1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

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

Ibuprofen, codeine phosphate, paracetamol

Sugar free

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share MYBULEN 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 MYBULEN is and what it is used for

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

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

MYBULEN also contains paracetamol. Paracetamol, an analgesic, acts to relieve pain.

MYBULEN is indicated for the relief of mild to moderate pain of inflammatory origin with or without fever for a maximum period of 5 days.

2. What you need to know before you take MYBULEN

Do not take MYBULEN:

- if you are hypersensitive (allergic) to ibuprofen, paracetamol, codeine phosphate or any of the other ingredients of MYBULEN (listed in section 6).
- 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 an active or a history of recurrent stomach (gastrointestinal) ulcers, bleeding or perforations.
- if you have liver or kidney problems.
- if you are hypersensitive to aspirin or other non-steroidal anti-inflammatory medicines. This is because of the possibility of cross-sensitivity due to structural relationships, which exists among non-steroidal anti-inflammatory medicines (NSAIDs); acute allergic reactions may be more likely to occur in patients who have exhibited allergic reactions to these compounds.

- if you have heart failure or heart disease secondary to chronic lung disease.
- if you have or have had cardiovascular diseases (you may have had chest pain, or tightness, or discomfort, shortness of breath; or pain, numbness, weakness or coldness in your legs or arms, if the blood vessels in those parts of your body are narrowed; or you might have had a blood clot).
- if you have respiratory depression, acute asthma, uncontrolled asthma, difficulty breathing or breathing problems, head injuries or increased pressure inside the skull.
- if you regularly drink large quantities of alcohol (acute alcoholism).
- if you have had operations on your biliary tract (for example your liver, gall bladder or bile ducts).
- if you are taking a medicine classified as a monoamine oxidase inhibitor (MAOI), or within 14 days of stopping such treatment.
- if you are taking coumarin anticoagulants (blood-thinning tablets).
- if you have nasal polyps associated with aspirin-induced bronchospasm.
- if you are pregnant, do not use NSAIDs, including MYBULEN at 30 weeks or later in your pregnancy because these medicines may cause problems in your unborn baby.
- if you are breastfeeding your baby, as the safety in breastfeeding has not been established.

Warnings and precautions

Take special care with MYBULEN:

MYBULEN 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.

- MYBULEN contains codeine, which is an opioid medicine. Repeated use of MYBULEN may result in you becoming accustomed to it (needing to take higher doses). Repeated use of MYBULEN may also lead to dependence, abuse and addiction, which may result in life-threatening overdose.

  If you are taking MYBULEN 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 MYBULEN, 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')
- if you have a history of high blood pressure and/or heart failure, as fluid retention (oedema) in association with swelling of your limbs have been reported with MYBULEN therapy (see section 'Do not take MYBULEN').
- if you have heart problems including, angina (chest pain).
- if you are an elderly patient. The elderly have an increased frequency of adverse reactions to NSAIDs, such as MYBULEN, especially gastrointestinal bleeding and perforation, which may be fatal. The risk of gastrointestinal bleeding or perforation is

higher with increasing doses of MYBULEN, in patients with a history of ulcers, and in the elderly. If gastrointestinal bleeding or ulceration occurs when you are taking MYBULEN, treatment with MYBULEN should be stopped.

- if you have serious skin reactions, including shedding of scaly dead skin, extremely serious allergic skin reactions, Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) and toxic skin degeneration or if you develop or have a history of Fixed Drug Eruptions (FDE) (may look like round or oval patches and swelling of the skin), blistering (hives), itching. MYBULEN 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 take dosages in excess of those recommended, MYBULEN may cause severe liver damage. In the event of overdosage or suspected overdosage, prompt medical attention is critical for adults as well as children, even if there are no obvious signs or symptoms. The nearest doctor, hospital or poisons control centre must be contacted immediately.
- if you are recovering from any form of liver disease, MYBULEN should not be taken.
- if you are consuming alcohol or taking other sedatives, MYBULEN may potentiate the effect of alcohol and other sedatives.
- if used with anti-diarrhoeal medicines (such as diphenoxylate) as there is a risk of severe constipation.
- if used with other medicines used for stomach cramps, motion sickness or ulcers, as there is an increased risk of constipation and urinary retention.
- if you have an infection since symptoms such as fever and inflammation may be masked. It is therefore possible that MYBULEN may delay appropriate treatment of infection, which may lead to an increased risk of complications. If you take this

medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

- if you suffer from systemic lupus erythematosus SLE (a systemic autoimmune disease), mixed connective tissue diseases or a similar condition.
- if you have pre-existing disorders of blood coagulation or anaemia.
- if you have an inherited disorder of the red blood pigment, haemoglobin (porphyria).
- if you have disturbances in the formation of blood cells.
- if you have a history of gastrointestinal disease (e.g. ulcerative colitis, Crohn's disease, hiatus hernia, gastro-oesophageal reflux disease or angiodysplasia (a small vascular malformation of the gut)) as these conditions may be exacerbated.
- if you have previously had an ulcer in the stomach or intestines, especially if this has been complicated by perforation or accompanied by bleeding. In this case, you should look out for any unusual symptoms in the abdomen and report them to your doctor at once, especially if these symptoms occur at the beginning of treatment. The risk for bleeding or ulceration of the digestive tract is higher in this case, especially in elderly patients. If bleeding or ulceration of the digestive tract occurs, the treatment has to be stopped.
- if you have acute abdominal (stomach) conditions.
- 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, as MYBULEN may decrease respiratory drive and increase resistance.
- 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 dependent on drugs.
- if you have gallbladder disease or gallstones, as this may cause biliary tract spasm.
- if you have had recent gastrointestinal tract surgery or any major 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 have a stiff neck, headache, nausea, vomiting, fever or disorientation, as these may be symptoms of meningitis.
- 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 have myasthenia gravis (a neuromuscular disorder).
- If you are taking an antibiotic called flucloxacillin with MYBULEN, as it may cause increased acid levels in your body especially if you have severe renal problems, severe reaction to infection (sepsis), malnutrition and other conditions that cause less glutathione to be produced by the body. Close monitoring is recommended.
- if you have a personal or family history of substance abuse or mental health conditions, as you may be at an increased risk of becoming addicted to MYBULEN.

