

CLEAN PROPOSED PATIENT INFORMATION LEAFLET FOR
CORYX

SCHEDULING STATUS: S2

CORYX Effervescent tablets

Chlorpheniramine maleate, pseudoephedrine hydrochloride, aspirin, vitamin C

Contains sweetener: aspartame 53 mg per tablet

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

CORYX is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use CORYX carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share CORYX 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 10 days.

What is in this leaflet

1. What CORYX is and what it is used for
2. What you need to know before you take CORYX
3. How to take CORYX
4. Possible side effects

5. How to store CORYX

6. Contents of the pack and other information

1. What CORYX is and what it is used for

CORYX belongs to a class of medicines known as preparations for the common cold.

CORYX is used in adults and children over 16 years for the treatment of symptoms associated with colds and flu.

2. What you need to know before you take CORYX

Do not take CORYX

- if you are hypersensitive (allergic) to chlorpheniramine, pseudoephedrine, aspirin (or any other nonsteroidal anti-inflammatory medicine, such as diclofenac or ibuprofen) or vitamin C (ascorbic acid) or any of the other ingredients of CORYX (listed in **section 6**).
- if you have heart problems, high blood pressure, heart failure, an overactive thyroid gland (hyperthyroidism) or epilepsy.
- if you are pregnant or breastfeeding your baby.
- if you are taking monoamine oxidase inhibitors or within 14 days of stopping such treatment.
- if you have a history of perforation of the gut, stomach ulcers (sores in the lining of the gut).
- if you have bleeding related to previous use of nonsteroidal anti-inflammatory medicines (NSAIDs), such as diclofenac, ibuprofen or aspirin used for pain or inflammation.

- if you have problems with blood clotting (haemophilia).
- if you have kidney disease or impaired kidney function.
- if you are receiving oral anticoagulant therapy (medicines that help prevent blood clots).
- if you currently have, or in the past had a recurring ulcer, haemorrhage (bleeding) or perforation.
- if you are a child under the age of 16 years.
- if you have nasal polyps associated with the use of aspirin.
- if you have phenylketonuria.
- 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

Warnings and precautions

CORYX may lead to heart problems, stomach problems, or skin reactions which may be fatal.

Do not use for more than 10 days without consulting your doctor, as it may lead to anaemia (decreased red blood cell count), other blood disorders, bleeding or ulceration (sores) of the gut, or kidney problems.

CORYX contains 53 mg aspartame in each tablet.

Aspartame is a source of phenylalanine. It will be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up

because the body cannot remove it properly.

Take special care with CORYX:

- if you have kidney or liver disease, or struggle to urinate.
- if you have asthma or any allergic disorders.
- if you are also using alcohol, or if you are taking other medicines such as sedatives, tranquilisers or sleeping tablets, as it may lead to drowsiness and impaired concentration. You should take care not to drive or operate machinery, particularly at the start of treatment, until you know how CORYX affects you (see **Driving and using machines**).
- if you are a child over 16 years of age (also see **Do not take CORYX**), or a teenager, with chickenpox or the flu. Talk to your doctor or pharmacist before taking CORYX, as you may need to use another medicine that does not contain aspirin.
- if you have heart disease, cardiovascular disease, irregular or fast heartbeat.
- if you have narrowed blood vessels (occlusive vascular disorders), including hardening or thinning of the arteries (arteriosclerosis or aneurysms), or chest pain (angina pectoris)
- if you have high blood sugar levels (diabetes mellitus), increased pressure in the eye (glaucoma) or an enlarged prostate gland (prostatic hyperplasia).
- if you are over 65 years of age, as you may be more prone to develop side effects such as perforation of the gut, stomach ulcers or bleeding, which may be fatal.
- if you have a history of stomach ulcers, inflammatory bowel diseases such as ulcerative colitis or Crohn's disease, hiatus hernia, acid reflux, angiodysplasia

or obstruction of the gut.

- if you are scheduled to go for surgery. Talk to your doctor, as you may need to stop treatment several days before surgery.
- if you are to have a spinal or epidural anaesthetic, tell your anaesthetist, as the procedure may need to be delayed.
- if you notice any blistering skin rash, lesions inside the mouth, or any other sign of allergic reaction while taking CORYX. You should immediately stop taking CORYX and report to your doctor, as you may be suffering from a severe allergic skin reaction, which may be fatal.
- if you are scheduled for a thyroid function test, or an allergy skin-prick test.
- if you have kidney stones, or high levels of oxalate in your urine (hyperoxaluria).

Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) 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 CORYX 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).

