PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

CORENZA COLD AND FLU SYRUP

Pseudoephedrine hydrochloride 15 mg, Chlorpheniramine maleate 2 mg,

Paracetamol 120 mg

Preservative: Methylparaben 0,12 % m/v

Contains sweetener: 70 % Sorbitol solution 400 mg and Saccharin sodium 5,5 mg

Alcohol free

Tartrazine free

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

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

- Keep this leaflet. You may need to read it again.
- Do not share CORENZA COLD AND FLU SYRUP with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

PATIENT INFORMATION LEAFLET

What is in this leaflet

1. What CORENZA COLD AND FLU SYRUP is and what it is used for

2. What you need to know before you use CORENZA COLD AND FLU SYRUP

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1. What CORENZA COLD AND FLU SYRUP is and what it is used for

Symptomatic treatment and relief of colds and influenza.

2. What you need to know before you use CORENZA COLD AND FLU SYRUP

Do not take CORENZA COLD AND FLU SYRUP:

- if you are hypersensitive (allergic) to paracetamol, pseudoephedrine hydrochloride or chlorpheniramine maleate or any of the other ingredients of CORENZA COLD AND FLU SYRUP (listed in section 6).
- if you suffer from hyperthyroidism (overactive thyroid).
- if you have a growth known as pheochromocytoma which can cause an increase
- in your blood pressure and your heartbeat.
- if you are pregnant or breastfeeding (see “Pregnancy and breastfeeding”).
- if you have cardiovascular disease (group of disorders of the heart and blood vessels) such as ischaemic heart disease and coronary insufficiency (inadequate blood/oxygen supply to the heart muscle), dysrhythmias (irregular heartbeat) or tachycardia (increased rate of heartbeat).

- if you have high blood sugar (diabetes mellitus).
- if you have closed angle glaucoma (glaucoma causes raised pressure in the eye).
- if you have urinary retention (condition in which you cannot empty all the urine from your bladder).
- if you have enlargement of the prostate gland.
- if you have severe liver impairment.
- if you are having an asthma attack.
- if you are being treated with medicines known as monoamine oxidase inhibitors (MAOIs) for depression and Parkinson's disease, or within 14 days of stopping this treatment.
- in children under two years of age.
- if you are going to receive an anaesthetic (to make you unconscious) given as a gas that you inhale during an operation/procedure.
- If you have very high blood pressure (severe hypertension) or hypertension not controlled by your medication
- If you have severe acute (sudden)or chronic (long-term) kidney disease or kidney failure
- Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.
- Do not take together with any pain or high blood pressure medication at the same time.

Warnings and precautions

In the event of overdosage or suspected overdosage and even if the person is not showing any symptoms, the nearest doctor, hospital, or poison control centre must be contacted immediately.

Take special care with CORENZA COLD AND FLU SYRUP:

- Dosages in excess of those recommended may cause severe liver damage.
- Consult your doctor if you have no relief using the recommended dosage.
- If you suffer from mild to moderate liver and kidney disease, you should take CORENZA COLD AND FLU SYRUP under medical supervision.
- If you suffer from emphysema (a lung disease which makes it hard to breath), chronic bronchitis (lung infection with a cough that produces mucous), asthma, or where you are coughing up excessive mucous, you should only take CORENZA COLD AND FLU SYRUP after seeing your doctor.
- If you are using medicines to treat depression.
- If you suffer from epilepsy.
- If you feel sudden abdominal pain, and rectal bleeding (bleeding from the anus), you should stop taking CORENZA COLD AND FLU SYRUP and see your doctor.
- If you have pyloroduodenal obstruction (a blockage at the outlet of your stomach).
- Serious skin reactions such as toxic epidermal necrolysis (TEN), Steven-Johnson syndrome (SJS) (potentially life-threatening skin rashes), acute generalized exanthematous pustulosis (AGEP) (rare skin reaction caused by medicine), Drug rash with eosinophilia and systemic symptoms (DRESS) (a severe reaction affecting the skin, blood and internal organs) /Drug-induced hypersensitivity Syndrome (DIHS) and fixed drug eruptions (FDE). If your child experiences any signs of serious skin reactions such as swelling, itching, red severe rash, stop using CORENZA COLD AND FLU SYRUP immediately and contact your doctor (see Section 4).
- Cases of posterior reversible encephalopathy syndrome (PRES) (brain swelling with

usually temporary effects such as headache, changes in vision, reduced consciousness and seizures) and reversible cerebral vasoconstriction syndrome (RCVS) (recurrent thunderclap headaches) have been reported following use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that can involve reduced blood supply to the brain. Stop using CORENZA COLD AND FLU SYRUP immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section 4 "Possible side effects" for symptoms)

- Alcohol may increase the toxicity of paracetamol in the liver
- When taken together with flucloxacillin (antibiotic), in patients with severe kidney impairment, sepsis (blood infection) and other sources of glutathione (antioxidant) deficiency may cause drastic acid build-up in the body
- Long term use of antihistamines may decrease saliva flow and may cause infection and discomfort.

