1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

MYBUCOD 10 mg/200 mg/350 mg film-coated tablets

Codeine phosphate, ibuprofen, paracetamol

Sugar free

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

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

- Keep this leaflet. You may need to read it again.
- Do not share MYBUCOD with any other person.
- Ask your healthcare 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 MYBUCOD is and what it is used for

MYBUCOD contains codeine which belongs to a group of medicines called opioid analgesics. Analgesics help to relieve pain.

MYBUCOD contains ibuprofen which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs help in reducing swelling.

MYBUCOD contains paracetamol which belongs to a group of medicines called non-opioid analgesics, help to relieve pain.

MYBUCOD is indicated for the relief of mild to moderate pain or fever of inflammatory origin for a maximum treatment period of 5 days.

2. What you need to know before you take MYBUCOD

Do not take MYBUCOD:

- if you are hypersensitive (allergic) to codeine, ibuprofen or paracetamol or any of the other ingredients of MYBUCOD (listed in section 6).
- if you have difficulty breathing or breathing problems, acute asthma, uncontrolled asthma, head injuries or increased pressure inside the skull.
- if you have heart failure or heart disease.
- if you regularly drink large quantities of alcohol (acute alcoholism).
- if you are taking a medicine classified as a monoamine oxidase inhibitor (MAOI), or within 14 days of stopping such treatment.
- if you have diarrhoea associated with pseudomembranous colitis.
- if you have liver or kidney problems.
- if you have had a history of stomach (gastrointestinal) perforation, ulceration or bleeding in the stomach or small intestine (duodenum)

(PUBs) related to previous use of medicines for pain and inflammation such as non-steroidal anti-inflammatory medicines (NSAIDs).

- if you have or have had an ulcer, bleed or perforation in the stomach.
- if you are allergic to aspirin or other non-steroidal anti-inflammatory medicines.
- during an asthma attack, while you are having difficulty breathing or if you have heart failure secondary to chronic lung disease.
- if you have painless growths on the inside of your nose (nasal polyps), associated with aspirin-induced bronchospasm.
- if you have bleeding disorders.
- if you are taking coumarin anticoagulants (blood-thinning medicine) like warfarin.
- if you are pregnant, do not use NSAIDs, including MYBUCOD at 30 weeks or later in your pregnancy because these medicines may cause problems in your unborn baby.
- if you are breastfeeding, as safety while breastfeeding has not been established.

Warnings and precautions

MYBUCOD should not be taken for longer than 5 days.

MYBUCOD 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 MYBUCOD:

- if more than the recommended dosage is taken, this medicine may cause severe liver damage.
- if you use more than what you should or for longer periods, this may lead to dependence and addiction, increased risk of liver toxicity (especially in alcoholics), kidney problems, low potassium levels, stomach ulcers, stomach perforations and severe anaemia (less red blood cells in your blood).
- if you have acute abdominal (stomach) conditions.
- if you have an irregular heartbeat, as this may be induced or exacerbated.
- if you have had convulsions or history thereof, as this may be induced or exacerbated.
- if you are consuming alcohol or taking other sedatives, MYBUCOD may potentiate the effect of alcohol and other sedatives.
- if you have gallbladder disease or gallstones, as this may cause biliary tract spasm.
- if you have had recent gastrointestinal tract surgery.
- if you have hypothyroidism (a condition where the thyroid gland does not produce sufficient thyroid hormone).
- if you have adrenocortical insufficiency (a condition in which the adrenal glands, located above the kidneys, do not produce adequate amounts of steroid hormones).
- if you have inflammatory or obstructive bowel disorders.
- if you have an enlarged prostate or have had recent urinary tract surgery.
- if you are taking antidiarrhoeal medicine as this can lead to severe constipation.

