

## PATIENT INFORMATION LEAFLET

### [RESTOCIN]

#### PARACETAMOL BP 500 MG, PHENYLEPHRINE HYDROCHLORIDE BP 5 MG, CHLORPHENAMINE MALEATE BP 2 MG, CAFFEINE BP 30MG TABLETS

[Paracetamol + Phenylephrine Hcl + Chlorphenamine Maleate + Caffeine Anhydrous]

#### **Read all of this leaflet carefully before you start using this medicine.**

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your physician, health care provider or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist.

#### **WHAT IS IN THIS LEAFLET:**

1. What Restocin tablets is and what it is used for
2. Before you use Restocin tablets
3. How to use Restocin tablets
4. Possible side effects
5. How to store Restocin tablets
6. Further information

#### **1. WHAT RESTOCIN TABLETS IS AND WHAT IT IS USED FOR**

It contain active ingredient fixed dose combination of paracetamol, phenylephrine hydrochloride, chlorphenamine maleate, caffeine. Paracetamol: It is a well-established analgesic and antipyretic. Phenylephrine hydrochloride: It is a sympathomimetic agent with mainly direct effects on adrenergic receptors (predominantly alpha-adrenergic activity) producing nasal decongestion. Chlorphenamine maleate: It is a potent antihistamine (H1-antagonist). Antihistamines diminish or abolish the actions of histamine in the body by competitive reversible blockade of histamine H1-receptor sites on tissues. Chlorphenamine also has anticholinergic activity. Antihistamines act to prevent the release of histamine, prostaglandins and leukotrienes and have been shown to prevent the migration of inflammatory mediators. The actions of chlorphenamine include inhibition of histamine on smooth muscle, capillary permeability and hence reduction of oedema and wheal in hypersensitivity reactions such as allergy and anaphylaxis. Caffeine: It is the most active xanthine derivative in respect of stimulation of the central nervous system, producing a condition of wakefulness and increased mental activity. It is indicated for symptomatic relief of fever, headache, nasal congestion & rhinitis, associated with influenza and common cold.

#### **2. BEFORE YOU USE RESTOCIN TABLETS**

It is contraindicated in patient with known hypersensitivity to paracetamol, phenylephrine hydrochloride, chlorphenamine maleate, caffeine or to any of excipients. It is not to be taken by asthmatic patients or by patients with a known hypersensitivity to any of the active ingredients. Do not administer concurrently with monoamine oxidase inhibitors or within 14 days of stopping such treatment. Contra-indicated in most types of cardiovascular disease, hypotension, hyperthyroidism, hyperexcitability, Pheochromocytoma, closed-angle glaucoma, diabetes mellitus, peptic ulceration and epilepsy. Contra-indicated in most types of cardiovascular disease,

hypotension, hyperthyroidism, hyperexcitability, Pheochromocytoma, closed-angle glaucoma, diabetes mellitus, peptic ulceration and epilepsy. Do not take if any of the above apply to you. If you are not sure, talk to your physician, pharmacist or nurse before having Restocin tablets. **Take special care with Restocin tablets: Warnings and Precautions:** Talk to your physician before taking Restocin tablets. Use with caution on elderly patients, chronic alcoholism, serious liver or kidney disease, diabetes, heart or thyroid disease, high blood pressure. Chronic lung disease, glaucoma. Difficulty in urination due to enlarged prostate or pregnant or nursing or taking anti-depressants, other antihistamines, tranquilizer, or sedative drugs. Avoid driving a motor vehicle or operating machinery while taking this drug. Keep all the medicines out of reach of children.

Do not take additional fever-reducing and pain-relieving medicines or medicines for common cold without consulting a doctor or a pharmacist, in order to prevent paracetamol toxicity. **Using other medicines:** Tell your physician if you are taking Aspirin and salicylates, drugs affecting the Central Nervous System (e.g. sedatives, drugs for pain and fever, hypnotics, drugs for Parkinsonism, epilepsy), cough and cold preparations, antiasthmatic preparations, non-steroidal anti-inflammatory agents, antidepressants from the monoamine oxidase inhibitor group, or aminoglycoside antibiotics.

**Using Restocin tablets with food and drink:** It may be taken with or without food or as directed by physician. **Pregnancy and breast-feeding:** Before taking any medicine for advice consult to direction of **physician. Pregnancy:** Category C. There are no adequate and well-controlled studies in pregnant women. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Use in breast-feeding:** It may excrete in breast milk. Caution should be exercised when used in lactating mother. **Driving and using machines:** Avoid driving a motor vehicle or operating machinery while taking this drug. **Important information about some of the ingredients of Restocin tablets** contains each uncoated coated tablet contains lactose monohydrate, patients with rare hereditary problems of galactose intolerance, total-lactase deficiency or glucose-galactose malabsorption should not take this medicine. Talk to your physician.

### 3. HOW TO USE RESTOCIN TABLETS

It should be taken as directed by physician. **Method of administration:** For oral use only. It may be taken with or without food or as directed by physician. It should be swallowed with a glass of water. **The usual recommended doses: Adult:** 1 Tablet, 3 to 4 times a day. **Children (6 to 12 years):** 1/2 Tablet, 3 to 4 times a day. **Children (2 to 6 years):** 1/4 Tablet, 3 to 4 times a day or as directed by the physician.

**If you more Restocin tablets than you should:** Limited data are available in regard to over dosage in humans. If you accidentally take too many tablets, contact your Physician immediately. The most likely manifestation of over dosage would be include blurred vision; confusion; hallucinations; seizures; severe dizziness, lightheadedness, or headache; severe drowsiness; unusually fast, slow, or irregular heartbeat; vomiting. Treatment: Treatment should be symptomatic and supportive. **If you forget to Restocin tablets:** If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten tablet. If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

### 4. POSSIBLE SIDE EFFECTS

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist. Following less frequent adverse effects may have report. Slight to moderate drowsiness may occur other possible adverse reactions

may include restlessness, Dry mouth, nervousness, visual disturbances, dermatitis, weakness and nausea. In therapeutic doses, paracetamol is relatively non-toxic chronic use of large doses of Paracetamol may produce more significant toxicity. Hepatic toxicity has been associated with Paracetamol in overdose. Neutropenia and thrombocytopenia purpura have been reported and rarely agranulocytosis. Laryngeal edema, angioedema and anaphylactoid reactions may occur. May aggravate. Bronchospasm in patient's sensitive to acetyl salicylic acid or other analgesics.

## 5. HOW TO STORE RESTOCIN TABLETS

Keep this medicine out of the sight and reach of children. Store below 30°C. Protect from light. Do Not Freeze. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

## 6. FURTHER INFORMATION

It contain active substances as Paracetamol BP, Phenylephrine Hydrochloride BP, Chlorphenamine Maleate BP, Anhydrous Caffeine BP, Excipients Lactose, Potassium Dihydrogen Phosphate, Povidone (PVPK-30), Magnesium Stearate, Purified Talc, Sodium Starch Glycolate (Type-A), Purified Water Q.S. Colour: Ponceau 4R. Pack size: Pink coloured, round shaped, flat, uncoated tablet breakline on one side and plain on other side. 4 Tablets are packed in a strip Pack. Such 1 strip is packed in a printed catch cover. Such 50 each covers are packed in a printed carton with a packing insert.

### Manufactured by:

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