SCHEDULING STATUS: **S2**

LENBUCOD, 10 mg/ 200 mg/ 350 mg film-coated tablets

Codeine phosphate, ibuprofen and paracetamol

Sugar free

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

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

- Keep this leaflet. You may need to read it again.
- Do not share **LENBUCOD** 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 five days.

What is in this leaflet

1. What LENBUCOD is and what it is used for

LENBUCOD belongs to a group of medicines called analgesics which works by reducing pain. **LENBUCOD** is indicated for the relief of mild to moderate pain (caused by inflammation) with or without fever, for a maximum period of 5 days.

2. What you need to know before you take LENBUCOD

Do not take LENBUCOD:

- If you are hypersensitive (allergic) to paracetamol, ibuprofen, codeine phosphate or any of the other ingredients of **LENBUCOD** (listed in section 6).
- If you may have reacted to any other anti-inflammatory medicine (commonly known as NSAIDs) with sensitivity reactions like asthma, acute rhinitis (runny nose), angioedema (swelling) and urticaria (itchy skin rash).
- If you have had bleeding in the digestive tract (this can include blood in vomit, bleeding when emptying bowels, fresh blood in faeces or black, tarry faeces), perforation or the formation of ulcers in your digestive tract after you have taken other NSAIDs (e.g. aspirin, or other ibuprofen-containing medicines).
- If you have an active or a history of gastrointestinal (stomach or small intestine) ulcers, perforation or bleeding that repeatedly reoccurs.
- If you have any active bleeding (including bleeding in the brain).
- If you suffer from a condition of unknown origin resulting in abnormal formation of blood cells.
- If you have or previously have had medical problems with your kidney or liver (see section 2, Other medicines and **LENBUCOD**).
- If you have had any cardiovascular disease (you may have had chest pain, tightness, discomfort, or shortness of breath; pain, numbness, weakness or coldness in your legs or arms if the blood vessels in those parts of your body are narrowed).
- If you have had severe heart failure secondary to chronic lung disease (e.g. chronic obstructive pulmonary disease or pneumonitis).
- If you have breathing problems (such as bronchial asthma, uncontrolled asthma, an asthma attack or spasm of your airways).
- If you have polyps (abnormal tissue growth) on the lining of the nose or sinuses associated with aspirin-induced bronchospasm (difficulty breathing).

- If you have had an operation on the biliary tract (for example your liver, gall bladder or bile ducts).
- If you regularly drink large quantities of alcohol.
- If you have previously had head injuries, or if you have a condition in which the pressure in your skull has increased.
- If you have breathing problems, especially in the presence of cyanosis (a bluish colour of the skin, nails and around the eyes), and coughing up fluid or mucus from your lungs.
- If you are taking coumarin-type blood thinners, such as warfarin to prevent blood clots.
- If you are taking medicines to treat depression or bipolar disorder called monoamine oxidase inhibitors or have taken these medicines within the last 14 days (see section 2, Other medicines and **LENBUCOD**).
- If you are suffering from severe dehydration due to vomiting, diarrhoea or insufficient fluid intake.
- If you are in the third trimester of pregnancy (from 28 weeks onwards).
- If you are breastfeeding.
- If you/your child are under 12 years old.
- For pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome.

Warnings and precautions

Ibuprofen as in LENBUCOD

Take special care with **LENBUCOD**:

- If you have had gastrointestinal disease e.g. ulcerative colitis (inflammation and sores in your digestive tract), Crohn’s disease (inflammation of your digestive track), hiatus hernia (stomach pushing through an opening in the diaphragm), gastroesophageal reflux disease (stomach acid flows back into the food pipe), as **LENBUCOD** can cause these conditions to worsen.

