# Summary of product characteristics

## 1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

**BIACOLD**

**INN:** Paracetamol BP

Phenylephrine Hydrochloride BP

Pheniramine Maleate BP

Ascorbic acid (Vitamin C) BP

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 g Sachet Contains:
- Paracetamol BP …….500 mg
- Pheniramine Maleate BP ……....20 mg
- Ascorbic Acid (Vitamin C) BP …….50 mg
- Phenylephrine HCl BP ……10 mg

Excipient know effect Each tablet contains:Sucrose,Sunset yellow colour.

## 3. PHARMACEUTICAL FORM

White to Orange colour powder with characteristic orange flavor.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications:

- Cold symptoms (treatment)
- Congestion, nasal (treatment)
- Congestion, sinus (treatment)—Antihistamine, decongestant, and analgesic combinations are indicated for the temporary relief of nasal and sinus congestion and headaches, pains, and general discomfort due to colds, flu, or allergies. The antihistamine in these combinations

mayprovide added relief of nasal congestion, rhinorrhea, and sneezing. It may also serve as an adjunct because of its anticholinergic drying effects response, enhance mental clarity and prevent vitamin deficiency diseases

### 4.2 Posology

Dissolve the contents of one sachet in a standard mug of hot, but not boiling, water (approx. 250ml). Allow to cool to a drinkable temperature.

Adults, the Elderly and children aged 12 years and over: One sachet Repeat every four hours as required, but do not exceed four doses (sachets) in any 24 hours.

Do not give to children under 12 years, except on medical advice.
Do not give to patients with hepatic or severe renal impairment, except on medical advice.
Seek medical advice if symptoms persist for more than 3 days.

**4.3 CONTRAINDICATIONS:**

• Hypersensitivity to the active ingredients (or drug substances) or to any of the excipients.
• Concomitant use of other sympathomimetic decongestants.
• Phaeochromocytoma.
• Closed angle glaucoma.
• Hepatic or severe renal impairment, hypertension, hyperthyroidism, diabetes, heart disease or those taking tricyclic antidepressants or beta-blocking drugs and those patients who are taking or have taken in the last two weeks monoamine oxidase inhibitors

**4.4 SPECIAL WARNING PRECAUTION FOR USE**

• The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.
• Patients suffering from chronic cough or asthma should consult a physician before taking this product.
• Patients should stop using the product and consult a health care professional if cough lasts for more than 5 days or comes back, or is accompanied by a fever, rash or persistent headache.
• Do not take with a cough suppressant.
• Medical advice should be sought before taking this product in patients with these conditions:
• An enlargement of the prostate gland
• Occlusive vascular disease (e.g. Raynaud's phenomenon)
• Cardiovascular disease
• This product should not be used by patients taking other sympathomimetics (such as decongestants, appetite suppressants and amphetamine-like psychostimulants)
• Concomitant use of other paracetamol-containing products, or with alcohol, should be avoided.
• If symptoms persist consult your doctor.
• Do not exceed the recommended dose.

• Keep out of the reach and sight of children.

Special label warnings

Contains paracetamol. Do not take with any other paracetamol-containing products.

Immediate medical advice should be sought in the event of an overdose, even if you feel well.

Do not take with other flu, cold or decongestant products.

Special leaflet warnings

Contains paracetamol. Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.

This medicinal product contains 19% v/v ethanol (alcohol) i.e. 3.8 ml per 20 ml dose, equivalent to 76 ml beer or 31.6 ml wine.

Harmful for those suffering from alcoholism

To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.

Fluctor contains sunset yellow:

Sunset yellow color is quite a notorious yellow food dye that causes a number of allergies and side effects. Some of the common allergies and intolerances associated with sunset yellow color are sunset yellow e110 affects the body's immune system and hyperactivity in kids.