- if you have myasthenia gravis (an auto immune disease that causes severe muscle weakness).
- if you have high blood pressure.
- if you are an elderly patient. The elderly have an increased frequency of adverse reactions to NSAIDs, such as MYBUCOD, especially gastrointestinal bleeding and perforation, which may be fatal. The risk of gastrointestinal bleeding or perforation is higher with increasing doses of MYBUCOD in patients with a history of ulcers, and in the elderly. If gastrointestinal bleeding or ulceration occurs when you are taking MYBUCOD, treatment with MYBUCOD should be stopped
- if you have serious skin reactions, which may include shedding of scaly dead skin, extremely serious allergic skin reactions, fever, facial swelling and blisters. MYBUCOD can cause Drug Rash with Eosinophilia and Systemic Symptoms (DRESS), toxic epidermal necrolysis (TEN), Steven-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), Drug induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE). MYBUCOD should be discontinued immediately at the first appearance of skin rash, fever, mucosal lesions, or any other sign of hypersensitivity. You should also contact your doctor as soon as possible.
- if you have asthma, it may be worsened with MYBUCOD.
- if you suffer from systemic lupus erythematosus SLE (a systemic autoimmune disease), mixed connective tissue diseases or a similar condition.
- if you have a stiff neck, headache, nausea, vomiting, fever or disorientation, as these may be symptoms of meningitis.

- if you are taking MYBUCOD for pain, including arthritic pain, and the pain persists for longer than 5 days, or if taking for fever and the fever persists for longer than 3 days, or if the condition deteriorates or new symptoms develop, a healthcare provider needs to be contacted as additional treatment may be necessary.
- if you have an infection, as MYBUCOD can hide symptoms such as fever and inflammation, which can result in not treating the inflammation effectively.
- if you are diabetic, you may experience a false result with blood glucose tests.
- if you have anaemia (less red blood cells) or other blood disorders.
- if you are pregnant or plan to become pregnant. Taking NSAIDs 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 healthcare provider may need to monitor the amount of fluid in your womb around your baby. You should not take NSAIDs around 30 weeks of pregnancy or later.
- if you will be having surgery you may experience excessive bleeding.
- if you have allergies, hay fever, long term swelling inside the nose, adenoids and lung disease.

Children

Do not give MYBUCOD to children 12 years of age and younger.

Other medicines and MYBUCOD

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

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

- Non-steroidal anti-inflammatory medicines (NSAIDs) used for pain and swelling (including aspirin and COX-2 inhibitors): the use of two or more NSAIDs concomitantly could result in an increase in side effects.
- Monoamine oxidase inhibitors (MAOIs), medicine used to treat depression: sometimes fatal reactions may occur in patients taking MAOIs, and also within 14 days of stopping such treatment.
- Blood thinners such as anticoagulants (e.g. heparin and warfarin) and antiplatelet medicines (e.g. clopidogrel, ticlopidine and aspirin), as these may increase the risk of stomach (GI) bleeding.
- Methotrexate (used for some inflammatory diseases and some cancers). There may be an increase in the plasma concentration of methotrexate and thus an increased risk of methotrexate toxicity.
- Oral corticosteroids (an anti-inflammatory medicine) since the risk of gastrointestinal bleeding and ulceration is increased.
- Selective serotonin reuptake inhibitors (SSRIs) used to treat depression, may increase the risk of gastrointestinal bleeding.
- Cardiac glycosides (for example digoxin), used to treat heart problems, as MYBUCOD may increase plasma concentrations of digoxin.
- Ciclosporin or tacrolimus (medicines used to treat some inflammatory diseases and after transplants) since the risk of toxicity of the kidney may be increased.
- Mifepristone (a medicine used to end pregnancy) since MYBUCOD can reduce the effect of mifepristone.

- Central nervous system depressants such as anaesthetics, hypnotics and sedatives.
- Anticholinergics, such as atropine, as there is an increased risk of severe constipation.
- Medicines used to treat diarrhoea (e.g diphenoxylate) may increase the risk of severe constipation.
- Medicines for high blood pressure such as beta blockers, ACE inhibitors (e.g captopril) and diuretics as MYBUCOD may decrease the effects of these medicines.
- The effect of other blood pressure lowering medicines could be increased with MYBUCOD.
- Enzyme-inducing and hepatotoxic (liver toxic) medicines: together with MYBUCOD it may increase the risk of liver toxicity and decrease the effect of MYBUCOD.
- Metoclopramide (anti-nausea medicine) as it my increase MYBUCOD'S absorption in the body.
- Probenecid and sulfinpyrazone (used to treat gout) may have a decreased effect when used with MYBUCOD and may affect MYBUCOD excretion from the body.
- Colestyramine (used to decrease cholesterol levels in your blood) may affect MYBUCOD'S absorption.
- Bisphosphonates (medicines used to treat osteoporosis), since the risk of gastrointestinal bleeding and ulceration is increased.
- Oxpentifylline (medicines used to increase blood circulation) since the risk of gastrointestinal bleeding and ulceration is increased.