- If you have high blood pressure.
- If you have a medical condition affecting your kidney or liver.
- If you have disturbances in the formation of blood cells.
- If you have blood thickening disorders or anaemia.
- If you suffer from allergies including hay fever, chronic rhinitis (inflammation of the inner lining of the nose for longer than 4 days), swelling of the sinuses or adenoids (glands located above the roof of the mouth, behind the nose).
- If you suffer from asthma or chronic obstructive disorders of the breathing airway.
- If you have had any recent major surgery.
- If you are an elderly person, you may have a higher possibility of abdominal side effects. The risk for complications (which can be life-threatening) such as bleeding, perforation or ulceration of the digestive tract is also higher in the elderly patients.
- If you have had history of gastrointestinal problems, especially if this has been complicated by perforation or accompanied by bleeding. You should report any unusual symptoms affecting your abdomen, especially if these symptoms occur at the start of therapy. If bleeding or ulceration of the digestive tract occurs, the treatment should be stopped.
- If you are using other anti-inflammatory medicines (NSAIDs), corticosteroids (e.g. prednisone), anti-platelet medicines (e.g. acetylsalicylic acid (aspirin)), selective serotonin reuptake inhibitors (antidepressants such as citalopram) or anticoagulants (warfarin or heparin), the risk of ulceration or bleeding is increased, and caution should be advised (see section 2, Other medicines and **LENBUCOD**).
- If you are currently taking low-dose aspirin for the prevention of heart attack or stroke, as you may experience more gastrointestinal adverse reactions.
- If you have high blood pressure or heart failure as **LENBUCOD** may cause water retention, which can result in heart failure.

- If you have a severe skin reaction, including blistering and peeling of the skin (e.g. Stevens-Johnson syndrome). Stop taking **LENBUCOD** at the first appearance of skin rash, or any other sign of hypersensitivity and go to your doctor or nearest hospital.
- If you have chickenpox (varicella virus infection), as you are more prone to develop skin and soft tissue infections.
- If you have impaired liver or kidney function.
- If you are elderly, taking medicines such as ACE inhibitors (e.g. enalapril) and diuretics (water tablets), history of liver or kidney dysfunction or heart failure, as it can provoke renal failure.
- If you have a history of asthma, as the use of **LENBUCOD** may worsen your asthma.
- If you have an infection, as **LENBUCOD** can hide symptoms such as fever and inflammation, which can affect the timely treatment of infection.
- If you suffer from systemic autoimmune disease e.g. Systemic Lupus Erythematosus (SLE), mixed connective tissue diseases or a similar condition.
- If you have porphyria (a disorder resulting from the build-up of certain chemicals related to red blood cell proteins),
- If you have a headache, stiff neck, nausea, vomiting, fever or disorientation, as the use of **LENBUCOD** may cause meningitis.
- If you experience hypersensitivity reactions, treatment must be stopped.
- Bronchospasm (constriction of the airways), angioedema (welts forming, swelling or redness) or urticaria (hives and itching) may be precipitated in patients with history of or are suffering from chronic rhinitis (inflammation of the inner lining of the nose for longer than four days),

  bronchial asthma, nasal polyps, sinusitis, adenoids (glands located above the roof of the mouth, behind the nose) or allergic diseases.
- Long-term use of **LENBUCOD** for headache can make them worse.

- Continuous use of analgesics (painkillers, such as **LENBUCOD**) may cause permanent damage to your kidneys.
- If you are consuming alcohol, **LENBUCOD** may increase the effect of alcohol on the central nervous system or increase the risk of gastrointestinal problems, eye symptoms, weight gain, fluid retention (accumulation of fluid in body tissues and cavities) or skin rash.
- Tell your doctor or health care provider if you are pregnant or plan to become pregnant. Taking NSAIDs, including ibuprofen as contained in **LENBUCOD**, 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 28 weeks of your pregnancy, your health care provider may need to monitor the amount of fluid in your womb around your baby.
- If you have a serious skin reaction known as Drug Reaction with Eosinophillia and Systemic Symptoms (DRESS), (life-threatening condition which may resemble a flu-like infection, other signs may include rash, facial swelling, abdominal pain and abnormal heartbeat).

