SCHEDULING STATUS

S2

GRIPPON COLD AND FLU, TABLETS

Phenylephrine hydrochloride 5 mg, chlorphenamine maleate 2 mg, paracetamol 150 mg, caffeine 15 mg

Contains sugar: lactose 75 mg

Read all of this leaflet carefully because it contains important information for you.

GRIPPON COLD AND FLU tablets is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to take GRIPPON COLD AND FLU tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share GRIPPON COLD AND FLU tablets with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve within 10 days.

What is in this leaflet

1. What GRIPPON COLD AND FLU tablets is and what it is used for.
2. What you need to know before you take GRIPPON COLD AND FLU tablets.
3. How to take GRIPPON COLD AND FLU tablets.
4. Possible side effects.
5. How to store GRIPPON COLD AND FLU, tablets.
6. Contents of the pack and other information.

1. What GRIPPON COLD AND FLU tablets is and what it is used for

GRIPPON COLD AND FLU tablets contain the active ingredients paracetamol, caffeine anhydrous, phenylephrine hydrochloride and chlorphenamine maleate.

GRIPPON COLD AND FLU tablets are indicated for the relief of symptoms associated with colds and flu such as fever, nasal stuffiness, sneezing, headache and minor aches and pains.

2. What you need to know before you take GRIPPON COLD AND FLU tablets

Do not take GRIPPON COLD AND FLU tablets:

- If you are hypersensitive (allergic) to paracetamol, caffeine anhydrous, phenylephrine hydrochloride, chlorphenamine maleate or any of the other ingredients of GRIPPON COLD AND FLU tablets (listed in section 6).
- If you have asthma (long-term inflammatory disease of the airways of the lungs).
- If you are taking or have been taking within the last 14 days antidepressant medicines (Monoamine oxidase inhibitors).
- If you have cardiovascular disease (disorders affecting the heart and blood circulation).
- If you have hypotension (low blood pressure).
- If you have hyperthyroidism (an overactive thyroid gland which can cause hyperactivity, sweating, weight loss and thirst).
- If you have hyperexcitability (a state in which there are very strong reactions to stimuli).
- If you have phaeochromocytoma (a tumour of the adrenal gland).
- If you have closed angle glaucoma (damage to the nerve in the eye caused by pressure inside the eye rising rapidly because fluid cannot drain out).
- If you have diabetes mellitus (a group of diseases that affect how the body uses blood sugar).
- If you have peptic ulceration (ulcers in the stomach or the duodenum).
- If you have epilepsy (seizure disorders).
- If you have severe liver impairment.
- If you have an enlarged prostate, impaired bowel movement, bowel blockage
- If you are taking decongestants (cough & cold or allergy medicines), antidepressants or antihypertensive medicines.

- If you are suffering from alcoholism, inflammation of the liver or recovering from any form of liver disease.
- Do not give GRIPPON COLD AND FLU tablets to children under the age of 12 years.

Warnings and precautions

Take special care with GRIPPON COLD AND FLU tablets:

- If you use more than what is recommended, it may cause severe liver damage. Do not use in combination with any other medicines containing paracetamol. Paracetamol overdose may cause liver failure, which may require liver transplant or lead to death.
- Consult your doctor if no relief is obtained with the recommended dosage.
- Do not use continuously for longer than 10 days without consulting your doctor.
- Consult your doctor before use, if you have liver or kidney disease.
- If you have glutathione (an antioxidant found naturally in your body) depleted states, the use of paracetamol may increase the risk of metabolic acidosis (a condition in which acids build up in your body).
- If you have bronchitis (inflammation of the airways in the lungs), bronchiectasis (when airways have become weakened and scarred).
- Serious skin reactions such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), drug reaction with eosinophilia and systemic symptoms (DRESS)/Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) have been reported in patients receiving paracetamol. If you experience any signs of serious skin reactions such as swelling, itching, red severe rash, stop using GRIPPON COLD AND FLU tablets immediately and contact your doctor (see Section 4).
- If you have hyperacidity (a condition in which the level of acid in the gastric juices is excessive).
- With prolonged use some degree of tolerance and psychic dependency may occur.