The symptoms that help in discerning the fd&c yellow 6 allergies are:

Gastric upset, Urticaria or nettle rash, Diarrhea, Vomiting, Numbness, Swollen skin, Sore and watery eyes, Headache, Constipation, Blood pressure Disorders, Sleeping Disorders

The only way to prevent these allergies, intolerances and side effects is to stay away from colored foods as far as possible. Though it's not possible to avoid all of the colored foods, but still a little precaution is required especially if one is an allergy to sunset yellow dye.

Fluctor contains sucrose

Fluctor contains sucrose (a type of sugar). If you have been told that you have intolerance to some sugars contact your doctor before taking this medicine.

**4.5INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION**

Anticoagulants - the effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding. Occasional doses have no significant effect.

Enzyme-inducing drugs may increase hepatic damage, as does excessive intake of alcohol. The speed of absorption of paracetamol may be increased by metoclopromide or domperidone and absorption reduced by colestyramine. These interactions are considered to be of unlikely clinical significance in acute use at the dosage regimen proposed.

**4.6 PREGNANCY AND LACTATION:**

Due to the phenylephrine content this product should not be used in pregnancy or whilst breast-feeding without medical advice. Phenylephrine may be excreted in breast milk.

**4.7 EFFECT ON ABILITY TO DRIVE AND USE MACHINES**

None known

**4.8 Undesirable effects:**

Adverse events from historical clinical trial data are both infrequent and from small patient exposure. Events reported from extensive post-marketing experience at therapeutic/labeled dose and considered attributable are tabulated below by MedDRA System Organ Class. Due to limited clinical trial data, the frequency of these adverse events is not known (cannot be estimated from available data), but post-marketing experience indicates that adverse reactions to paracetamol are rare and serious reactions are very rare.

| **Body System** | **Undesirable effect** |
|---|---|
| Blood and lymphatic system disorders | Thrombocytopenia<br>Agranulocytosis<br>These are not necessarily causally related to paracetamol |
| Immune system disorders | Anaphylaxis<br>Cutaneous hypersensitivity reactions including skin rashes, angiodema and Stevens Johnson syndrome |
| Respiratory, thoracic and mediastinal disorders | Bronchospasm in patients sensitive to aspirin and other NSAIDs |

| | |
|---|---|
| Hepatobiliary disorders | Hepatic dysfunction |
| Gastrointestinal disorders | Acute pancreatitis |

The following adverse events have been observed in clinical trials with phenylephrine and may therefore represent the most commonly occurring adverse events.

| **Body System** | **Undesirable effect** |
|---|---|
| Psychiatric disorders | Nervousness, irritability, restlessness, and excitability |
| Nervous system disorders | Headache, dizziness, insomnia |
| Cardiac disorders | Increased blood pressure |
| Gastrointestinal disorders | Nausea, Vomiting, diarrhoea |

Adverse reactions identified during post-marketing use are listed below. The frequency of these reactions is unknown but likely to be rare

| | |
|---|---|
| Eye disorders | Mydriasis, acute angle closure glaucoma, most likely to occur in those with closed angle glaucoma |
| Cardiac disorders | Tachycardia, palpitations |
| Skin and subcutaneous disorders | Allergic reactions (e.g. rash, urticaria, allergic dermatitis).<br>Hypersensitivity reactions – including that cross-sensitivity may occur with other sympathomimetics. |
| Renal and urinary disorders | Dysuria, urinary retention. This is most likely to occur in those with bladder outlet obstruction, such as prostatic hypertrophy. |

**Special Precautions:**

If you notice any undesirable effects not listed in this leaflet, please inform your doctor or your pharmacist.

**4.9 OVER-DOSAGE**

**Paracetamol**

Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk factors:

If the patient

a. Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.

Or

b. Regularly consumes ethanol in excess of recommended amounts.

Or

c. Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms:

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Management:

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N- acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with the NPIS or a liver unit.

**Phenylephrine**

Symptoms and signs

Phenylephrine overdosage is likely to result in effects similar to those listed under advserse reactions. Additional symptoms may include hypertension and possibly reflux bradycardia. In severe cases confusion, hallucinations, seizures and arrythmias may occur. However the amount required to produce serious phenylephrine toxicity would be greater than required to cause paracetamol- related toxicity.