Paracetamol as in LENBUCOD

This product contains paracetamol which may be fatal in overdose. 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.

Take special care with **LENBUCOD**:

- If you have liver or kidney problems or struggle with alcohol dependency, your doctor should monitor you more closely.

- If you take more paracetamol, as in **LENBUCOD**, you may cause severe damage to your liver. The risk for liver damage is especially high in alcoholics, and the consumption of alcohol should be avoided.
- 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 the patient experiences any signs of serious skin reactions such as swelling, itching, red severe rash, stop using **LENBUCOD** immediately and contact your doctor (see Section 4).

Codeine as in LENBUCOD

Take special care with **LENBUCOD**:

- *Tolerance dependence, and addiction:*

Increased risk of addiction in patients with personal or family history of substance abuse or mental health disorders.

LENBUCOD contains codeine, which is an opioid medicine.

Repeated use of LENBUCOD may result in you becoming accustomed to it (needing to take higher doses). Repeated use of LENBUCOD may also lead to dependence, abuse and addiction, which may result in life-threatening overdose.

If you are taking LENBUCOD for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

If you experience any of the following signs whilst taking LENBUCOD, talk to your doctor or pharmacist as it could be an indication that you are dependent or addicted.

- **You need to take this medicine for longer than advised**
- **You need to take more than the recommended dose**
- **You are using this medicine for reasons other than medical reasons, for instance, 'to stay calm' or to 'help you sleep'**
- **You have made repeated, unsuccessful attempts to quit or control the use of this medicine**
- **When you stop taking this medicine you feel unwell, and you feel better once taking this medicine again ('withdrawal effects')**

- *Opioid induced hyperalgesia*

  Taking opioid medications for too long can paradoxically induce or sensitise patients to acute pain. This condition is called opioid-induced hyperalgesia. The type of pain experienced might be the same as or different from the original underlying pain, and in some cases, patients may experience pain from ordinarily non-painful stimuli (allodynia).
- If you take more tablets than recommended or if you use the tablets for a longer period of time than recommended, it may lead to dependency and addiction.
- If you have acute abdominal (stomach) problems, as the use of **LENBUCOD** may mask the symptoms, making it difficult for your doctor to treat you.
- If you have asthma or lung diseases.
- If you have an irregular heartbeat or convulsion (seizures), as **LENBUCOD** can make this condition worse.
- If you have a history of or having alcohol or drug dependency, or have a history of alcohol or drug abuse. The consumption of alcohol together with **LENBUCOD** should be avoided.
- If you have gallbladder disease or gallstones, as this may cause spasms in the biliary tract.
- If you have had recent surgery of the digestive tract.

- If you have a decreased liver function.
- If you have kidney impairment (decreased kidney function), since the use of **LENBUCOD** may lead to urinary retention. This may lead to an increase in adverse effects, due to the accumulation of **LENBUCOD**.
- If you have an under active thyroid gland (a condition where the thyroid gland does not produce enough hormones), may cause difficulty breathing and problems with your central nervous system.
- If you have adrenocortical insufficiency (e.g. Addison's disease, a condition where your body doesn't produce certain hormones).
- If you have inflammatory or obstructive bowel disorders (such a chronic ulcerating colitis).
- If you have an enlarged prostate gland, obstruction or dysfunctions of the urinary tract or having recently undergone surgery, as urinary retention may be worsened.
- If you are in shock.
- If used with anti-diarrhoeal medicines (such as diphenoxylate) as there is a risk of severe constipation.
- If you have myasthenia gravis (a neuromuscular disorder).
- If you have pain and fever that get worse, if new symptoms appear or if redness or swelling is present, as these could be sign of a serious infection. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult your health care provider immediately.
- If you are an elderly patient or you are in a compromised medical state, your dosage should be reduced.

Children

LENBUCOD is contraindicated in children under 12 years of age.