- If you have porphyria (an inability to break down chemicals called porphyrins), hypertension (high blood pressure) and cardiac arrhythmias (abnormal or irregular heartbeat).
- Use with caution when using in children and elderly patients as they are more likely to experience increased energy, restlessness and nervousness.
- If you have a heart condition characterised by rapid heartbeat.
- If you have thyrotoxicosis (condition of too much thyroid hormone in the body which may result in heat intolerance, fast heartbeats, anxiety, fatigue, weight loss, irregular menses in women, and tremor).
- If you have cardiac insufficiency or failure and in cardiac surgery.
- If you have kidney disease, alcohol dependence, chronic malnutrition or dehydration.
- If you are using it at the same time with flucloxacillin (antibiotic), it will cause metabolic acidosis (a condition in which there is too much acid in the body fluids which presents as nausea and deteriorating renal function).
- Concurrent use with medicines which can cause sedation, such as anxiolytics and hypnotics, may cause an increase in sedative effects.
- Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption.
- Colour Erythrosine Red E127 which may cause allergic reactions.

Other medicines and GRIPPON COLD AND FLU tablets

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

The following medicines may cause an interaction when used with GRIPPON COLD AND FLU tablets:

- The sedative effect is increased when used with *alcohol*, *barbiturates* (medicines used for anxiety, sleeplessness and seizure disorders), *hypnotics* (medicines used for

sleeplessness), *narcotic analgesics* (chronic pain relief medicines), *sedatives* and *tranquillizers* and may produce a soothing effect in certain individuals.

- The effects of anticholinergic drugs such as *atropine* (medicine used to reduce saliva and fluid in the respiratory tract during surgery) and *tricyclic antidepressants* may be increased.
- Caffeine may increase the high blood pressure and fast heartbeat further when used with sympathomimetics.
- Medicines that may increase caffeine levels in the blood:
    - *Allopurinol* (medicine used to treat gout and certain types of kidney stones), some *antiarrhythmics* (medications that prevent and treat a heart rhythm that is too fast or irregular),
    - *Cimetidine* (a gastric acid reducer used in the short-term treatment of duodenal and gastric ulcers),
    - *Disulfiram* (medicine used to help overcome your drinking problem),
    - *Fluvoxamine* (an antidepressant medication that works in the brain),
    - *Interferon alfa* (medicine is used to treat various cancers),
    - *Macrolide antibacterials* (class of drugs used to manage and treat various bacterial infections),
    - *Quinolones* (a class of broad-spectrum antibiotics used in the management and treatment of many different bacterial infections),
    - *Oral contraceptives* (Birth control pills),
    - *Thiabendazole* (an antifungal agent, and an antiparasitic agent)
    - *Viloxazine* (medicine used to treat attention deficit hyperactivity disorder).
- Medicines that may reduce caffeine levels in the blood:
    - *Ritonavir* (a protease inhibitor used for the treatment of HIV/AIDS)
    - *Rifampicin* (medicine used for the treatment of tuberculosis)
    - *Sulfinpyrazone* (medicine used to treat chronic or intermittent gouty arthritis)
- All sedatives, including alcohol, will increase the side effects related to the brain.

- Chlorphenamine can lead to phenytoin toxicity.
- Simultaneous use with *ergot alkaloids* (therapy of acute migraine headaches) may cause an increased risk of ergotism (poisoning produced by eating food affected by ergot, typically resulting in headache, vomiting, diarrhoea, and gangrene of the fingers and toes)
- Increased risk of bleeding when there is prolonged daily use of medicines that prevent the blood from clotting *(warfarin and other coumarins)*
- Medicines that increase liver toxicity due to the paracetamol in GRIPPON COLD AND FLU tablets
    - Enzyme inducing medicines: carbamazepine, barbituarates, fosphenytoin, phenytoin, primidone (medicines used to treat seizures)
    - Tricyclic antidepressants
    - Alcohol
    - Hepatotoxic medicines
    - Antivirals
- Medicines that affect the absorption of paracetamol in GRIPPON COLD AND FLU tablets
    - Metoclopramide, domperidone (medicine used to treat nausea & vomiting).
    - Cholestyramine (medicines used to lower cholesterol levels).
- Prolonged concurrent use of paracetamol, as in GRIPPON COLD AND FLU tablets, with salicylates (pain medicines) increases the risk of adverse kidney effects.
- Probenecid (medicine used to treat gout) may increase paracetamol in the blood.
- Increased antiviral effect of interferon alfa (Immune suppressant medicine).
- Oral contraceptives may cause the paracetamol in GRIPPON COLD AND FLU tablets to be excreted faster.
- Caution should be taken when using together with antibiotics.
- The antihistamine effects (drowsiness; dry mouth, nose, or throat; dizziness; upset stomach) are increased by *antihypertensives* (*guanethidine*, *reserpine, methyldopa*) and *tricyclic antidepressants*.

