CORILIEF SINUS PAIN & ALLERGY RELIEF

REGISTRATION NUMBER: TBA

PROPIETARY NAME : Corilief® Sinus Pain and Allergy Relief

COMPOSITION:

Each tablet contains:

Paracetamol	500 mg
Pseudoephedrine Hydrochloride	30 mg
Chlorpheniramine Maleate	2 mg

PHARMACOLOGICAL CLASSIFICATION:

R01BA52 – Nasal Preparations – Pseudoephedrine Combinations

PHARMACOLOGICAL ACTION:

Corilief Sinus Pain and Allergy Relief has analgesic, anti-pyretic, decongestant and antihistaminic properties.

INDICATIONS:

For the symptomatic relief of sinus pain, including maxillary, frontal or facial pain. Also for associated malaise, fever and congestion of the nasal, sinus and Eustachian tube mucosa, also for the symptomatic relief of allergic rhinitis (hayfever), vasomotor rhinitis, influenza and the common cold.

CONTRA-INDICATIONS:

Contra-indicated in patients hypersensitive to any of the ingredients.
Contra-indicated in children under 6 months of age.
Paracetamol should not be used in patients with severe liver and renal disease.
Pseudoephedrine should be avoided in patients undergoing inhalation anaesthesia.
Not to be given concurrently with any monoamine oxidase inhibitor (MAOI) for depression or within 14 days of stopping such treatment.
Contra-indicated in most types of cardiovascular disease, including angina and hypertension, and also in hyperthyroidism, phaeochromocytoma, closed angle glaucoma and diabetes mellitus.

WARNINGS:
Do not use continuously for more than ten days; if symptoms persist, irrespective of therapy used, consult your doctor. Dosage in excess of those recommended may cause severe liver, or kidney damage.

This medicine may lead to drowsiness and impaired concentration which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents.
Patients should be warned not to drive a motor vehicle, operate dangerous machinery, or climb dangerous heights, as impaired decision making could lead to accidents.

Patients suffering from liver or kidney disease should take paracetamol only if instructed to do so by a doctor.

Consult your doctor if no relief is obtained with the recommended dosage.

INTERACTIONS:
Combinations containing any of the following medications, depending on the amount, may also interact with this medication.

Chlorpheniramine may enhance the effects of central nervous system depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and antipsychotics, and other drugs with anti-cholinergic properties such as tricyclic anti-depressants.
Cardiac arrhythmias may occur when Pseudoephedrine is used prior to anaesthesia with inhalation anaesthetics such as Chloroform, Cyclopropane, Enflurane, Halothane, Isoflurane, Methoxyflurane; and Trichloroethylene or concurrently with digitalis glycosides.

Anticholinergic effects may be potentiated when Corilief Sinus Pain and Allergy Relief is used concurrently with anticholinergics or other medications with anticholinergic activity.
Concurrent use with Corilief Sinus Pain and Allergy Relief may also potentiate the cardiovascular effects of sympathomimetic amines. Pseudoephedrine may reverse the action of cardiovascular medications and therefore special care is patients receiving such therapy.

Antihypertensive effects may be reduced when these medications are used concurrently with sympathomimetic amines.

Concurrent use of beta-adrenergic blocking agents with sympathomimetic amines may result in significant hypertension and excessive bradycardia with possible heart block.

CNS stimulants used concurrently with pseudoephedrine may result in additive CNS stimulation to excessive levels, which may cause unwanted effects, such as nervousness, irritability insomnia, or possibly convulsions or cardiac arrhythmias.

Doxapram used concurrently with Corilief Sinus Pain and Allergy Relief may increase the pressor effects of either doxapram or sympathomimetic amines.

Monoamine oxidase inhibitors used concurrently with antihistamines may prolong and intensify the anticholinergic and CNS depressant effects of SINATUB Sinus Allergy Congestion & Pain. Concurrent use of MAOI's with sympathomimetic amines may prolong and intensify the cardiac stimulant and vasopressor effects of pseudoephedrine. These medications should not be administered during or within 14 days following the administration of a MAO inhibitor.

Concurrent use with ototoxic medications may mask the symptoms of ototoxicity such as tinnitus, dizziness or vertigo.

Concurrent use with rauwolfia alkaloids may inhibit the indirect-acting sympathomimetic action of pseudoephedrine.

The risk of hepatotoxicity with single toxic doses or prolonged use of high doses of paracetamol may be increased in alcoholics or in patients regularly taking other hepatotoxic medications or hepatic enzyme inducers.