Take CORYX as directed by your doctor or pharmacist. If you take more CORYX than you should, you may experience severely low blood potassium levels (hypokalaemia) and a kidney disorder known as renal tubular acidosis (RTA).

Please consult your doctor or pharmacist for advice before taking CORYX if you

have any of the above.

Other medicines and CORYX

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

Care should be taken if concomitantly taking CORYX with the following:

- alcohol, sleeping tablets (barbiturates), sedatives (hypnotics), pain medicines (opioid analgesics), tranquillisers, medicines for anxiety (anxiolytic sedatives) or psychoses (antipsychotics), antidepressants [tricyclic antidepressants, monoamine oxidase inhibitors (MAOIs) or reversible MAOIs].
- medicines for high blood pressure (reserpine, methyldopa), or atropine.
- anaesthesia.
- medicines for heart conditions (e.g. digoxin, or quinidine), medicines for migraines or Parkinson's disease (ergot alkaloids) or oxytocin.
- medicines for inflammation, such as nonsteroidal anti-inflammatory medicines (e.g. diclofenac, ibuprofen, aspirin), or corticosteroids (e.g. betamethasone, prednisone, triamcinolone).
- medicines that prevent blood clots (anticoagulants, such as warfarin), oral medicines (tablets) for diabetes, certain antibiotics (sulphonamides, aminoglycosides), and certain antidepressants [selective serotonin reuptake inhibitors (SSRIs)].
- medicines used for gout (probenecid, sulphinpyrazone).
- if you are scheduled for an allergy skin-prick test, as CORYX should be stopped several days before the test.

- dipyridamole (an anticoagulant), metoclopramide (for nausea, vomiting or acid reflux), medicines for high blood pressure or heart problems (metoprolol, calcium channel blockers, such as verapamil, and spironolactone), medicines for glaucoma (carbonic anhydrase inhibitors), for heartburn, indigestion or an upset stomach (antacids and adsorbents), for rheumatoid arthritis (gold compounds), medicines for diabetes (sulfonylureas), zafirlukast (for asthma), methotrexate (an immune suppressant), medicines for epilepsy (phenytoin, valproate), or mifepristone.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of CORYX with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

CORYX with food and drink and alcohol

It is preferable to take CORYX after meals (see **section 3**).

Do not use alcohol and CORYX at the same time, as it may lead to drowsiness and impaired concentration, and may worsen the effects of CORYX on the stomach.

Pregnancy and breastfeeding

CORYX should not be taken during pregnancy or breastfeeding (see **Do not take CORYX**).

Taking CORYX around 20 weeks or later in pregnancy may cause kidney problems in your unborn baby, which may lead to low levels of amniotic fluid that surrounds the

baby. Complications may occur with low levels of amniotic fluid.

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 healthcare provider for advice before taking CORYX.

Driving and using machines

CORYX may make you feel drowsy/sleepy:

- do not drive because CORYX could interfere with your ability to drive safely.
- do not operate any tools or machines.
- do not climb dangerous heights or perform potentially dangerous tasks where impaired decision making could lead to accidents.

It is not always possible to predict to what extent CORYX 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 CORYX affects them.

CORYX contains aspartame

CORYX contains 53 mg aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly. Patients with phenylketonuria must not take CORYX.

3. How to take CORYX

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

Always take CORYX exactly as described in this leaflet or as your doctor, or

pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Use the lowest effective dose for the shortest possible duration of treatment.

Adults and children over 16 years

One tablet every 8 hours if necessary.

Place one tablet in a glass of warm (or cold if so wished) water and allow to dissolve.

Drink all the contents immediately once the whole tablet has dissolved (see **section 6**). Take CORYX preferably after meals.

Children under 16 years

Do not take CORYX if you are under the age of 16 years (see **Do not take CORYX**).

If you take more CORYX than you should

If you take more CORYX than you should, you may experience an increase in side effects listed below (see **section 4**).

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take CORYX

Always take CORYX as directed. If you forget a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule of one tablet every 8 hours if necessary.

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

4. Possible side effects

CORYX can have side effects.

Not all side effects reported for CORYX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CORYX, please consult your healthcare provider for advice.

If any of the following happens, stop taking CORYX 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.
- blistering skin rash or itching, with or without redness of the skin.
- loss of consciousness and unresponsiveness (due to cardiac arrest).

These are all very serious side effects. If you have them, you may have had a serious reaction to CORYX. 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:

- easy bruising, unusual bleeding, pinpoint red spots on the skin, bleeding from the gums, pale skin, unusual tiredness or weakness, fever and/or chills, as a combination of these symptoms may be due to abnormal blood cell and platelet counts.
- fast, slow or pounding heartbeat, abnormal heart rhythm, chest pain (angina), swelling of the ankles, feet and legs (oedema), heart failure.