GRIPPON COLD AND FLU tablets with food, drink and alcohol

GRIPPON COLD AND FLU tablets may be taken with or without food.

Do not drink alcohol while you are taking GRIPPON COLD AND FLU tablets.

Pregnancy, breastfeeding and fertility

The use of GRIPPON COLD AND FLU tablets in pregnancy and lactation has not been established. In the absence of sufficient data, the use is not recommended. No fertility data available. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking GRIPPON COLD AND FLU tablets.

Driving and using machines

The effects of GRIPPON COLD AND FLU tablets on the ability to drive and use of machines may be impaired. It is not always possible to predict to what extent GRIPPON COLD AND FLU tablets may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which GRIPPON COLD AND FLU tablets affects them.

GRIPPON COLD AND FLU tablets contains lactose.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

GRIPPON COLD AND FLU tablets contains Colour Erythrosine Red [E127]

Erythrosine Red [E127] may cause allergic reactions.

3. How to take GRIPPON COLD AND FLU tablets

Do not share medicines prescribed for you with any other person.

Always take GRIPPON COLD AND FLU tablets exactly as described in this leaflet or as your health care professional has told you. Check with your health care professional if you are not sure.

The usual dose is:

Adults: 2 tablets 3 times a day

Children 12 years and older: 1 tablet 3 times a day

Not intended for use in children under the age of 12.

Do not take GRIPPON COLD AND FLU tablets continuously for more than 10 days without consulting your doctor.

If you take more GRIPPON COLD AND FLU tablets than you should:

In cases of overdose, treatment is symptomatic and supportive. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the rest of the remaining tablets with you so the doctor will know what you have taken.

GRIPPON COLD AND FLU tablets contains paracetamol which may be fatal in overdose. Prompt treatment is essential. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or poison centre must be contacted immediately.

If you forget to take GRIPPON COLD AND FLU tablets:

Use your next dose at your regular time.

Do not take a double dose to make up for forgotten individual doses.

4. Possible Side Effects

GRIPPON COLD AND FLU tablets can have side effects.

Not all side effects reported for GRIPPON COLD AND FLU tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GRIPPON COLD AND FLU tablets, please consult your health care provider for advice.

If any of the following happens, stop taking GRIPPON COLD AND FLU tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Mouth ulcers, cold sores and ulcers or soreness of your tongue
- Skin lumps or hives (raised, red or white, itchy patches of skin)
- Blisters on your skin or inside your mouth, nose, vagina or bottom
- The appearance of a rash or sunburn when you have been outside (even on a cloudy day)
- Swelling of the eyelids, face, tongue or lips
- Severe dizziness
- Difficulty in breathing
- Serious skin reactions such as swelling, itching, red severe rash especially those covering your whole body (appearing as allergic wheals), stop taking GRIPPON COLD AND FLU tablets immediately and contact your doctor (see Section 2).