Use in children with breathing problems:

Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

Other medicines and LENBUCOD:

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines).

Ibuprofen as in LENBUCOD

The combined use of:

- Anti-platelet medicine such as aspirin should be avoided, as its intended blood thinning effect may be lowered and may increase the risk of side effects.
- Non-steroidal anti-inflammatory medicine, including COX-2 inhibitors should be avoided, since the use of two or more anti-inflammatory medicines may cause an increase in stomach or bowel side effects (such as bleeding or ulcers).
- The combined use of anti-coagulants (blood thinning medicines), such as heparin or warfarin, and **LENBUCOD**, as the effect of the anti-coagulant may be enhanced.
- Methotrexate (used for some inflammatory diseases and some cancers) should be avoided since the toxicity of methotrexate may increase the risk of side effects.
- Corticosteroids such as prednisone and cortisone (medicines that lowers the inflammation response in the body) should be used with caution as the risk of gastrointestinal adverse reactions may increase (such as bleeding or ulceration).
- Selective serotonin reuptake inhibitors (SSRIs) (medicines used in the treatment of depression) and anti-platelet medicines (medicines that reduce the risk of forming blood clots), increases the risk of gastrointestinal bleeding and ulceration.
- Anti-hypertensives (medicines used to treat high blood pressure such as ACE inhibitors, beta-blockers, angiotensin-II receptor antagonists or diuretics (water tablets)) should be

used with caution if you have decreased kidney function since the effects of these medicines may lead to further kidney failure.

- The use of captopril with **LENBUCOD** counteracts the sodium excreting effect of captopril.
- Aminoglycoside antibiotics (used to treat bacterial infections), since **LENBUCOD** may decrease excretion of aminoglycosides, and increase their toxicity.
- Sulphonylureas (medicines used to treat diabetes) since the effect of sulphonylureas may be enhanced. Your blood glucose levels should be closely monitored.
- **LENBUCOD** may worsen cardiac failure, decrease the rate of filtration in the kidneys and increase the levels of cardiac glycosides e.g. digoxin, (medicines used to treat heart problems) in the plasma.
- The combined administration of **LENBUCOD** with digoxin, phenytoin (medicine used to treat epilepsy) or lithium (used to treat certain mental illnesses), as the level of these medicines may be increased.
- Ciclosporin or tacrolimus (medicines used to treat some inflammatory diseases and after transplants) and certain NSAIDs can lead to the risk of developing kidney toxicity and kidney damage. This effect cannot be ruled out for the combination of ciclosporin and ibuprofen, as in **LENBUCOD**, either.
- Cholestyramine, used in lowering your cholesterol levels and ibuprofen (as in **LENBUCOD**) causes a prolonged and reduced absorption of ibuprofen. You should take these medicines at least one hour apart.
- Mifepristone (a medicine used to end pregnancy), as **LENBUCOD** can reduce the intended effect of mifepristone, when used within an interval

  period of eight to twelve days after mifepristone administration.
- Probenecid or sulfinpyrazone (medicines used to treat gout), may cause a delay in the elimination of ibuprofen (as in **LENBUCOD**). The action of these medicines to reduce gout, may be decreased.

- Quinolone antibiotics (medicines used to treat infections) with **LENBUCOD**, may increase your chances of convulsions (seizures).
- Zidovudine (medicine used in HIV-infection), since toxicity may occur in the blood, bleeding in a joint may occur (also known as haemarthrosis) and the accumulation of blood outside of veins and arteries. Your health care professional should monitor your blood counts one to two weeks after starting combination therapy.
- Ritonavir (medicine used in HIV-infection) may increase the concentration of NSAIDs such as ibuprofen (as in **LENBUCOD**)
- Bone marrow depressants e.g. azathioprine - using **LENBUCOD** and these medicines may lead to reduction in blood platelets, which increases risk of bleeding or bruising, and reduction in the number of white blood cells which makes infections more likely.
- Alcohol, bisphosphonates (medicines used to treat osteoporosis) or oxypentifylline (medicines used to increase blood circulation), since the risk bleeding and ulceration is increased when used with **LENBUCOD**.
- Baclofen (medicine used to treat muscle spasticity - an abnormal increase in muscle tone or stiffness of muscle) should be used with caution since the risk for baclofen toxicity may be higher.
- Voriconazole and fluconazole (also known as CYP2C9 inhibitors) (medicines used for fungal infections), as the effect of **LENBUCOD** may increase. The dose of **LENBUCOD** should therefore be lowered.
- Gingko biloba (an herbal medicine) as there is a chance you may experience bleeding side effects more easily if you are taking this with **LENBUCOD**.

