Summary Product Characteristics (SPC):

1. Name of the Medicinal Product

Colimex Tablets
Dicycloverine Hydrochloride and Paracetamol tablets

2. Qualitative and Quantitative composition

Each film tablets contains :
Dicycloverine Hydrochloride BP 500 mg
Paracetamol tablets BP 20 mg

For a full list of excipients, see section 6.1..

3. Pharmaceutical form

Tablet

4. Clinical particulars

4.1 Therapeutic indications

Dicyclomine HCl & Paracetamol Tablet is a medicine that is used for the treatment of Stomach and intestinal cramping, Periods pain, Fever, Cold, Irritable bowel syndrome, Headache and other conditions The complete list of uses and indications for Dicyclomine HCl Paracetamol Tablet is as follows:

- Stomach and intestinal cramping
- Periods pain
- Fever
- Cold
- Irritable bowel syndrome
- Headache
- Febrility
- Catarrh
- Joint pain
- Cephalalgia
- Period pain
- Ear pain
- Tooth ache
- Flu
- Toothache

4.2 Posology and method of administration

Adults : 1 tablet 3 - 4 times daily or as required.
Children : ½ tablet thrice daily or as required.

4.3 Contraindications

Summary Product Characteristics (SPC):

Hypersensitivity to Dicyclomine HCl Paracetamol Tablet is a contraindication. In addition, Dicyclomine HCl Paracetamol Tablet should not be used if you have the following conditions:

- Hepatic impairment
- Hypersensitivity
- Obstructive uropathy
- Severe ulcerative colitis

4.4 Special warnings and special precautions for use

Some health conditions may make you more susceptible to the side-effects of the drug. Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important counseling points are listed below.

- Avoid using it if allergic to paracetamol
- Do not drive or operate machinery
- Do not exercise in hot weather
- Do not take paracetamol if you consume alcoholic beverages every day
- Drink a lot of fluids
- Pregnant, planning to become pregnant or breastfeeding

Interaction with other medicinal products and other forms of interaction

If you use other drugs or over the counter products at the same time, the effects of Dicyclomine HCl Paracetamol Tablet may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that you doctor can help you prevent or manage drug interactions. Dicyclomine HCl Paracetamol Tablet may interact with the following drugs and products:

- Alcohol
- Digoxin
- Interfere with certain laboratory tests
- Juxtapid mipomersen
- Ketoconazole
- Leflunomide
- Levodopa
- Pramlintide
- Prilocaine
- Teriflunomide

4.6 Pregnancy and lactation

Reproduction studies for Dicycloverine have been performed in rats and rabbits at doses of up to 100 times the maximum recommended dose (based on 60mg per day for an adult person) and have revealed no evidence

of impaired fertility or harm to the foetus due to dicycloverine. Since the risk of teratogenicity cannot be excluded with absolute certainty for any product, the drug should be used during pregnancy only if clearly needed.

Pregnancy:

Epidemiological studies in pregnant women with products containing dicycloverine hydrochloride (at doses up to 40mg/day) have not shown that dicycloverine hydrochloride increases the risk of foetal abnormalities if administered during the first trimester of pregnancy. Epidemiological studies in human pregnancy have shown no effects due to paracetamol used in the recommended dosage. However, paracetamol should be avoided in pregnancy unless considered essential by the physician.

Lactation:

It is not known whether dicycloverine is secreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when dicycloverine is administered to a nursing mother. Paracetamol is excreted in breast milk but not in a clinically significant amount.

Available published data do not contraindicate breast feeding

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Paracetamol

In contrast to aspirin, therapeutic doses of paracetamol do not produce gastric irritation, erosion, blood loss or massive bleeding, do not interfere with platelet function, do not appreciably potentiate the action of oral anticoagulants and do not enhance uric acid excretion.

Paracetamol has been much less implicated in analgesic nephropathy than other analgesics. Nephropathy has not been reported in patients abusing only paracetamol. Nevertheless, the chronic consumption of paracetamol in high doses should certainly be avoided.

On the whole, therapeutic doses of paracetamol are remarkably free from adverse effects. Hypersensitivity to paracetamol occurs rarely and is usually manifested by erythematous or urticarial skin rashes. There is no cross sensitivity between aspirin and paracetamol.

Dicycloverine

The common side effects associated with dicycloverine administration include dry mouth, increased ocular tension, blurred vision, headache, drowsiness, weakness, dizziness, flushing, urinary retention, insomnia, nausea/vomiting urticaria and a bloated feeling. With the injectable form, there may be a temporary sensation of light-headedness. Some local irritation and focal coagulation necrosis may occur following the I.M. injection of the drug.