Treatment

Treatment should be as clinically appropriate. Severe hypertension may need to be treated with an alpha blocking drug such as phentolamine.

**Pheniramine**

Symptoms and signs

Convulsions (especially in children), loss of consciousness, coma.

**Ascorbic acid**

Symptoms and signs

High doses of ascorbic acid (>3000 mg) may cause transient osmotic diarrhoea and gastrointestinal effects such as nausea and abdominal discomfort. Effects of overdose of ascorbic acid would be subsumed by severe liver toxicity caused by paracetamol overdose.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Paracetamol: An analgesic and antipyretic.

Phenylephrine hydrochloride: A sympathomimetic decongestant

Pheniramine Maleate: An antihistamine with anticholinergic properties used to treat allergic conditions such as hay fever or urticaria.

Ascorbic acid: A common ingredient of cold and influenza combination products included to compensate for Vitamin C losses which may occur in the initial stages of acute viral infections.

The active ingredients are not known to cause sedation.

### 5.2 Pharmacokinetic properties:

Paracetamol: is readily absorbed from the gastrointestinal tract. It is metabolised in the liver and excreted in the urine, mainly as glucoronide and sulphate conjugates.

Phenylephrine Hydrochloride: is irregularly absorbed from the gastrointestinal tract and undergoes first-pass metabolism by monoamine oxidase in the gut and liver; orally administered phenylephrine thus has reduced bioavailability.

It is excreted in the urine almost entirely as the sulphate conjugate.

Pheniramine Maleate: is readily absorbed from gastrointestinal tract. It is metabolised in the liver to form N-desmethylpheniramine and N-didesmethylpheniramine. It is excreted in the urine as unchanged drug and metabolites.

Ascorbic Acid: is readily absorbed from the gastrointestinal tract and is widely distributed in the body tissues, 25% bound to plasma proteins. Ascorbic Acid in excess of the body's needs is eliminated in the urine as metabolites.

### 5.3 Preclinical safety data

Pre-clinical safety data on these active ingredients in the literature have not revealed any pertinent and conclusive findings which are of relevance ti the recommended dosage and use of the product and which have not already been mentioned elsewhere in this Summary.The toxicity of paracetamol has been indicated single dose oral $LD_{50}$values of 3.7 g/Kg and 338 mg/Kg, respectively. Chronic toxicity in these species at large multiples of the human therapeutics dose, occurs as degeneration and necrosis of hepatic, renal and lymphoid tissue, and blood count changes. The metabolites believed responsible dor these effects have also been demonstrated in man. Paracetamol should not, therefore, br taken for long periods of time, and in excessive doses. At normal therapeutics doses, paracetamol is not associated with genotoxic or carcinogenic rosk. There is no evidence of embryo-or foeto-toxicity from paracetamol in animal studies.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of Excipients

Aerosil (Colloidal Anhydrous Silica) BP

Saccharin Sodium BP

Sodium citrate BP

Sucrose BP

Sunset Yellow colour IH

Tartaric acid BP

Citric acid anhydrous BP

Orange flavor IH

**6.2 Incompatibilities**

Not application

**6.3 Shelf life**

36 Month from the date of manufacture

**6.4 Special precautions for storage**

Store at cool and dry place and protect from heat and light.
Keep out of reach of children.

**6.5 Nature and contents of container**

5g sachet of aluminium foil
1 box: 10 sachet x 5 g

**6.6 Instruction for use and handling**

**No special requirements.**

**7. MARKETING AUTHORISATION HOLDER:**

**BDA HEALTHCARE PVT. LTD.,**

Plot No.: B-1, B 2, B 3, Near Gov. ITI MIDC, Parseoni – 441105,

Taluka: Parseoni, District: Nagpur, M.S., India.

**8. MARKETING AUTHORISATION NUMBER(S)**

06430/08298/NMR/2020

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

26.07.2021

**10. DATE OF REVISION OF THE TEXT:**

02 July 2023