Paracetamol as in LENBUCOD

The concomitant use of:

- Liver enzyme-inducing or other medicines that can lead to liver damage, as there is an increased risk of liver toxicity, as well as a lowered effect of paracetamol.

- Metoclopramide (medicine used to treat nausea), since the way paracetamol (as in **LENBUCOD**) is absorbed in the body, may be altered.
- Cholestyramine (medicine used to lower your cholesterol levels), as the absorption of paracetamol (as in **LENBUCOD**) is reduced when given within one hour of cholestyramine.
- Probenecid (medicines used to treat gout), since the way **LENBUCOD** is eliminated by the body may be altered.

Codeine as in LENBUCOD

The concomitant use of:

- Monoamine oxidase inhibitors (usually used to treat depression or bipolar disorder), if you are using this medication or have used it within the last 14 days. Sometimes fatal reactions may occur.
- Alcohol or other central nervous system depressants (e.g. calming or tranquilizing medications, hypnotics, anaesthetics, sedatives and medicines known as phenothiazines) may lead to increased side effects such as drowsiness and impaired concentration, caused by codeine.
- Anticholinergics (atropine or antihistamines such as diphenhydramine), as it may cause severe constipation
- Medicines used to treat diarrhoea, as it may cause severe constipation and central nervous system depression.
- Blood pressure lowering medicines, since the effects of these medicines may be increased when used together with codeine as in **LENBUCOD**.

LENBUCOD with alcohol

Do not drink alcohol whilst taking this **LENBUCOD**. Alcohol may make you feel more drowsy, increase your risk of having a peptic ulcer and bleeding, and increase your risk of liver damage.

Pregnancy, breastfeeding and fertility

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 this medicine.

Pregnancy

You should not take **LENBUCOD** if you are already at 20 weeks or later in your pregnancy. Taking NSAIDS, including ibuprofen as contained in **LENBUCOD** at around 20 weeks of pregnancy or later may harm your unborn baby (see 'Warnings and precautions' above). **LENBUCOD** must not be taken at 20 weeks or later in your pregnancy since it may cause major heart, lung and kidney disorders in the unborn child (see 'Do not take **LENBUCOD**' above). If used at the end of pregnancy, it may cause bleeding tendencies in both mother and child and weaken the strength of uterine contractions delaying the onset of delivery.

Breastfeeding

You should not take **LENBUCOD** if you are breastfeeding your baby.

Breastfed infants of mothers taking codeine may be at an increased risk of toxicity from its metabolite morphine.

Fertility

LENBUCOD belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine.

Driving and using machines

LENBUCOD may cause dizziness, visual disturbances, drowsiness or loss of attention, which could have an influence on the ability to drive and to perform or execute tasks (see Possible side effects).

It is not always possible to predict to what extent **LENBUCOD** may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which **LENBUCOD** affects you.

3. How to take LENBUCOD

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

Always take **LENBUCOD** exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

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

DO NOT EXCEED THE RECOMMENDED DOSE.

The usual dose for adults and children over the age of 12 years is:

Take one to two (1 to 2) tablets six (6) hourly if necessary, and not more than six tablets within a twenty-four hours period.

Consult your health care provider if you require further treatment after five days.

