PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

CORENZA-C® effervescent tablet

Moroxydine HCl, Phenylephrine HCl, Chlorphenamine maleate, Acetylsalicylic acid (aspirin), Vitamin C (ascorbic acid)

Sugar free

Contains sweetener: Sodium saccharin 2,5 mg and mannitol 200 mg per tablet

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

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

- Keep this leaflet. You may need to read it again.
- Do not share CORENZA-C® 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.

Date of approval: 15 September 2023

PATIENT INFORMATION LEAFLET

What is in this leaflet

1. WHAT CORENZA-C® IS AND WHAT IT IS USED FOR:

CORENZA-C® forms part of the group of medicines for the common cold, including nasal decongestants and antihistamines.

CORENZA-C® provides relief from the symptoms of colds and flu, such as sneezing, stuffy or runny nose and inflammation of the throat and vocal cords.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CORENZA-C®:

Do not take CORENZA-C®:

- If you are hypersensitive (allergic) to moroxydine HCl, phenylephrine HCl, chlorphenamine maleate, acetylsalicylic acid (aspirin) or vitamin C (ascorbic acid), or any of the other ingredients of CORENZA-C® (listed in section 6).
- If you often suffer from indigestion, or stomach ulcers
- If you have kidney or liver dysfunction
- If you have haemophilia (a disease in which your blood does not clot) or any other bleeding

disorders.

- If you have hyperthyroidism (overactive thyroid), gout, diabetes mellitus, prostatic hyperplasia (prostate gland enlargement), high blood pressure, heart conditions, asthma, chronic urticaria (hives), chronic rhinitis (swelling and information inside of the nose),
- hypersensitivity to pseudoephedrine and other NSAIDs should be cautious.
- If you have heart failure
- If they have had a history of gastric holes, ulcers or bleeding related to previous anti-inflammatory medicines use.
- If the patient is a child under 12 years of age (see Warnings and Precautions).
- If you are pregnant, do not use NSAIDs (non-steroidal anti-inflammatory drugs) like acetylsalicylic acid (aspirin) in CORENZA-C® at 30 weeks or later in your pregnancy because these medicines may cause problems in your unborn baby.

Warnings and precautions

Special care should be taken with CORENZA-C®:

- A doctor should be consulted before giving CORENZA-C® to children due to the increased risk of Reye's syndrome (swelling of the brain and liver) associated with aspirin.
- If you have G6PD deficiency (abnormality in the activity of the red blood cell enzyme, as the active ingredient aspirin can cause haemolytic anaemia (low red blood cell count).
- If you are sensitive to pseudoephedrine hydrochloride.
- If you have connective tissue disorders or in (juvenile idiopathic arthritis) children with arthritis
- You should stop using CORENZA-C® several days before a scheduled surgery as aspirin lengthens bleeding time.
- Chronic use of aspirin in the elderly should be avoided due to the increased risk of gastric bleeding.
- Chlorphenamine maleate in CORENZA-C® may lead to drowsiness and impaired

concentration that may be worsened by simultaneous intake of alcohol or other central nervous system depressants (see section 4.7).

- If you have angle-closure glaucoma (an eye condition that leads to damage to the optic nerve due to increased pressure in eye), an inability to urinate, or an obstruction in the stomach.
- If you have phaeochromocytoma (a rare tumour of adrenal gland tissue).
- If you have a history of hypertension or heart failure
- When gastrointestinal bleeding or ulceration occurs in patients receiving CORENZA- C®, treatment with CORENZA-C® should be stopped.
- CORENZA-C® should be given with caution to patients with a history of gastrointestinal disease [e.g. ulcerative colitis (inflammation & ulcers in the digestive tract), Crohn's disease (type of inflammatory bowel disease), hiatus hernia (bulging of an organ), gastro-oesophageal reflux disease, angiodysplasia (vascular malformation)] as the condition may be worsened.
- If you have serious skin reactions. CORENZA-C® should be discontinued at the first appearance of skin rash
- May have a mild laxative effect.
- Tell your doctor or health care provider if you are pregnant or plan to become pregnant. Taking NSAIDs (like acetylsalicylic acid (aspirin) in CORENZA-C®) at around 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 30 weeks of your pregnancy, your health care provider may need to monitor the amount of fluid in your womb around your baby. You should not take NSAIDs (like acetylsalicylic acid (aspirin) in CORENZA-C®) around 30 weeks of pregnancy or later.

Other medicines and CORENZA-C®

Always tell your healthcare provider if you are taking any other medicine. (This includes all

complementary or traditional medicines.)

