CORILIEF ® 5 FLU

PROPIETARY NAME: CORILIEF 5 FLU tablets

PHARMACOLOGICAL CLASSIFICATION: NO2BE51 **-** Other analgesics and antipyretics & Other cold preparations

CATEGORY OF DISTRIBUTION: Pharmacy Only

COMPOSITION:

Each tablet contains: Diphenhydramine hydrochloride 12.5 mg
Pseudoephedrine hydrochloride 22.5mg
Paracetamol 500mg

PHARMACOLOGICAL ACTION:

Diphenhydramine hydrochloride: has antitussive and antihistaminic properties
Paracetamol: has analgesic and antipyretic properties
Pseudoephedrine Hydrochloride: a decongestant
.

INDICATIONS: For the relief of symptoms associated with colds and flu; including coughing, fever, headache, minor aches and pains and nasal congestion.

CONTRA-INDICATIONS:

Known hypersensitivity to any of the ingredients. Most types of cardiovascular disease, including angina and hypertension, and also in hyperthyroidism, hyperexcitability, phaeochromocytoma and closed angle glaucoma. Concomitant use of monoamine oxidase inhibitors, or within 14 days of stopping treatment with this class of medicines. Severe liver disease. Should be avoided in patients undergoing anaesthesia with cyclopropane, halothane or other halogenated anaesthetics.

Pregnancy and lactation

Safe use in pregnancy has not been established

WARNINGS: Do not use continuously for more than 10 days: if symptoms persist, irrespective of therapy used, consult your doctor. Dosages in excess of those recommended may cause severe liver damage. This medicine may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant agents. Patients should be warned not to drive, operate dangerous machinery, or climb dangerous heights, as impaired decision making could lead to accidents.

DOSAGE AND DIRECTIONS FOR USE

Adults, the elderly and children and over 16 years:

Adults and children aged 16 years and over	Take two tablets, up to 4 times a day
Children 10 – 15 years	Take one tablet, up to 4 times a day

This medicine is not recommended for children under **10 years** old

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Diphenhydramine hydrochloride: the most common side effects are sedation, varying from slight drowsiness to deep sleep, and includes lassitude, dizziness and inco-ordination. Other side effects include gastrointestinal disturbances such as nausea, vomiting diarrhoea or constipation, anorexia or increased appetite, and epigastric pain. Antimuscarinic effects include hypotension, muscular weakness tinnitus, euphoria, and headache. In infants and children it may act as a cerebral stimulant. Symptoms of stimulation include insomnia, nervousness, tachycardia, tremors and convulsions. Large doses may precipitate fits in epileptics.. Deepening coma, extrapyramidal effects and photosensitization of the skin may occur. Elderly patients are more susceptible to the central nervous system depressant and hypotensive effects, allergic reactions and anaphylaxis may occur. Blood dyscrasias may occur. The positive skin tests may be suppressed.

Paracetamol: Patients with impaired kidney or liver function should take paracetamol under medical supervision only. May cause pancreatitis and other allergic reactions. Sensitivity reactions resulting in rash, laryngeal oedema angioedema and anaphylaxis have been reported less frequently. **Pseudoephedrine hydrochloride**: central effects include fear, anxiety, restlessness, tremor, insomnia, confusion, irritability, and psychotic states. Appetite may be reduced and nausea and vomiting may occur. Effects on the cardiovascular system include hypertension, cerebral haemorrhage and pulmonary oedema, reflex bradycardia, tachycardia and cardic arrhythmias, angina pain, palpitations, and cardiac arrest. Other effects include headache, difficulty in micturition and retention, dyspnoea, weakness, altered metabolism including changes in blood sugar levels, sweating and hypersalivation.

Interactions: Diphenhydramine may potentiate the effects of the other CNS depressants, minor tranquilisers, neuroleptics, barbiturates and alcohol, and other drugs with anti-cholinergic properties such as tri-cyclic antidepressants. Pseudoephedrine may reverse the effect of antihypertensive agents which modify sympathetic activity, and concomitant use with other sympathomimetic agents such as decongestants, tricyclic anti-depressants and appetite suppressants or with monoamine oxidase inhibitors, which interfere with the catabolism of sympathomimetic amines may cause a rise in blood pressre. An increased risk of arrhythmias may also occur if sympathomimetic agents are given to patients receiving cardiac glycosides, quinidine, or tricyclic antidepressants.

KNOWN SYMPTOMS OVERDOSAGE AND TREATMENT:

Diphenhydramine hydrochloride: Overdosage may be fatal especially in infants and children. In infants and children CNS stimulation predominates over depression causing ataxia, excitement, tremors, psychoses, hallucinations and convulsions, progressing to respiratory failure or possibly cardiovascular collapse. Paracetamol: nausea, vomiting and anorexia. Liver damage may be fatal, may only appear after a few days. Acute intoxication may cause kidney failure. Pseudoephedrine hydrochloride: Convulsions and hyperpyrexia in children due to cerebral stimulation. In adults symptoms of stimulation include insomnia, nervousness, tachycardia, tremors, muscle twitching and convulsions. Prompt treatment is essential in the event of an overdosage, consult a doctor immediately or take the person to a hospital directly. Since this product contains paracetamol a delay in starting treatment may mean the antidote is given too late to be effective. Symptomatic and supportive treatment will also be helpful.

IDENTIFICATION: Yellow Oval-Shaped film-coated tablets embossed with 4RFLU on one side and plain on the reverse side.

PRESENTATION: Blister packs of 24's and white HDPE bottles of 20's.

STORAGE CONDITIONS:

Do not store above 30°C, protected from light. KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER: TBA

NAME OF APPLICANT AND MANUFACTURER

VARICHEM PHARMACEUTICALS (PVT) LTD
Varichem Pharmaceuticals (Pvt) Ltd
194 Gleneagles Road,Willowvale, Harare, Zimbabwe
Tel: +263 (04) 620181-7,Fax: +263 (04) 660424
Email: marketing@varipharm.co.zw

Date of publication: August 2020