LENBUCOD is contraindicated in children under 12 years of age.

If you take more LENBUCOD than you should

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

Immediate medical attention is critical. Even if you do not show symptoms of an overdose, immediately go to your nearest hospital or Poison Centre.

*Ibuprofen as in **LENBUCOD***

The most frequently reported symptoms of overdose include nausea,

abdominal pain, lethargy (state of sleepiness or deep unresponsiveness and inactivity), vomiting, blurred vision, drowsiness and other central nervous system (CNS) symptoms (such as headache, dizziness, ringing in the ears known as tinnitus, convulsion, and loss of consciousness). Other symptoms of an overdose may include nystagmus (involuntary rhythmic motion of the eyes), feeling or being cold, bleeding in the digestive tract bleeding, coma, apnoea (short periods of no breathing) and diarrhoea. Disorientation, excitation, fainting and cardiovascular toxicity, including low blood pressure, and slow or fast heartbeats have been reported. In cases of significant overdose, renal failure and liver damage are possible.

In more serious poisoning, toxicity is seen in the central nervous system, displaying as vertigo (having no balance or feeling that the world is spinning), dizziness, drowsiness, occasionally excitation and loss of consciousness or coma.

Your asthma may also be worsened.

LENBUCOD contains paracetamol and an overdose, can be fatal.

The symptoms of an overdose can include nausea, vomiting, anorexia and stomach pain.

You may show signs of liver damage only 12 to 48 hours, or later, after an overdosage. This may lead to coma or death. Kidney failure as well as metabolic acidosis (the buildup of acid in the body due to kidney disease or kidney failure) and heart rhythm problems may occur.

If you forget to take LENBUCOD

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

4. Possible side effects

LENBUCOD can have side effects.

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

If any of the following happens, stop taking **LENBUCOD** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, tongue and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Blisters on your skin or inside your mouth, nose, vagina or bottom, as these may be due to serious allergic reactions known as Stevens-Johnson Syndrome (SJS) or toxic epidermal necrolysis (TEN).
- Rapid heartbeat (also known was tachycardia), drop in blood pressure to a point of life-threatening shock.
- Mouth ulcers, cold sores and ulcers or soreness of your tongue.
- Skin lumps or hives (raised, red or white, itchy patches of skin).
- The appearance of a rash or sunburn when you have been outside (even on a cloudy day).

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

- Shortness of breath, chest pains or swelling (which may be a symptom of heart failure).
- Pain in the chest (also known as angina pectoris).
- Fast or irregular heartbeats.
- A blockage of blood flow to the heart muscle, also known as a heart attack (myocardial infarction).
- Difficulty breathing (respiratory depression) or a build-up of fluid in the lungs (known as pulmonary oedema).

- Bronchospasm (where your airways go into spasm making it difficult to breathe which may cause wheezing or coughing).
- Inflammatory lung disorder with symptoms of coughing and rapid, shallow breathing (alveolitis), as well as the infiltration of white blood cells into the lungs (known as pulmonary eosinophilia), causing a dry cough, fever, rapid breathing and shortness of breath.
- Stomach pain, indigestion, heartburn, wind, nausea (feeling sick), vomiting (being sick), diarrhoea or constipation and dry mouth.
- Bleeding in the stomach or intestine (gastrointestinal haemorrhage) e.g. black, tarry stools (melaena) or vomiting blood (haematemesis), or sometimes to a life-threatening extent and ulcers.
- Inflammation of the bowels or the worsening of inflammation of the colon (colitis) and digestive tract (Crohn's disease), as well as complications of diverticula of the large bowel (perforation or fistula), bloating and decreased appetite.
- Yellowing of skin or the whites of your eyes (jaundice or hepatitis).
- Kidney or liver failure.
- Aseptic meningitis (inflammation of the protective membranes covering the brain) with symptoms including stiff neck, headache, nausea, vomiting, fever or disorientation.
- Asthma attacks.
- Increased pressure inside your skull.
- A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).
- A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis).

