dysarthria (slurred speech), respiratory depression, shallow respiration, ataxia (uncontrolled muscle movement), tremor, urinary retention, seizures, and coma.

Phenylpropanolamine HCl
Signs and symptoms of phenylpropanolamine overdosage include tachycardia, arrhythmia (irregular heart beat), high blood pressure, excitation, enlargement of the pupils. Cases of heart attack, stroke, intracranial hemorrhage/cerebral hemorrhage (bleeding from a ruptured blood vessel in the brain), seizures, and death have also been reported.

Paracetamol
Overdosage of paracetamol usually involves 4 phases with the following signs and symptoms:

I. Eating disorder, nausea, vomiting, malaise, and excessive sweating
II. Right upper abdominal pain or tenderness, liver enlargement which may be characterized by abdominal discomfort of "feeling full", elevated bilirubin and liver enzyme concentrations, prolongation of prothrombin time, and occasionally decreased urine output
III. Eating disorder, nausea, vomiting, and malaise recur and signs of liver failure (e.g., jaundice) and possibly kidney failure and cardiomyopathy (disorder of the heart muscle) may develop
IV. Recovery or progression to fatal complete liver failure

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

If you have taken more than the recommended dosage, consult a doctor or contact a poison control center right away, even if you seem well, because of the risk of delayed, serious liver damage. Quick medical attention is important for adults as well as for children even if you do not notice any signs or symptoms.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE

- Use with caution in patients with high blood pressure, toxic goiter, benign prostatic hypertrophy, heart rate irregularity, glaucoma, and in those taking antidepressants.
- Patients with heart disease and uncontrolled/untreated high blood pressure should consult a doctor prior to taking phenylpropanolamine.

- **Liver Warning:** This product contains paracetamol. Severe liver damage may occur if:
  - o An adult or child 12 years and older takes more than 4 g of paracetamol in 24 hours, which is the maximum daily amount;
  - o Taken with other medicines containing paracetamol (or acetaminophen);
  - o An adult has 3 or more alcoholic drinks everyday while using this product.
- Do not use with any other medicine containing dextromethorphan, phenylpropanolamine or paracetamol (prescription or nonprescription). If you are not sure whether a medicine contains these three active ingredients, ask a doctor.
- Do not take this medicine if you are at risk of developing respiratory failure (e.g., those with chronic bronchitis, emphysema or during an asthma attack).
- Do not take this medicine if you have persistent or chronic cough (i.e., cough lasting for more than 3 weeks) or when coughing is accompanied by excessive secretions unless directed by a doctor.
- A persistent cough may be a sign of a serious condition. If cough persists for more than one week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a doctor.
- May cause drowsiness and dizziness; patients should observe caution while driving or performing other tasks requiring alertness.
- Ask a doctor before use if you have liver or kidney disease.
- Ask a doctor before use if you are taking warfarin, a blood thinning medicine.
- Do not take more than the recommended dose.
- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

- Before taking this medication, tell your doctor if you have:
  - o High blood pressure or any type of heart problems
  - o Glaucoma
  - o Thyroid problems
  - o Diabetes
  - o Liver or kidney disease
  - o An enlarged prostate, bladder problems or difficulty urinating
- Stop use and ask a doctor if:
  - o Fever gets worse or lasts more than 3 days
  - o New symptoms occur

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph.
By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY: In box of 100's and envelope by 4's (foil strip x 4's)
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No. 66 United Street, Mandaluyong City, Metro Manila, Philippines
for **UNILAB, Inc.**
No. 66 United Street, Mandaluyong City, Metro Manila, Philippines

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