Other medicines and CORENZA COLD AND FLU SYRUP:

- If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of CORENZA COLD AND FLU SYRUP with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.
- CORENZA COLD AND FLU SYRUP may enhance the sedative effects of central nervous system depressants such as *alcohol*, medicines used to make you sleep (e.g., *barbiturates, sedatives, or hypnotics*), medicines used for strong pain relief (e.g., *narcotic analgesics*), *sedatives* and medicines that help with anxiety (*tranquillisers*).
- Pseudoephedrine hydrochloride, one of the ingredients in CORENZA COLD AND FLU SYRUP should be avoided or used with care if you are receiving atropine or tricyclic antidepressants (medicine used for the treatment of depression).

- CORENZA COLD AND FLU SYRUP may mask the warning signs of damage caused by ototoxic (inner ear damage) medicines such as aminoglycoside antibiotics.
- If you are on chronic warfarin therapy paracetamol may possibly affect your INR.
- Liver toxicity is increased in alcoholics and patients taking hepatic enzyme inducers.
- Using the product along with Non-steroidal anti-inflammatory medicines may affect the kidney negatively.
- Paracetamol may cause *Zidovudine* (medicine used to treat HIV/AIDS) to stay longer in the bloodstream.
- Aluminium-hydroxide containing preparations may increase the absorption rate of pseudoephedrine hydrochloride.
- May reduce the effect of *antihypertensives*.
- *Doxapram* (medicine used to stimulate the lungs) may increase blood pressure.
- There is an increased risk of an abnormal heart rate when used with medicine to treat *heart conditions*.
- Chronic use of *anticonvulsants* (medicine used to prevent epilepsy)
- When taken together with *flucloxacillin* (antibiotic), in patients with severe kidney impairment, sepsis (blood infection) and other sources of glutathione (antioxidant) deficiency may cause drastic acid build-up in the body
- *Metoclopramide* and *domperidone* (medicines used to treat nausea & vomiting) may accelerate the absorption of paracetamol.
- *Probenecid* (medicine used to treat gout) may increase the concentration of paracetamol in the blood.
- *Colestyramine* (medicine used to lower high levels of cholesterol in the blood) reduces the absorption of paracetamol if given within one hour of CORENZA COLD AND FLU SYRUP.

Pregnancy, breastfeeding and fertility:

In the absence of sufficient data, the use during pregnancy and lactation 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 CORENZA COLD AND FLU SYRUP.

Driving and using machinery

CORENZA COLD AND FLU SYRUP may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol and other central nervous system depressant agents.

It is not always possible to predict to what extent CORENZA COLD AND FLU SYRUP 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 CORENZA COLD AND FLU SYRUP affects them.

CORENZA COLD AND FLU SYRUP contains sorbitol

This medicine contains 400 mg 70 % sorbitol solution in each 5 ml. Patients with the rare hereditary condition of sorbitol intolerance should not take CORENZA COLD & FLU SYRUP.

CORENZA COLD AND FLU SYRUP contains propylene glycol

If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

CORENZA COLD AND FLU SYRUP contains methylparaben

May cause allergic reactions (possibly delayed).

3. How to use CORENZA COLD AND FLU SYRUP

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

Always use CORENZA COLD AND FLU SYRUP exactly as described in this leaflet.

Check with your doctor or pharmacist if you are unsure.

The usual dosage is:

Adults: Three to four medicine measures (15 ml to 20 ml) three times daily.

Children 6 to 12 years: One to two medicine measures (5 ml to 10 ml) three times daily.

Children 2 to 5 years: Half to one medicine measure (2,5 ml to 5 ml) three times daily.

Shake Well Before Use.

DO NOT EXCEED THE RECOMMENDED DOSE.

CORENZA COLD AND FLU SYRUP should not be administered to children under 2

years of age.

Do not use continuously for more than seven days. If symptoms persist or get worse, or

if new symptoms occur, irrespective of therapy used, patients should stop use and

consult your doctor.

Please consult your doctor before using CORENZA COLD & FLU SYRUP if

you are elderly or have kidney or renal impairment.

If you have the impression that the effect of CORENZA COLD AND FLU SYRUP is too strong or too weak, talk to your pharmacist or doctor.

If you use more CORENZA COLD AND FLU SYRUP than you should

Side effects will occur or be of increased severity. 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 effervescent tablets with you so the doctor will know what you have taken.

The following symptoms may occur:

Paracetamol: Paleness, nausea, vomiting, loss of appetite and possible abdominal pain. Mild symptoms during the first two days of severe poisoning do not reflect the potential seriousness of the overdosage.

Pseudoephedrine hydrochloride: Symptoms usually appear within 4 to 8 hours of the overdose. These symptoms include mild anxiety; an increased heartbeat rate and/or a mild high blood pressure.