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:

- Dizziness.
- Heartburn, indigestion, abdominal cramps and pain, nausea constipation, diarrhoea, vomiting and wind, decreased appetite.
- Skin rash, itchiness (known as pruritis).

Less frequent side effects:

- Inflammation of the nose (rhinitis).
- Changes in certain components of your blood that can include fever, sore throat, mouth ulcers, flu-like symptoms, fatigue nose and skin bleedings.
- Confusional state, nervousness, sleeplessness, depression, restlessness, anxiety, changes in mood, hallucination, feeling that the world is spinning.
- Drowsiness, headache, fatigue, agitation, irritability,
- Blurred vision and other eye reactions such as double vision.
- Ringing in the ears.
- Rhinitis (seasonal runny nose), and bronchospasm and respiratory depression (difficulty breathing).
- Abnormalities of liver function tests, inflammation of the liver, liver dysfunction.
- Photosensitivity reaction (a condition where your skin is extremely sensitive to sunlight) and other skin reactions.
- Impairment of kidney function, kidney pain and inflammation of the kidneys, and other changes to your normal kidney function.
- Changes in certain substances in your blood
- Inflammation of the pancreas.

- Feeling of extreme happiness.
- Changes in the way your heart beats.
- Feeling faint upon standing (orthostatic hypotension).
- Nausea, vomiting, constipation or dry mouth.
- Pain in your upper abdomen, caused by spasm of your gallbladder or -tube.
- Difficulties in passing urine, ureteric or biliary spasm.
- Drop in body temperature (hypothermia).
- Abdominal pain including risk of inflammation of pancreas, which causes severe pain in the abdomen and back.

Side effects of an unknown frequency:

- A decrease in the number of white blood cells (neutropenia).
- An abnormal sensation, typically tingling or pricking (‘pins and needles’) also known as paraesthesia.
- Changes in your eyesight.
- Changes in your hearing and a sensation that the world is spinning (vertigo).
- Swelling (oedema), high blood pressure and heart failure.
- Lung problems.
- Liver damage caused by a toxicity of your liver.
- Feeling unwell (malaise).
- It can also cause very low levels of potassium in your blood (see section 2)
- **LENBUCOD**, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis) (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

- Facial swelling, scaly flaky skin, a pink or red rash with or without pus-filled bumps ore blisters and ulcers or soreness of your tongue, Blisters on your skin or inside your mouth, swollen saliva glands. The appearance of a rash or sunburn when you have been outside (even on a cloudy day).
- Serious skin reactions such as swelling, itching, red severe rash especially those covering your whole body (appearing as allergic wheals), dry mouth, headache, seizures, fever and coma.
- Skin lumps or hives (raised, red or white, itchy patches of skin), burning and pain (Fixed drug eruptions).

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 (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **LENBUCOD**.

For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email Adcock.aereports@adcock.com.

5. How to store LENBUCOD

Store all medicines out of reach of children.

- Store at or below 25 ºC.
- 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 LENBUCOD contains

The active substances are codeine phosphate 10 mg, ibuprofen 200 mg and paracetamol 350 mg.

The other ingredients are:

Colloidal silicon dioxide, colour FD&C blue no. 1 aluminium lake, glycerol monocaprylocaprate, macrogol (PEG) polyvinyl alcohol graft copolymer, microcrystalline cellulose PH102, polyvinyl alcohol, pregelatinised starch, stearic acid, talc.

What LENBUCOD looks like and contents of the pack

LENBUCOD is a blue, oblong, double convex, film-coated tablet.

LENBUCOD (30 tablets) is packed in a white high-density polyethylene (HDPE) bottle, fitted with a white polypropylene (PP) closure which is sealed with a heat induction liner.

Holder of Certificate of Registration

Adcock Ingram Limited

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Customer Care: 0860 ADCOCK / 232625

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