1.3.2.1 Patient Information Leaflet

SCHEDULING STATUS

S2

IBUCOD 10 mg/200 mg tablets

Codeine phosphate, Ibuprofen

Sugar free

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

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

- Keep this leaflet. You may need to read it again.
- Do not share IBUCOD 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 5 days.

What is in this leaflet

1. What IBUCOD is and what it is used for
2. What you need to know before you take IBUCOD
3. How to take IBUCOD
4. Possible side effects
5. How to store IBUCOD
6. Contents of the pack and other information

1. What IBUCOD is and what it is used for

IBUCOD contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain.

IBUCOD also contains ibuprofen. Ibuprofen, a non-steroidal anti-inflammatory medicine (NSAID), also acts to reduce swelling (inflammation).

IBUCOD is used for short term relief of mild to moderate pain and fever of inflammatory origin in adults and children 12 years and older, for a maximum treatment period of 5 days.

2. What you need to know before you take IBUCOD

Do not take IBUCOD:

- If you are hypersensitive (allergic) to ibuprofen, codeine phosphate or any of the other ingredients of IBUCOD (listed in section 6).
- If you have had a history of gastrointestinal (affecting the stomach and intestines) 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 liver or kidney problems.
- If you are hypersensitive to aspirin or other non-steroidal anti-inflammatory medicines (nsaids).
- If you have uncontrolled asthma or bronchospasm (constriction of air passages) and/or acute (sudden or severe) respiratory depression (abnormally slow and/or shallow breathing) in the presence of cyanosis (bluish discolouration of skin due to lack of oxygen) and excessive bronchial secretion (mucous released by the lungs).

- If you have or have had cardiovascular (heart and blood vessels) disease, heart failure, which may or may not be secondary to chronic lung disease.
- If you have nasal polyps (abnormal growth of tissue) associated with aspirin-induced bronchospasm (constriction of air passages).
- If you are receiving warfarin.
- If you are using monoamine oxidase inhibitors (maois) (medicines prescribed for the treatment of depression), or within 14 days of stopping such treatment.
- If you have diarrhoea associated with pseudomembranous colitis (severe inflammation of the colon).
- If you suffer from alcoholism.
- If you have a head injury with raised intracranial pressure (the pressure inside the skull and brain tissue) or intracranial lesions (tumours or abscesses in your skull).
- If you are pregnant or breastfeeding.

Warnings and precautions

Take special care with IBUCOD:

- if you have hypertension (high blood pressure).
- if you have pre-existing disorders of blood clotting or anaemia (decreased number of red blood cells which can make the skin pale and cause weakness or breathlessness).
- if you suffer from allergies, hay fever, chronic swelling of nasal mucosa, sinuses, adenoids, respiratory impairment, or chronic obstructive disorders of the respiratory tract. The risk for developing narrowing of the airways with difficulty in breathing (bronchospasm) is greater.
- if you have had recent gastrointestinal (stomach or intestines), or urinary tract surgery due to an enlarged prostrate or any other major surgeries.

- if you are an elderly patient. The elderly have an increased frequency of adverse reactions to NSAIDs, such as IBUCOD, especially gastrointestinal bleeding and perforation, which may be fatal. The risk of gastrointestinal bleeding or perforation is higher with increasing doses of IBUCOD, in patients with a history of ulcers, and in the elderly. If gastrointestinal bleeding or ulceration occurs when you are taking IBUCOD, treatment with IBUCOD should be stopped.
- if you have a history of stomach disease e.g. ulcerative colitis (inflammation of the colon), Crohn's disease (chronic inflammatory disease of the large and small intestine and/or other parts of the digestive tract), hiatus hernia (where the upper part of the stomach protrudes up into the diaphragm), gastro-oesophageal reflux disease, angiodysplasia (swollen blood vessels in the colon that may bleed) as the condition may become more severe.
- if you are a smoker, or have diabetes
- if you have serious skin reactions, some of them fatal, including exfoliative dermatitis (shedding of scaly dead skin), Stevens-Johnson syndrome (blistering of the skin, mouth, eyes and genitals), toxic epidermal necrolysis (serious illness with blistering of the skin) and Drug Rash with Eosinophilia and Systemic Symptoms and (DRESS) have been reported. IBUCOD should be discontinued at the first appearance of skin rash, mucosal lesions (abnormal tissue growths) or any other sign of allergy. You should also contact your doctor as soon as possible.
- if you suffer from SLE (a systemic autoimmune disease) 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 experience blurred or diminished (less or reduced) vision, or changes in colour vision.