Tell your doctor if you are taking any of the following medicines:

- *Vitamin C* may increase the absorption of *iron* in patients who suffer from iron deficiency.
- *Chlorphenamine maleate* in CORENZA-C® may enhance the sedative effects (feeling sleepy) of *alcohol*, *barbiturates* (anxiety, anti-seizure or sleeping medicines), *hypnotics* (sleeping medicines), *opioid analgesics* (narcotic pain relievers), *anxiolytic sedatives* (anxiety or sleeping medicines) and *antipsychotics* when used together.
- May have additive effects with *atropine* (medicine used to slow the heart rate or to treat poisoning) and some *antidepressants*.
- May mask the signs of damage caused by ear sensitive drugs such as *aminoglycoside antibacterials*.
- Phenylephrine in CORENZA-C® may lead to very high blood pressure when used together with *Monoamine oxidase inhibitors* (medicine prescribed for the treatment of depression).
- If you are using any other NSAID (anti-inflammatory) medicine such as sodium diclofenac, ibuprofen etc. The simultaneous use can cause damage to your stomach.
- The risk of gastrointestinal bleeding also increases when *aspirin* is used together with *corticosteroids*.
- *Aspirin* in CORENZA-C® may increase the activity of the following medicine: *coumarin anticoagulants* (blood thinning medication such as warfarin), *sulfonylurea hypoglycaemic* drugs (used in the treatment of diabetes), *zarfilukast* (used in the treatment of asthma), *methotrexate* (used in cancer treatment), *phenytoin* and *valproate* (medicine for epilepsy).
- The effects of *probenecid* (used in the treatment of gout) may be decreased when used together with *aspirin.*
- Aspirin may change the efficacy of mifepristone (medicine used in abortion)
- *Griseofulvin* (antifungal medicine) might interfere with the absorption of *aspirin*.
- *Aspirin* may reduce the ability of *ACE inhibitors* to lower blood pressure.

CORENZA-C® and laboratory tests

- *Vitamin C* in CORENZA-C® may interfere with laboratory tests and can cause falsely elevated or false negative test results.

CORENZA-C® with food, drink and alcohol

CORENZA-C® should be taken with food to minimise gastric irritation (irritation of the stomach wall) (see section 3). CORENZA-C® should not be taken in combination with alcohol as it will increase side effects and make you feel sleepy (drowsy).

Pregnancy, breastfeeding and fertility

Taking NSAIDs (like acetylsalicylic acid (aspirin) in CORENZA-C®) at around 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs for more than 2 days when you are between 20 and 30 weeks of your pregnancy, your health care provider may need to monitor the amount of fluid in your womb around your baby. You should not take NSAIDs (like acetylsalicylic acid (aspirin) in CORENZA-C®) around 30 weeks of pregnancy or later. 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-C®.

Driving and using machines

CORENZA-C® may lead to drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants.
It is not always possible to predict to what extent CORENZA-C® 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-C® affects them.

3. How to take CORENZA-C®

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

Always take CORENZA-C® exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose is:

Adults: 2 tablets immediately, thereafter 1 tablet 3 to 4 times a day as required.

CORENZA C should not be used in children under the age 12 years.

Drop the tablet in half a glass of cold water. The tablet quickly dissolves producing an effervescent drink. Drink the mixture as soon as the effervescing has stopped

Always use the lowest effective dose.

Do not use for more than 10 days without consulting your doctor.

If you have the impression that the effect of CORENZA-C® is too strong or too weak, tell your doctor or pharmacist.

If you take more CORENZA-C® than you should:

You may experience nausea, dizziness, vomiting, mental clouding, stomach irritation and resultant indigestion, vomiting of blood and the passing of dark sticky faeces containing partly digested blood.

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

If you forget to use CORENZA-C®

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

4. POSSIBLE SIDE EFFECTS:

CORENZA-C® can have side effects.

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

If any of the following happens, stop taking CORENZA-C® and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- Rash or itching.
- Fainting.

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

Tell your doctor if you notice any of the following:

Frequent side effects:	**Less Frequent side effects:**
slight blood loss, anorexia (eating disorder), headache, CNS depression (slight drowsiness to deep sleep, fatigue, dizziness and inco-ordination), oedema (swelling), hypertension, cardiac failure, dyspnoea (shortness of breath), peptic ulcers, perforation or gastrointestinal bleeding, nausea, vomiting, diarrhoea, flatulence, constipation, indigestion, abdominal pain, melaena (dark, bloody stools), haematemesis (vomiting blood), ulcerative stomatitis (inflammation of the mouth), worsening of irritable bowel disease, inflammation of gastric tract, weakness.	Agranulocytosis (low white blood cell count), leukopenia (decreased white blood cell count), thrombocytopenia (decreased platelet count), pancytopenia (reduction in all blood cell count), aplastic anaemia (when the body stops producing new blood cells) and haemolytic anaemia (abnormal breakdown of red blood cells), epigastric pain, rashes.

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 “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of CORENZA-C®.

5. HOW TO STORE CORENZA-C®

Store all medicines out of reach of children.

Store in a cool place at or below 25 °C.

Protect from moisture.

Do not store in a bathroom.

Store in the original container.

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

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-C® contains

The active ingredients are:

Each tablet contains:	
Moroxydine hydrochloride	100 mg
Phenylephrine HCl	7,5 mg
Chlorphenamine maleate	2 mg
Acetylsalicylic acid (aspirin)	500 mg
Vitamin C (ascorbic acid)	500 mg

The other ingredients are citric acid anhydrous [E330], docusate sodium, mannitol, polyvidone 30 oral, purified water, sodium bicarbonate [E500], sodium carbonate anhydrous and sodium citrate [E331]

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What CORENZA-C® looks like and contents of the pack

White, effervescent tablet in aluminium tubes of 10 and 20 tablets.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Customer Care: 0860 ADCOCK / 232625

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15 September 2023

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C661 (Act 101/1965)

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