Tell your doctor if you notice any of the following:

Frequent Side effects:

- Blurred vision, dizziness
- Tiredness
- Nausea, dry mouth

Less Frequent Side effects:

- Thrombocytopenia (low levels of blood platelets which can lead to bleeding and bruising), agranulocytosis (very low level of a type of white blood cell which are important for fighting

off infection), leucopoenia (low levels of white blood cells), neutropenia (low levels of neutrophils, a type of white blood cell that fights infection), pancytopenia (low levels of blood cells) and anaemia (low levels of red blood cells)

- Anaphylaxis (sudden, severe allergic reaction with breathing difficulty, swelling, light-headedness, fast heartbeat, sweating and loss of consciousness), skin rash, angioedema (rapid swelling under the skin), Stevens-Johnson syndrome (life-threatening reaction with flu-like symptoms and painful rash affecting the skin, mouth, eyes and genitals), toxic epidermal necrolysis (life-threatening reaction with flu-like effects and blistering in the skin, mouth eyes and genitals), drug-induced hypersensitivity syndrome (DIHS)
- Bronchospasm (excessive and prolonged contraction of the airway muscles causing breathing difficulty) in patients sensitive to aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs)
- Inflammation of the pancreas
- Inflammation of the liver or liver dysfunction
- Inflammation of the skin or skin rashes
- Renal colic (pain felt when kidney stones block the urinary tract), kidney failure and sterile pyuria (presences of white blood cells in urine in the absence of infection), kidney damage

Side effects of Unknown frequency

- Haemolytic anaemia (excessive breakdown of red blood cells), blood disorders
- Hypersensitivity reactions characterised by red itchy rash, shortness of breath, and hypotension (see Section 4.4).
- Altered metabolism, anorexia (loss of appetite) or increased appetite
- Anxiety, fear, restlessness, shakiness, irritability, confusion, weakness, headache, sedation varying from slight drowsiness to deep sleep, inability to concentrate, depression, nightmares, sleeplessness, nervousness, confusion, excitation
- Sensory disturbances

- Tinnitus (constant ringing sound in the ear), hearing loss
- Tachycardia (rapid heartbeat), cardiac arrhythmias (abnormal heartbeat), angina pectoris (pains to the chest, jaw and back, brought on by physical effort and due to problems with the blood flow to the heart), palpitations (abnormal heartbeat), hypertension, hypotension with dizziness
- Headache, tingling, heaviness and weakness of the hands, Hypotension
- Tight chest, thickening of bronchial secretions
- Vomiting, diarrhoea, constipation, heartburn, abdominal pain, GI bleeding
- Muscular weakness and incoordination, shakiness, muscle twitching, seizures
- Difficulty with urinating, urinary retention, urinating a lot, reduced kidney function
- Lack of energy

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

Reporting of side effects

If you have any side effects, talk to your doctor or, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

You can report side effects to the **Adcock Ingram Pharmacovigilance** department by e-mail to Adcock.Aereports@adcock.com

By reporting side effects, you can help provide more information on the safety of GRIPPON COLD AND FLU tablets.

5. How to store GRIPPON COLD AND FLU tablets

Store at or below 25 °C in a well-closed container protected from light.

Exposure to air should be kept to a minimum.

Keep all medicines out of reach and sight of children.

Return all unused medicine to your pharmacist for proper disposal.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

What GRIPPON COLD AND FLU tablets contain:

Each tablet contains:	
Phenylephrine hydrochloride	5 mg
Chlorphenamine maleate	2 mg
Paracetamol	150 mg
Caffeine anhydrous	15 mg

The other ingredients are colour erythrosine red [E127], gelatin, lactose, purified water, starch [E1400], stearic acid [E570] and talc [E553(b)]

What GRIPPON COLD AND FLU tablets looks like and contents of the pack:

Pink cylindrical biconvex tablets with "GRIPPON" imprinted on the upper face and a break bar on the lower face.

20's blister pack: Blisters composed of printed aluminium foil and PVC film.

250's Securitainer pack: White polypropylene Securitainer with a white LDPE cap.

500's Securitainer pack: - White polypropylene Securitainer with a white LDPE cap.

Not all pack sizes are marketed.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand,

1685

Customer Care: 0860 ADCOCK /232625

This leaflet was last revised on

11 September 2025

Registration number

C 773 (Act 101/1965).

Botswana: S3 B9311090

Namibia: NS1 12/5.8/0095

adcock ingram