- if your treatment is prolonged your doctor should do regular blood counts and monitor your liver and kidney function. Depending on the results, your doctor may decide to stop your treatment.
- non-steroidal anti-inflammatory medicines, including IBUCOD, should be used with caution in patients with infections since symptoms such as fever and inflammation may be masked.
- if you are consuming alcohol or taking other sedatives, IBUCOD may potentiate the effect of the alcohol or other sedatives.
- if you have acute, sudden or severe abdominal(stomach) conditions.
- if you have irregular heartbeat (symptoms may be palpitations, dizziness, fainting, shortness of breath and chest discomfort) as this condition may become more severe.
- if you have convulsions (fits or seizures) or history thereof as this condition may become more severe.
- if you take more than the prescribed dose, together with prolonged use of IBUCOD, you may become dependent and addicted which may result in life-threatening overdose. IBUCOD contains codeine, which is an opioid medicine. Repeated use of IBUCOD may result in you becoming accustomed to it (needing to take higher doses). If you are taking IBUCOD for longer than the recommended time or at higher than recommended doses you are at risk of serious harm. These include serious harm 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 IBUCOD, talk to your doctor or pharmacist as it could be an indication that you are dependent or addicted:
    - If you need to take this medicine for longer than advised.
    - If you are using this medicine for reasons other than medical reasons, for instance, ‘to stay calm’ or to ‘help you sleep’.

- If you or a relative have been told by a doctor that you have mental health disorders as these may cause you to become addicted to this medicine.
- If you have made repeated, unsuccessful attempts to quit or control the use of this medicine.

- if you have gallbladder disease or gallstones, as this may cause biliary tract spasm (blockage of the bile ducts which may cause symptoms such as abdominal pain, nausea and vomiting).
- if you have hypothyroidism (an underactive thyroid).
- if you have adrenocortical insufficiency (your adrenal gland does not produce adequate steroid hormones; symptoms may include weight gain, depression and/or tiredness).
- if you have inflammatory or obstructive bowel disorders.
- if used with anti-diarrhoeal medicines (such as diphenoxylate) as there is a risk of severe constipation.
- if the pain or fever persists or gets worse, consult a doctor.
- if you feel that you are experiencing even more pain (hyperalgesia) or an increased sensitivity to pain (allodynia). You will need to inform your doctor.
- if you suffer from myasthenia gravis (an autoimmune neuromuscular disease that results in muscle weakness).
- if you plan to become pregnant. Taking NSAIDs such as ibuprofen as in IBUCOD, may make it difficult to fall pregnant.

Children

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

Other medicines and IBUCOD

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), including aspirin and COX-2 inhibitors, since the use of two or more NSAIDs concomitantly could result in an increase in side effects.
- Anti-platelet and anticoagulants (blood thinning tablets), such as aspirin, heparin or warfarin.
- Methotrexate, medicines for the treatment of some inflammatory diseases and some cancers.
- Oral corticosteroids (medicine to reduce inflammation, pain and fever) since the risk of gastrointestinal bleeding and ulceration is increased.
- Medicines known as MAOIs and SSRIs used to treat depression. Sometimes fatal reactions may occur in patients taking MAOIs and also within 14 days of stopping such treatment (see “Do not take”).
- Medicines to treat high blood pressure (anti-hypertensives), heart rhythm disorders (beta blockers) and those that help to reduce the amount of water in the body (diuretics).
- Aminoglycoside and quinolone antibiotics (medicines that fight infections).
- Medicines to treat diabetes (sulphonylurea); the hypoglycaemic effects (abnormally low amounts of sugar in the blood) of these medicines may be enhanced.
- Digoxin, used to treat heart problems, as the level of digoxin may be increased.
- Lithium (used to treat some mental problems).