- Antidiabetic medicines taken with MYBUCOD may increase the hypoglycaemic effects.
- Lithium (used for psychiatric disorders) and phenytoin (used for epilepsy) can worsen heart failure and affect the kidneys if taken with MYBUCOD.
- Quinolone antibiotics (used for infections), as convulsions (seizures) may occur.
- Aminoglycoside antibiotics (used for infections) as use with MYBUCOD may increase aminoglycoside toxicity.
- Zidovudine or ritonavir (medicine used to treat HIV-infection) since an increased risk of blood toxicity exists when used with MYBUCOD.
- Bone marrow depressants (medicines that decrease the amount of blood cells produced by your bone marrow): The leucopenic (decreased white blood cells) and/or thrombocytopenic (decreased platelets) effects of these medicines may be increased.
- Baclofen (muscle relaxant) toxicity may be increased.
- Voriconazole, fluconazole (anti-fungal medicines) and other medicines that work on the same pathway (CYP2C9) may require MYBUCOD's dose to be reduced when taken together.
- Herbal extracts like ginkgo biloba may increase the risk of bleeding with MYBUCOD.

MYBUCOD with alcohol

Do not drink alcohol whilst taking this MYBUCOD. Alcohol may make you feel drowsier, 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 healthcare provider for advice before taking this medicine.

Pregnancy

You should not take MYBUCOD if you are pregnant.

If you take MYBUCOD when you are 30 weeks pregnant or later, it may affect your unborn baby (see section 'Do not take MYBUCOD').

Breastfeeding

You should not take MYBUCOD when you are breastfeeding your baby.

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

Fertility

MYBUCOD belongs to a group of medicines (NSAIDs) which may make it more difficult to become pregnant. This effect is reversible on stopping the medicine.

Driving and using machines

MYBUCOD may cause drowsiness, dizziness and visual disturbances which may affect your ability to perform skilled tasks; if you are affected, you should not drive or operate machinery.

It is not always possible to predict to what extent MYBUCOD may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which MYBUCOD affects you (see section 4).

3. How to take MYBUCOD

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

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

Adults (over the age of 12 years)

The usual dose of MYBUCOD is one to two tablets every four hours.

Do not take more than 6 tablets in a 24 hour period.

Consult your healthcare provider if you require further treatment after 5 days.

MYBUCOD is not recommended for children 12 years of age and younger.

Start with the lowest effective dose for the shortest possible time.

Exceeding the prescribed dose, together with prolonged and continuous use of MYBUCOD, may lead to dependency and addiction.

DO NOT EXCEED THE RECOMMENDED DOSAGE

If you take more MYBUCOD than you should

MYBUCOD contains paracetamol, which may be fatal in overdose. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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

The symptoms can include nausea, stomach pain, vomiting, or severe diarrhoea. In addition to these symptoms, drowsiness, tiredness, excitation,

disorientation headache, gastrointestinal bleeding, acute renal failure, convulsions, coma, blurred vision, shaky eye movement and breathing problems have been reported.

If you forget to take MYBUCOD

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

If you have missed a dose of MYBUCOD, take the dose that you have missed as soon as you remember.

4. Possible side effects

MYBUCOD can have side effects.

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

If any of the following happens, stop taking MYBUCOD 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,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Drug Rash with Eosinophilia and Systemic Symptoms (DRESS), Acute Generalised Exanthematous

Pustulosis (AGEP), Drug induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE).

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

- Stomach pain, indigestion, heartburn, wind, nausea (feeling sick), or vomiting (being sick) as you may be experiencing inflammation in your bowel, colon (colitis), or digestive tract (Crohn's disease), or complications of the large bowel (perforation or fistula),
- stomach (peptic) ulceration, perforation or any sign of bleeding in the stomach or intestine (gastrointestinal haemorrhage), such as, black, tarry stools when emptying your bowels (melaena) or vomiting blood (haematemesis), which may be fatal,
- renal tubular acidosis marked by confusion or decreased alertness, fatigue, muscle cramps and weakness,
- impairment of kidney function, kidney failure, a type of damage to the kidneys that can lead to further complications (papillary necrosis) and kidney disease involving inflammation (nephritic syndrome),
- liver damage (dark coloured urine, light coloured bowel movements, yellow skin and eyes and loss of appetite),
- pain or tenderness in the abdomen, fever or chills and shortness of breath as these may be signs of pancreatitis,