Reporting of suspected adverse reactions:

Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Paracetamol

Symptoms: Symptoms of paracetamol overdosage in the 1st 24 hrs are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hrs after ingestion. In severe poisoning, hepatic failure may progress to encephalopathy, coma and death. Liver damage is likely in adults who have taken 10 gm or more of paracetamol. It is considered that an excess quantity of a toxic metabolite becomes irreversibly bound to liver tissue.

Treatment: Prompt treatment is essential in the management of paracetamol overdosage. Any patient who has ingested 7.5 gm or more of paracetamol in the preceding four hours should undergo gastric lavage. Specific therapy with an antidote such as acetylcysteine or methionine may be necessary. Acetyl cysteine may be given intravenously or by mouth.

Dicycloverine

Symptoms: Symptoms of dicycloverine overdosage are headache, dizziness, nausea, dry mouth, difficulty in swallowing, dilated pupils and hot dry skin.

Treatment: Treatment may include emetics, gastric lavage and symptomatic therapy if indicated.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol

Paracetamol has analgesic and antipyretic actions similar to those of aspirin. The antipyretic effect stems from a direct action on the hypothalamic heat regulating centre that results in increased dissipation of body heat. Paracetamol has been shown to inhibit the action of endogenous pyrogens on the heat regulating centres. It has almost the same potency as aspirin in inhibiting brain prostaglandin synthetase but very much less effective than aspirin as an inhibitor of the peripheral enzyme.

Dicyclomine

Dicyclomine is an antimuscarinic, anticholinergic agent. The underlying mechanism of activity is unknown, but it is believed to exert a nonspecific, local, direct spasmolytic (musculotropic) action on the smooth muscle of the gastrointestinal tract, thereby decreasing muscular tone and motility. Dicyclomine also can relieve gastrointestinal smooth muscle spasm via effects exerted at the acetylcholinemuscarinic receptor. Dicyclomine has 1/8 the milligram potency of atropine.

5.2 Pharmacokinetic properties

Paracetamol

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral doses. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations. The elimination half-life of paracetamol varies from about 1 to 3 hours.
Paracetamol is metabolised mainly in the liver and excreted in the urine mainly as the glucuronide and sulfate conjugates. Less than 5% is excreted as unchanged paracetamol. A minor hydroxylated metabolite (N-acetyl-p-benzoquinoneimine) is usually produced in very small amounts by cytochrome P450 isoenzymes (mainly CYP2E1 and CYP3A4) in the liver and kidney. It is usually detoxified by conjugation with glutathione but may accumulate after paracetamol overdosage and cause tissue damage.

Dicyclomine

In man, dicyclomine is rapidly absorbed after oral administration, reaching peak values within 60 - 90 minutes. The drug is absorbed slightly faster following intramuscular injection than after oral administration. Comparison of the areas under the concentration-time curves (AUCs) for single 40 mg dose of dicyclomine hydrochloride oral solution and intramuscular injection indicate that the relative oral bioavailability of the drug is about 67% of that following intramuscular injection.

Mean volume of distribution for a 20 mg oral dose is approximately 3.65 l/kg suggesting extensive distribution in tissues.
The principal route of elimination is via the urine (79.5% of the dose). Excretion also occurs in the feces, but to a lesser extent (8.4%). The metabolic fate of dicyclomine has not been determined.
Mean half-life of plasma elimination in one study was determined to be approximately 1.8 hours when plasma concentrations were measured for 9 hours after a single dose. In subsequent studies, plasma concentrations were followed for up to 24 hours after a single dose,

showing a secondary phase of elimination with a somewhat longer half-life.

5.3 Preclinical safety data

Preclinical safety studies reveal no special hazard for humans.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch B.P.

Povidone B.P.

Colour Tartrazine Supra

Purified Water B.P.

Sodium Starch Glycollate B.P.

Purified Talc B.P.

Magnesium Stearate B.P.

Colloidal Anhydrous Silica B.P.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at a room temperature. Protect from light & moisture. Keep out of the reach of Children.

6.5 Nature and Contents of Container

5 Composite pack of 5 x 10 tablets packed in a Carton.

6.6 Special precautions for disposal

No special requirement

7.0 MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES.

Summary Product Characteristics (SPC):

7.1 Marketing Authorization Holder

Wallace Pharmaceuticals Pvt. Ltd.
Patto Plaza, EDC Complex, Panaji, Goa – 403 001
Tel: 91-832-2438156 to 61
Fax 91-832-2438151

8. Marketing authorization number

H2024/CTD7696/14912

9.Date of first authorization/renewal of the authorization

September 17, 2024

10 Date of revision of the text

September 17, 2024