Prolonged concurrent use of Paracetamol with other NSAIDs may also increase the risk or adverse renal effects.

Paracetamol may competitively inhibit the hepatic glucuronidation and decrease the clearance of zidovudine; Zidovudine may also inhibit the hepatic glucuronidation of Paracetamol.

Aluminium-hydroxide containing preparations may increase the absorption rate of Pseudoephedrine Hydrochloride.

PREGNANCY AND LACTATION:
Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Adults and children over 12 years:	Two tablets every six to eight hours.
	Do not exceed eight tables in 24 hours.

Not recommended for children under 12 years age.

Do not exceed the recommended dose.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Paracetamol:

Less frequently

Paracetamol may cause pancreatitis.

Sensitivity reactions resulting in skin rash, laryngeal oedema, angioedema and anaphylaxis have been reported less frequently. The rash is usually erythematous or urticarial but sometimes more serious and may be accompanied by fever and mucosal lesions.

Incidence rare (>1/10 000, <1/1 000)

Blood disorders such as neutropenia, pancytopenia, leucopenia and thrombocytopenia has also been reported rarely.

Chlopheniramine Maleate:

Incidence less frequent or rare (>1/10 000, <1/1 000)

The most common side-effect due to Chlorpheniramine is sedation, varying from slight drowsiness to deep sleep, including lassitude, dizziness and incoordination. Paradoxical central nervous system stimulation may occur especially in children, with insomnia, nervousness, euphoria, irritability, tremors and less frequently, nightmares, hallucinations and convulsions.

Other side-effects may include headache, dry mouth, thickened respiratory-tract secretions and tightness of the chest, blurred vision, urinary difficulty and retention, constipation and increased gastric reflux. In addition, gastro-intestinal disturbances may occur such as nausea, vomiting, diarrhea or epigastric pain.

Hypersensitivity reactions such as pruritus or rash may occur. Blood disorders including agranulocytosis, leucopenia, haemolytic anemia and thrombocytopenia have been reported. Other less frequently reported side-effects include sweating, myalgia, hypertension, tinnitus, headache, paraethesias, extrapyramidal effects, hypotension and hair loss.

Pseudoephedrine Hydrochloride:

Incidence more frequent or common (> 1/100. < 1/10)

Central effects include fear, anxiety, restlessness, tremor, insomnia, confusion, irritability, weakness, and psychotic states.

Incidence less frequent

Appetite may be reduced and nausea and vomiting may occur.

Effects on the cardiovascular system include hypertension, cerebral hemorrhage, pulmonary oedema, reflex bradycardia, tachycardia and cardiac arrthymias, angina pain, palpitations, and cardiac arrest. Hypotension with dizziness and fainting and flushing may occur. Hypokalemia may occur.
Other effects include headache, difficulty in micturition and urinary retention, dyspnea, altered metabolism, including changes in blood sugar levels, sweating and hypersalivation.
Tolerance with dependence may occur after continued use.
The effects of pseudoephedrine hydrochloride are lessened by medicines containing guanethidine, reserpine, methyldopa and may be diminished or enhanced by tricyclic anti-depressants.
Pseudoephedrine may increase blood pressure and therefore special care is advisable in patients receiving antihypertensive therapy.
Incidence rare (> 1/10 000. < 1/1000)
It may increase the possibility of irregular heart beat in patients taking digitals.

Special Precautions:

Paracetamol

Patients with impaired kidney or liver function should take paracetamol under medical supervision only.

Chlorpheniramine Maleate:

Chlorpheniramine should be given with care to patients with glaucoma, urinary retention, prostatic hypertrophy or pyloroduodenal obstruction. Caution is advised in patients with epilepsy and severe cardiovascular disorders.

Elderly patients are more susceptible to the central nervous system depressant and lowering of blood pressure effects even at dose quantities effective for treatment.

The warning signs of damage caused by ototoxic medicines may be masked by chlorpheniramine. Chlorpheniramine may enhance the sedative effect of central nervous system depressants including alcohol, barbiturates, hypnotics, analgesics, sedatives and tranquillisers. Care should be taken when taking medicines containing tricyclic anti-depressants or atropine together.

Pseudoephedrine Hydrochloride

Corilief Sinus Pain and Allergy Relief should not be used by patients with cardiovascular disease, hyperthyroidism, liver disease, renal disease, glaucoma or diabetes.
(See Contraindicatons)

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See “Side-effects and Special Precautions”

Paracetamol: Nausea, vomiting and anorexia. Liver damage, which may be fatal, may only appear after a few days. Acute intoxication may cause kidney failure.
Prompt treatment is essential. In the event of an over dosage, consult a doctor immediately, or take the person to a hospital directly. A delay in starting treatment may mean that antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed.