- heart failure, chest pain, low blood pressure, irregular heartbeat, or abnormal heart rhythm; symptoms include palpitations, dizziness, fainting, shortness of breath and chest discomfort,
- severe fall in blood pressure or life-threatening shock,
- breathing disorders such as slow, ineffective or difficulty breathing which may cause wheezing or coughing, asthma attacks,
- inflammatory lung disorder with symptoms of coughing and rapid, shallow breathing which may develop even with moderate exercise (alveolitis),
- sudden filling of your lungs with water, resulting in difficulty to breathe, high blood pressure, water retention and weight gain,
- blood disorders such as decrease in white blood cells (leucopoenia), decrease in red blood cells (anaemia) and a decrease in most blood cells (pancytopenia). The first symptoms may include fever, sore throat, surface mouth ulcers, flu-like symptoms, severe tiredness, nasal and skin bleeding or unexplained bruising.
- an increase in a certain type of white blood cell in the lung disrupting normal air spaces (pulmonary eosinophilia),
- brain injury or increasing pressure inside your skull (intracranial pressure),
- aseptic meningitis (serous inflammation of the linings of the brain with headache and fever),
- low blood pressure, tiredness, muscle cramps as you may be experiencing hypokalaemia,
- high blood pressure (hypertension),
- drop in body temperature (hypothermia),

- seeing or hearing things that are not real (hallucinations).

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, stomach cramps and pain, nausea, constipation, diarrhoea, vomiting and wind.

Less frequent side effects:

- worsening of asthma and increased breathing difficulties,
- rhinitis (swelling and inflammation of the mucous membrane inside the nose),
- depression, nervousness, drowsiness, headache, sleeplessness (insomnia), anxiety, tiredness, agitation, irritability
- confusion, sensation of spinning (vertigo), restlessness, changes in mood, feeling excited (euphoria),
- blurred or double vision, miosis (decrease in pupil size), other ocular (eye) reactions and ringing in the ears (tinnitus),
- kidney pain, pus in urine (sterile pyuria), fluid retention (oedema),
- sweating, facial flushing,
- difficulties in passing urine, ureteric or biliary spasm,
- increased sensitivity to sunlight (photosensitivity),
- cough suppression,
- dry mouth, bloating,
- inflammation of the lining of the stomach (gastritis) which may cause nausea, vomiting, stomach pain and loss of appetite,

- narrowing of the intestines (intestinal strictures) which causes stomach pain and cramps, vomiting, inability to pass gas and constipation,
- inflammation of the oesophagus (oesophagitis) which may cause pain and difficulty swallowing and chest pain when eating,
- increase of blood urea nitrogen, serum transaminases and alkaline phosphatase, which will be shown by laboratory tests,
- decrease in haemoglobin and haematocrit values, inhibition of platelet aggregation and prolonged bleeding time, decrease of serum calcium and increase in serum uric acid values, which will be shown by laboratory tests.

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, pharmacist or nurse. You can also report side effects to

SAHPRA: via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27 (0)11 239-6200

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

5. How to store MYBUCOD

Store all medicines out of reach of children.

Store at or below 25 °C in airtight containers.

Protect from light.

Keep in original packaging until required for use.

Do not store in a bathroom.

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 MYBUCOD contains

The active substances are 10 mg Codeine phosphate, 200 mg Ibuprofen and 350 mg Paracetamol.

The other ingredients are brilliant blue (C.I. 42090), magnesium stearate, methocel, microcrystalline cellulose, polyvinylpyrrolidone povidone, pregelatinised starch, purified talc.

Sugar free

What MYBUCOD looks like and contents of the pack

MYBUCOD is a blue, capsule-shaped, film-coated tablet with a break score on one side.

30 tablets are packed into a white, round, polypropylene container and sealed with a tamper evident, round, burnt-orange low density polyethylene cap, together with a leaflet and silica gel sachet.

Holder of Certificate of Registration

PHARMACARE LIMITED

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This leaflet was last revised in

26 January 2024

Registration number

36/2.8/0379

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information

Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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