

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1-Name of the Medicinal Product:

#### 1.1 Product Name

Flucor Day Softgel Capsule

#### 1.2 Strength

Paracetamol 250.0 mg  
Dextromethorphan Hydrochloride 10.0 mg  
Pseudoephedrine Hydrobromide 30.0 mg

#### 1.3 Pharmaceutical Dosage Form

Softgel Capsule

### 2-Quality and Quantitative Composition:

ACTIVE INGREDIENTS	PER CAPSULE (MG)
Paracetamol	250 mg
Dextromethorphan Hydrochloride	10 mg
Pseudoephedrine Hydrobromide	30 mg

For excipients, see 6.1

### 3-Pharmaceutical Form:

Oblong, pink soft gelatin capsule filled with transparent liquid.

### 4-Clinical Particulars

#### 4.1 Therapeutic indications

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

#### Posology and method of administration

##### Oral

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

#### 4.2 Contraindications

Risk-benefit should be considered when the following medical problems exists:

- Active alcoholism, or hepatic disease, or viral hepatitis
- Phenylketonuria
- Renal function impairment
- Sensitivity to acetaminophen or aspirin, or dextromethorphan or pseudoephedrine or other sympathomimetic
- Asthma, chronic bronchitis, emphysema or productive cough
- Diabetes
- Cardiovascular diseases or hypertension

#### **4.4 Special warning and precautions for use**

- This preparation contains Paracetamol. Do not take any other paracetamol containing medicines at the same time.
- 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, are at higher risk of side effect from sympathomimetic amines. It should be used with caution in infants, especially newborn and premature infants because of higher than usual risk of side/adverse effects. Use of pseudoephedrine in geriatrics may require adjustment of dosage as elderly patients are more likely to have age-related prostatic hypertrophy.
- 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 heart 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.

#### **4.5 Interaction with other medicinal products and other forms of interactions Antacids, Sucralfate, Metal Cations**

Concurrent use of Flucor Day and the following drugs must be avoided or if necessary, use with care:

- Alcohol
- Hepatic enzyme inducers
- Hepatotoxic medications
- Anticoagulants, coumarin- or indandione-derivative
- Antihypertensive drugs
- Antidepressant drugs

#### **4.6 Pregnancy and lactation**

Not recommended in pregnancy and lactation.

#### **4.7 Effects on ability to drive and use machine**

NOT APPLICABLE

#### **4.8 Undesirable effects**

- 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 to be reported rarely.
- Adverse effects with dextromethorphan appear to be rare and may include dizziness and gastrointestinal disturbances.

#### **4.9 Overdose**

Symptoms of overdose include gastrointestinal upset (diarrhoea, loss of appetite, nausea and vomiting, stomach cramps or pains), increasing sweating, hepatotoxicity (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, convulsion, fast breathing, hallucinations, increased blood pressure and irregular (slow or fast) heartbeat.

### **5-Pharmacological Properties :**

#### **5.1 Pharmacodynamic properties**

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 receptor to mechanical or chemical stimulation. Paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat-regulating centre 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 centre in the medulla of the brain.

#### **5.2 Pharmacokinetic properties**

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 glucuronide 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 amount 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.

## 6-Pharmaceutical Particulars:

### 6.1 List of excipients

- a) Polyvinylpyrrolidone
- b) Sodium acetate trihydrate
- c) Sodium metabisulfite
- d) Polyethylene glycol
- e) Erythrosine
- f) Purified water
- g) Gelatin
- h) Glycerin
- i) Sorbitol solution.
- j) Polysorbate

### 6.2 Incompatibilities

NOT APPLICABLE

### 6.3 Shelf life

3 years from date of manufacture

### 6.4 Special precautions for storage

Store below 30°C. Protect from light and moisture

### 6.5 Nature and contents of container

Immediate Container/Packaging

<b>Primary Packaging</b>			
1	Material	:	Blister Pack
	Type	:	Push-through blister pack; consists of a transparent thermoflexible plastic material and a heat-sealed, lacquered backing material
2	Material	:	PVC Film-coated with PVDC
	Appearance	:	Clear transparent film
3	Material	:	Aluminium foil
	Description	:	Aluminium foil with high slip primer on bright surface and heat seal on matt surface

### Outer Container / Secondary Packaging

Type: Unit box, Package Insert & Paper Carton for Flucor Day Softgel Capsule.

**6.6 Special precautions for disposal**  
NOT APPLICABLE

**7-Registrant**

**Marketing Authorization Holder:**

Name : HOVID Bhd.  
Address : 121, Jalan Tunku Abdul Rahman,  
(Jalan Kuala Kangsar)  
30010 Ipoh, Perak, Malaysia

**Manufacturer and Manufacturing Site:**

Name : HOVID Bhd.  
Address : 121, Jalan Tunku Abdul Rahman,  
(Jalan Kuala Kangsar)  
30010 Ipoh, Perak, Malaysia

**8-Date of revision of the text :**  
May 2023

**9-Dosimetry (If applicable) :**  
Not Applicable

**10-Instruction for preparation of Radiopharmaceuticals (If applicable):**  
Not Applicable