- increased or decreased blood pressure, with dizziness, fainting or flushing.
- bleeding of the brain (causing numbness or weakness of the face, difficulty speaking or walking).
- difficult breathing (dyspnoea) with or without excess fluid in the lungs (lung oedema).
- stomach pain, with vomiting of blood or passing black stools, which may be due to irritation of the stomach lining, causing bleeding or perforation of the gut (ulcers, haematemesis and melaena), which may be fatal.
- stomach pain, cramping or diarrhoea, with red blood in the stool and a feeling of urgency to have a bowel movement (ischaemic colitis, or worsening of colitis).
- yellowing of the skin and eyes, dark urine and tiredness which may be symptoms of liver problems.
- blood in the urine, frequency or urgency to urinate, pain in the back or flank area, pain while urinating, decreased urine output (urinary retention), drowsiness, confusion, fatigue or weakness, as a combination of these symptoms may be due to kidney damage (analgesic nephropathy) or kidney stones.
- severely low blood potassium levels (hypokalaemia) and a kidney disorder known as renal tubular acidosis (RTA), with symptoms such as weakness, feeling tired, muscle cramps, confusion, constipation, irregular heartbeat, tingling or numbness, increased urination, fast breathing, kidney stones, or muscle weakness.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- anxiety, restlessness, sleeplessness.
- sleepiness, ranging from slight drowsiness to deep sleep, including lack of energy (lassitude), dizziness or incoordination.
- headache, slow thoughts or movements (psychomotor impairment).
- dry mouth, thickened lung secretions (causing wheezing), blurred vision, difficulty urinating, constipation or increased acid reflux (called antimuscarinic effects).
- stomach problems, nausea, indigestion, vomiting.

Less frequent side effects:

- seeing or hearing things that are not real (hallucinations), especially in children.
- stimulation or wakefulness (especially at high doses, in children and the elderly).
- loose stools (diarrhoea), stomach pain (epigastric pain or distress).

Frequency not known:

- serious conditions affecting blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS).
- increased or decreased blood sugar levels.
- sleep disturbances, confusion, fear, irritability, psychotic states, euphoria, nervousness.

- involuntary repetitive movements of the mouth, face or body (facial dyskinesia, extrapyramidal effects), adverse mental effects (especially in children), convulsions (seizures), pins and needles (paraesthesia), shakiness (tremor), depression, or tingling, heaviness and weakness of the hands.
- blurred vision, double vision.
- ringing in the ears (tinnitus), hearing loss.
- impaired sense of smell, dryness of the throat, tightness of the chest.
- impaired sense of taste.
- loss of appetite, constipation, dryness of the mouth, excess saliva (hypersalivation).
- flatulence (passing wind), stomach pain, sores or blisters inside the mouth (ulcerative stomatitis), worsening of Crohn's disease (an inflammatory bowel disease), inflammation of the stomach (gastritis).
- sweating, hair loss.
- muscle pain.
- weakness, fatigue.

Stop using CORYX 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 changes in vision

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. 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 or to Cipla Medpro (Pty) Ltd by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free).

By reporting side effects, you can help provide more information on the safety of CORYX.

5. How to store CORYX

Store all medicines out of reach of children.

Store in the tube, tightly closed at or below 25 °C.

Protect from light and moisture.

Keep in the original container until ready for use.

Keep the container in the outer carton.

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

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 CORYX contains

The active substances in each effervescent tablet are:

Chlorpheniramine maleate	4 mg
Pseudoephedrine hydrochloride	50 mg
Aspirin	600 mg
Vitamin C (ascorbic acid)	330 mg

The other ingredients are adipic acid, aspartame, beta-carotene 1 % CWS, citric acid anhydrous, colloidal silicon dioxide, macrogol 6000, pineapple flavour 76136-31, sodium bicarbonate, sodium carbonate anhydrous.

CORYX effervescent tablets produce a light yellow solution with a pineapple flavour once dissolved in $\pm$ 200 mL of water (see **section 3**).

What CORYX looks like and contents of the pack

CORYX effervescent tablets are round, biplane, beige to light yellow-coloured effervescent tablets.

CORYX effervescent tablets are packed in an aluminium tube with a white plastic closure, packed in a printed carton box. Each tube contains 12 tablets. Each carton contains one tube (12's).

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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This leaflet was last revised

06 November 2024

Registration number

27/5.8/0435

Namibia: NS1 04/17.5.8/1514

Botswana: S3 BOT0801262

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