Susceptibility to paracetamol toxicity is increased in patients who have taken repeated high doses (greater than 5 – 10 g/day) of paracetamol for several days, in chronic alcoholism, chronic liver disease, AIDS, malnutrition, and with the use of drugs that induce liver microsomal oxidation such as barbiturates, isoniazid, rifampicin, phenytoin and carbamazepine.

Symptoms of paracetamol over dosage in the first 24 hours include pallor, nausea, vomiting, anorexia and possibly abdominal pain. Mild symptoms during the first two days of acute poisoning, do not reflect the potential seriousness of the over dosage.

Liver damage may become apparent 12 to 48 hours, or later after ingestion, initially by elevation of the serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of the prothrombin time. Liver damage may lead to encephalopathy, coma and death.

Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Abnormalities of glucose metabolism and metabolic acidosis may occur. Cardiac arrhythmias have been reported.

Treatment for paracetamol over dosage:
Although evidence is limited it is recommended that any adult person who has ingested 5 -10 grams or more of paracetamol (or a child who has had more than 140 mg/kg) within the preceding four hours, should have the stomach emptied by lavage (emesis may be adequate for children) and a single dose of 50 g activated charcoal given via the lavage tube. Ingestion of amounts of paracetamol smaller than this may require treatment in patients susceptible to paracetamol poisoning (see above). In patients who are stuperose or comatose endotracheal intubation should precede gastric lavage in order to avoid aspiration.

N-acetylcysteine should be administered to all cases of suspected overdose as soon as possible, preferably within eight hour of overdosage, although treatment up to 36 hours after ingestion may still be of benefit, especially is more than 150 mg/kg of paracetamol was taken. An initial dose of 150 mg/kg N-acetylcysteine in 200 ml dextrose injection given intravenously over 15 minutes, followed by an infusion of 50mg/kg in 500 ml dextrose injection over the next four hours, and then 100 mg.kg in 1 000 ml dextrose injection over the next sixteen hours. The volume of intravenous

fluid should be modified for children. Although the oral formulation is not the treatment of choice. 140 mg/kg dissolved in water may be administered initially, followed by 70 mg/kg every four hours for seventeen doses.
A plasma paracetamol level should be determined four hours after ingestion in all cases of suspected overdosage. Levels done before four hours, unless high, may be misleading. Patients at risk of liver damage, and hence requiring continued treatment with N-acetylcysteine, can be identified according to their plasma paracetamol level. Monitor all patients with significant ingestions for at least ninety-six hours.

Chlorpheniramine Maleate.
Chlorpheniramine over dosage may be fatal especially in infants and children. The main symptoms being central nervous system stimulation and anti-muscarinic effects, including ataxia, excitement, hallucinations, muscle tremor, convulsions, dilated pupils, dry mouth, flushed face and hyperpyrexia. Deepening coma, cardiorespiratory collapse, and death may occur within 18 hours. The usual symptoms in adults are central nervous system depression with drowsiness, coma and convulsions. Hypotension may also occur.

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. Severe cardiovascular repercussions include hypertension, angina, arrhythmias, myocardial infarction and cerebral hemorrhage.

Treatment of overdose:
To decrease absorption
Because pseudoephedrine is rapidly absorbed from the gut, emetics and gastric lavage should be instituted within 4 hours of over dosage in order to be effective. Charcoal is useful only if administered within 1 hour.

To enhance elimination
Forced diuresis will increase elimination of pseudoephedrine provided renal function is adequate; however, diuresis is not recommended for severe over dosage.

Specific treatment
For delirium or convulsions, intravenous diazepam may be administered.
The cardiac state should be monitored and serum electrolytes measured. If there are signs of cardiac toxicity, intravenous propranolol may be indicated.

Hypokalemia may be treated, if necessary with a slow infusion of a dilute potassium chloride solution; serum potassium concentration should be monitored during and for several hours after administration of potassium chloride.

Consult a doctor or take the patient to the nearest hospital immediately. Specialised treatment is essential as soon as possible. The latest information regarding the treatment of over dosage can be obtained from the nearest poison centre.

IDENTIFICATION:
A round, orange, mottled, biconvex tablet embossed "COR S" on one side and plain on the other side.

PRESENTATION
PVC/Aluminium blister packs of 20s.

STORAGE INSTRUCTIONS
Do not store above 30°C. Protect from light and moisture. Do not remove tablets from the outer carton until required for use. **Keep out of reach of children**

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