- Medicines used to treat epilepsy (convulsions), such as phenytoin since the effect of phenytoin may be enhanced.
- Ciclosporin or tacrolimus (immunosuppressive medication used after organ transplants).
- Colestyramine, used in reducing cholesterol levels in your blood.
- Mifepristone, a medication used in abortion.
- Probenecid or sulfinpyrazone (used to treat gout) since the excretion of IBUCOD may be delayed.
- Zidovudine or ritonavir, medications used in the treatment of HIV.
- Alcohol, bisphosphonates (medicines for the treatment of osteoporosis), and oxypentifylline (used in conditions where blood vessels are hardened and narrowed.) increase the risk of gastrointestinal perforation, ulceration and bleeding (PUBs), when used with IBUCOD.
- Baclofen (a muscle relaxant), because of elevated baclofen toxicity.
- Voriconazole and fluconazole (CYP2C9 inhibitors) (used for fungal infections), since the effect of IBUCOD may increase.
- Gingko biloba (a herbal medicine) as there is a chance you may bleed more easily if you are taking this with IBUCOD.
- Bone marrow depressants (medicines that may result in a decrease in the number of blood cells that are responsible for protecting the body against infection).
- Investigations reveal that IBUCOD may interfere with thyroid function tests.
- Medicines that slow down brain activity and are used for treating anxiety, muscle tension, pain, insomnia (sleeplessness), severe or sudden stress reactions, panic attacks and seizure disorders, referred to as central nervous system depressants.
- Anticholinergic or antimuscarinics medicines used to treat a variety of conditions such as diarrhoea.

- Cimetidine and other medicines which influence metabolism by the liver, as they can enhance the effects of IBUCOD.
- Neuromuscular blocking agents (used during anaesthesia) as increased respiratory depression can occur.
- Anti-dysrhythmics (e.g. mexiletine, quinidine), as codeine, as contained in IBUCOD, delays the absorption of mexiletine. The pain-relieving activity of codeine, as contained in IBUCOD, is likely to be significantly impaired by quinidine which impairs the breakdown of codeine.
- Naloxone and naltrexone (used in addictions and overdose) works against/blocks the effects of codeine, as contained in IBUCOD.
- Interference with laboratory tests: Opioids may interfere with gastric emptying studies.
- Metoclopramide and domperidone (anti-nausea medicine) as it may increase IBUCOD's absorption in the body. IBUCOD can also prevent metoclopramide, cisapride and domperidone from working properly.

IBUCOD with food and alcohol

Do not drink alcohol when taking IBUCOD as the risk of gastrointestinal bleeding and ulceration is increased.

IBUCOD should be taken preferably with or after food.

Pregnancy, breastfeeding and fertility

You should not take IBUCOD if you are pregnant or breastfeeding your baby.

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.

Fertility

IBUCOD 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

IBUCOD may cause drowsiness, dizziness, fatigue 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 IBUCOD 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 IBUCOD affects you (see section 4).

3. How to take IBUCOD

Always take IBUCOD 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.

Adults (over the age of 12 years)

The usual dose of IBUCOD is one to two tablets three times a day if necessary.

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

IBUCOD should be taken preferably with or after food.

IBUCOD is not recommended for children under 12 years of age.

Do not use for longer than 5 days.

If you have the impression that the effect of IBUCOD is too strong or too weak, talk to your doctor or pharmacist.

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

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

DO NOT EXCEED THE RECOMMENDED DOSAGE.

If you take more IBUCOD than you should

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

If you forget to take IBUCOD

Take your missed dose as soon as you remember, if you are within a few hours after missing a dose.

If you only remember about the missed dose the following day, do not take a double dose to make up for the forgotten dose.