Chlorpheniramine: May cause general muscle relaxation, gastrointestinal and central nervous system effects.

If you forget to take CORENZA COLD AND FLU SYRUP

Take your next dose at your regular time.

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

4. Possible side effects

CORENZA COLD AND FLU SYRUP can have side effects.

Not all side effects reported for CORENZA COLD AND FLU SYRUP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CORENZA COLD AND FLU SYRUP, please consult your doctor, pharmacist, or other health care professional for advice.

The following side effects may be experienced while using CORENZA COLD AND FLU SYRUP**:**

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting
- serious conditions affecting blood vessels in the brain known as posterior
- reversible encephalopathy syndrome (PRES) and reversible cerebral
- vasoconstriction syndrome (RCVS)

These are all very serious side effects. If you have them, you may have had a serious reaction to CORENZA COLD AND FLU SYRUP. You may need urgent medical

attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain,
- angina,
- changes in the way your heart beats, for example, if you notice it beating faster,
- difficulty breathing,
- signs of recurrent infections such as fever or sore throat,
- less urine than is normal for you,
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems

These are all serious side effects. You may need urgent medical attention.

Stop using CORENZA COLD AND FLU SYRUP immediately and seek urgent medical attention if you develop symptoms, that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These include:

- severe headache with a sudden onset
- feeling sick
- vomiting
- confusion
- seizures
- change in vision

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nervousness, restlessness, hallucinations (particularly in children), fear, anxiety, irritability, and psychotic states, euphoria, nightmares, drowsiness (varying from slight drowsiness to deep sleep) including lethargy, incoordination.
- Sleeplessness, seizures, shakiness, dizziness, sleepiness, disturbance in attention, abnormal coordination
- Irregular or slow heartbeat, shortness of breath, or troubled breathing.
- Dry mouth, nausea
- Tolerance with dependence, asthenia (Physical weakness or a lack of energy)

Less Frequent side effects:

- Blood disorders
- Severe skin rashes
- Decreased appetite, not enough potassium in the blood, altered metabolism
- Headache, trembling, brain bleed
- Blurred vision, seeing double
- ringing, roaring, buzzing, or clicking noises in the ears
- fast heart rate, light headedness, swelling in the lungs, a change from the normal heartbeat, pain from not enough blood to the heart, irregular heartbeats that you can feel, heart stops beating, premature heartbeat
- Impaired circulation to the extremities, unusual paleness, high blood pressure, slow heartbeat, low blood pressure, fainting, tingling
- hard to breathe; short of breath, thickened respiratory tract secretions, and tightness of the chest.
- Mouth injuries, inflammation of pancreas, vomiting, increased saliva, constipation, diarrhoea, gastric reflux, and epigastric pain.
- Increased sweating

- Reduced flow of bile, liver inflammation, or other liver function abnormalities, kidney failure, absence of bacteria in the urine, difficult or painful urination, urinary retention, damage that occurs in your kidneys
- Early menses
- Fever, swelling, hair loss.
- Changes in blood sugar levels

Unknown side effects:

- Anorexia (condition in which person will not eat; lack of appetite)
- Depression
- Psychomotor impairment (slowing down of thought and physical movements), Posterior reversible encephalopathy syndrome (PRES) (rare condition in which parts of the brain are affected by swelling, usually as a result of an underlying cause and may cause may experience headaches, changes in vision, and seizures) (see , Reversible cerebral vasoconstriction syndrome (RCVS) (a disease characterized by a weeks-long course of thunderclap headaches))
- Cough, wheezing, nasal stuffiness
- Muscle twitching, muscle weakness

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

Reporting of side effects

If you get side effects talk to your doctor or pharmacist or nurse.

You can also report side effects to SAHPRA via the Med Safety App' (Med Safety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA's 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 CORENZA COLD & FLU SYRUP.

5. HOW TO STORE CORENZA COLD AND FLU SYRUP

Keep all medicines out of the reach and sight of children.

Store at or below 25 °C.

Store in the original container. Keep the container tightly closed and protect from light.

Do not store in bathrooms.

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What CORENZA COLD AND FLU SYRUP contains:

The active ingredients are:

Each 5 ml contains:	
Pseudoephedrine hydrochloride	15 mg
Paracetamol	120 mg
Chlorphenamine maleate	2 mg

The preservative is methylparaben 0,12 % *m/v*.

The other ingredients are polyvinylpyrrolidone K25, propylene glycol, purified water, flavour raspberry, raspberry red colour, saccharin sodium, sorbitol, and xanthan gum.

What CORENZA COLD AND FLU SYRUP looks like and contents of the pack

A clear, dark red syrup with an odour and taste of raspberry contained in:

50 ml, 100 ml, and 200 ml packed in amber glass and bottles with white polypropylene screw-on closure with EXPE Liner.

50 ml, 100 ml, and 200 ml amber PVC bottles with white snap-on pilfer proof closure.

Holder of Certificate of Registration

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