**Package insert**

# FLUCOR DAY

WIFLUxx-0 (MY)

## DESCRIPTION
Oblong, pink soft gelatin capsule filled with transparent liquid.

## COMPOSITION
Each soft gelatin capsule contains:

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| Paracetamol | 250.0 mg |
| Dextromethorphan HBr | 10.0 mg |
| Pseudoephedrine HCl | 30.0 mg |

## ACTIONS AND PHARMACOLOGY
Paracetamol, as an analgesic, may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and, to a lesser extent, through a peripheral action by blocking pain-impulse generation. The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitize pain receptors to mechanical or chemical stimulation. Paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat-regulating center to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating, and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

Pseudoephedrine acts on alpha-adrenergic receptors in the mucosa of the respiratory tract, producing vasoconstriction. The medication shrinks swollen nasal mucous membranes; reduces hyperemia, edema, and nasal congestion; and increases nasal airway patency. Also drainage of sinus secretions may be increased and obstructed Eustachian ostia may be opened.

Dextromethorphan suppresses the cough reflex by a direct action on the cough center in the medulla of the brain.

## PHARMACOKINETICS
Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral administration and is distributed into most body tissues. The elimination half-life of paracetamol varies from about 1 to 3 hours. It is metabolized predominantly in the liver and excreted in the urine mainly as the glucoronide and sulphate conjugates, less than 5% is excreted as unchanged paracetamol.

Pseudoephedrine is readily absorbed from the gastro-intestinal tract. It is resistant to metabolism by monoamine oxidase and is largely excreted unchanged in the urine together with small amounts of its hepatic metabolite. It has a half-life of about 5 to 8 hours; elimination is enhanced and half-life accordingly shorter in acid urine. Small amounts are distributed into breast milk.

Dextromethorphan is rapidly absorbed from the gastrointestinal tract. It is metabolized in the liver and excreted in the urine as unchanged dextromethorphan and demethylated metabolites including dextrophan, which has some cough suppressant activity.

## INDICATIONS
For the temporary relief of nasal congestion, minor aches and pains, headache, fever and cough associated with the common cold.

## CONTRAINDICATIONS
Risk-benefit should be considered when the following medical problems exist:
- Active alcoholism, or hepatic disease, or viral hepatitis
- Phenylketonuria
- Renal function impairment
- Sensitivity to acetaminophen or aspirin or dextromethorphan or pseudoephedrine or other sympathomimetics
- Asthma, chronic bronchitis, emphysema or productive cough
- Diabetes
- Cardiovascular diseases or hypertension

## WARNINGS AND PRECAUTIONS
- This preparation contains PARACETAMOL. Do not take any other paracetamol containing medicines at the same time.
- Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash. These should be signs of a serious condition. If these reactions occurs, stop use and seek medical assistance right away.
- Paracetamol should be given with care to patients with impaired kidney or liver function and to patients with alcohol dependence.
- Pseudoephedrine is distributed into breast milk; hence use by nursing mothers is not recommended as infants, especially newborn and premature infants because of higher than usual risk of side/adverve effects. Use of pseudoephedrine in geriatrics may require adjustment of dosage as elderly patients are more likely to have age-related prostatic hyperthrophy.
- Dextromethorphan should not be given to patient at risk of developing respiratory failure. Caution is needed in patients with a history of asthma and it should not be given during an acute attack.
- Do not exceed recommended dosage. Consult general practitioner should symptoms persist.
- This product contains sodium metabisulfite that may cause serious hypersensitivity reactions especially in patients with history of asthma or atopic allergy.
- Patients with hearts disease, thyroid disease, high blood pressure, breathing problems, persistent or chronic cough, asthma, diabetes, chronic bronchitis, glaucoma or difficulty in urination due to enlargement of the prostate gland should consult a doctor before using this product.

## PREGNANCY AND LACTATION
Not recommended in pregnancy and lactation.

## MAIN SIDE/ADVERSE EFFECTS
- Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome / Toxic Epidermal Necrolysis have been reported.
- Haematological reactions including thrombocytopenia, leukopenia, pancytopenia, neutropenia and agranulocytosis have been reported as side effects of paracetamol with skin rashes and other hypersensitivity reactions occur occasionally.
- The commonest adverse effects of pseudoephedrine include tachycardia, anxiety, restlessness and insomnia; skin rashes and urinary retention have occasionally occurred. Hallucinations have been reported rarely.
- Adverse effects with dextromethorphan appear to be rare and may include dizziness and gastrointestinal disturbances.

## DRUG INTERACTIONS
Concurrent use of Flucor Day and the following drugs must be avoided or if necessary, use with care:
- Alcohol
- Hepatic enzyme inducers
- Hepatotoxic medications
- Anticogulants, coumarin- or indandione-derivative
- Antihypertensive drugs
- Antidepressant drugs

## OVERDOSE AND TREATMENT
Symptoms of overdose include gastrointestinal upset (diarrhoea, loss of appetite, nausea and vomiting, stomach cramps or pains), increased sweating, hepatoxicity (pain, tenderness, and/or swelling in upper abdominal area), ataxia, blurred vision, coma, confusion, drowsiness or dizziness, respiratory depression, severe unusual excitement, nervousness, restlessness or irritability, urinary retention, convulsions, fast breathing, hallucinations, increased blood pressure and irregular (slow or fast) heartbeat.

**Treatment for overdose:**
- Emptying of stomach via induction of emesis or gastric lavage
- Assisted respiration
- Vital signs monitoring
- For convulsions, i.v. diazepam may be administered.

## DOSAGE AND ADMINISTRATION
Adults and children 12 years of age and over:
2 softgels every 4 hours; not exceeding 8 softgels in 24 hours.

Note: The information given here is limited. For further information, consult your doctor or pharmacist.

Storage: Store below 30°C.

Presentation/Packing:
Blister pack of 10 x 10's, 1 x 8's

Product Registration Holder / Manufactured by: HOVID Bhd.
121, Jalan Tunku Abdul Rahman (Jalan Kuala Kangsar),
30010 Ipoh, Perak, Malaysia.

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