4. Possible side effects

IBUCOD can have side effects.

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

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

- Swelling of your hands, feet, ankles, face, lips, 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) or Acute Generalised Exanthematous Pustulosis (AGEP).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to. 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),
- leucopenia, neutropenia, and/or agranulocytosis (abnormally low number of white blood cells which means you have a high risk of infection from bacteria),
- thrombocytopenia (low blood platelet levels that may result in some bruising, particularly the appearance of red or purple discolouration on the forearms, pinpoint haemorrhages on the skin, nosebleeds and/or bleeding gums),

- decreased number of red blood cells which can make the skin pale and cause general weakness or breathlessness (anaemia),
- stomach (peptic) ulceration, perforation, or any sign of bleeding (PUBs) in the stomach or intestine (gastrointestinal haemorrhage) such as black, tarry stools when emptying your bowels (melaena), vomiting blood (haematemesis), which may be fatal,
- yellowing of the skin or the whites of your eyes (jaundice), dark urine and pale or clay-coloured stools, fatigue (hepatitis),
- an unexpected change in the amount of urine passed, its frequency and/or its appearance, or difficulty in passing urine, blood in the urine,
- kidney failure or liver failure,
- kidney disease which affects the ability of the kidney to remove acids properly from your blood into your urine (renal tubular acidosis). This may also cause you to feel light-headed or have weakness of your muscles,
- very low levels of potassium in your blood (hypokalaemia),
- heart (cardiac) failure, chest pain, low blood pressure, irregular heartbeat, slow heart rate, or abnormal heart rhythm, with symptoms including, palpitations, dizziness, fainting, wheezing or shortness of breath (bronchospasm) and chest discomfort, and fluid retention (swelling),
- aseptic meningitis with symptoms of stiff neck, headache, nausea, vomiting (being sick), fever or disorientation and seizures,
- severe fall in blood pressure, loss of consciousness,
- inflammation of the pancreas with symptoms of nausea, vomiting and stomach pain.

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:

- Nausea (feeling sick), stomach (abdominal) cramps, constipation, dry mouth, pain; addiction and feeling that the medicine is no longer working.

Less frequent side effects:

- Swelling and inflammation of the mucous members in the nose, which may cause a stuffy or runny nose (rhinitis),
- nervousness, sleeplessness; confusion, mood changes,
- ringing in the ears, drowsiness, headache,
- hypertension (high blood pressure,
- indigestion, bloating, constipation, diarrhoea, decreased appetite,
- interstitial nephritis (inflammation in the kidneys),
- miosis (the pupil of the eye constricts and affects the amount of light that the pupil receives), blurred vision, changes in colour vision,
- biliary tract spasm (blockage of the bile ducts which may cause symptoms such as abdominal pain, nausea and vomiting),
- fever, disorientation or vomiting (being sick), sweating, facial flushing, decrease in body temperature.

Side effects with an unknown frequency:

- Impaired hearing, spinning (vertigo),
- depression, anxiety, hallucination,
- eosinophilia (chronic disorder resulting from an abnormally large number of particular white blood cells produced in bone marrow that help the body fight infection),
- paraesthesia (sensation of tickling, tingling, burning pricking or numbness of the skin),

- optic neuritis (inflammation of the optic (eye) nerve),
- photosensitivity reaction (allergy to the sun).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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 IBUCOD

5. How to store IBUCOD

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep in original packaging until required for use.

Do not store in a bathroom.

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 IBUCOD contains

The active substances are 200 mg of ibuprofen, 10 mg of codeine phosphate.

The other ingredients are magnesium stearate, microcrystalline cellulose, pregelatinized starch, silicon dioxide.

Sugar free

What IBUCOD looks like and contents of the pack

IBUCOD is a white, round, biconvex uncoated tablet with clean edges.

18 and 30 tablets are packed in a white polypropylene container sealed with a push-on polyethylene cap, together with a silica gel sachet, a white foam insert and a leaflet.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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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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