Children

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

Other medicines and MYBULEN

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.
- Anticoagulants (blood thinning tablets), such as aspirin, heparin or warfarin.
- Phenytoin (medicine used to treat epilepsy) since the effect of phenytoin may be enhanced.
- Sulphonylureas (medicine used to treat diabetes) since the effect of sulphonylureas may be enhanced.
- Anti-platelets, platelet aggregation inhibitors (medicines used against clotting) such as ticlopidine or clopidogrel, as its effect may be enhanced and may increase the risk of gastrointestinal bleeding.
- Anti-hypertensives (used for the treatment of high blood pressure) e.g. ACE inhibitors, beta-blockers, angiotensin-II receptor antagonists or diuretics (water tablets) since the effects of these medicines may be reduced.
- Potassium-sparing diuretics may increase the risk of too much potassium in the blood.
- Lithium (used to treat depression and mania) may increase the risk of gastrointestinal bleeding.

- Methotrexate (used for some inflammatory diseases and some cancers) may increase the plasma concentrations and thus enhance its effect.
- Ciclosporin or tacrolimus (medicines used to treat some inflammatory diseases and after transplants) since the risk of toxicity of the kidney may be increased.
- Quinolone antibiotics (used for infections), as convulsions (seizures) may occur.
- Cardiac glycosides (for example digoxin), used to treat heart problems, as MYBULEN may increase plasma concentrations.
- Selective serotonin reuptake inhibitors (SSRIs) used to treat depression, may increase the risk of gastrointestinal bleeding.
- Oral corticosteroids (an anti-inflammatory medicine) since the risk of gastrointestinal bleeding and ulceration is increased.
- Bisphosphonates (medicines used to treat osteoporosis), since the risk of gastrointestinal bleeding and ulceration is increased.
- Oxypentifylline (medicines used to increase blood circulation) since the risk of gastrointestinal bleeding and ulceration is increased.
- Zidovudine or ritonavir (medicine used to treat HIV-infection) since an increased risk of haematoxicity (effect on blood and blood-forming tissues) exists during the concomitant use.
- Aminoglycoside antibiotics (used to treat bacterial infections) since MYBULEN may decrease excretion of aminoglycosides.
- Antibacterial medicines (such as flucloxacillin).
- Mifepristone (a medicine used to end pregnancy) since MYBULEN can reduce the effect of mifepristone.
- Metoclopramide or domperidone, used as an anti-nausea medicine.
- Colestyramine, used in reducing cholesterol levels in your blood.

- Probenecid or sulfinpyrazone (used to treat gout) since the excretion of MYBULEN may be delayed.
- Monoamine oxidase inhibitors (MAOIs): sometimes fatal reactions may occur in patients taking MAOIs, and also within 14 days of stopping such treatment.
- Central nervous system depressants such as anaesthetics, hypnotics and sedatives.
- Medicines used to treat diarrhoea (antidiarrhoeals).
- Anticholinergics or muscle relaxants, such as atropine, as there is an increased risk of severe constipation.
- Anaesthetics or other medicines used in surgery (such as neuromuscular blocking medicines).
- Hydroxyzine (an antihistamine).
- Quinidine or mexiletine (used to treat certain heart conditions).
- Cisapride (used to treat heart burn).
- Cimetidine (used to treat stomach ulcers).
- Naloxone or naltrexone (used to treat drug abuse or overdose).
- Enzyme-inducing and hepatotoxic medicines (medicines which cause chemical-driven liver damage).
- Voriconazole and fluconazole (CYP2C9 inhibitors) (used for fungal infections), since the effect of MYBULEN may increase.
- Baclofen (a muscle relaxant) because of elevated baclofen toxicity.
- Gingko biloba (a herbal medicine) as there is a chance you may bleed more easily if you are taking this with MYBULEN.

MYBULEN with alcohol

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

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 MYBULEN when you are pregnant.

Breastfeeding

You should not take MYBULEN if you are breastfeeding your baby.

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

Fertility

MYBULEN 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

MYBULEN 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 MYBULEN 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 MYBULEN affects you (see section 4).

3. How to take MYBULEN

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

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

Adults (over the age of 12 years)

The usual dose of MYBULEN is one to two tablets every six hours if necessary.

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

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

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

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

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

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

DO NOT EXCEED THE RECOMMENDED DOSAGE.

If you take more MYBULEN than you should

MYBULEN 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 (may be blood streaked), or severe diarrhoea. In addition to these symptoms, headache, gastrointestinal bleeding, blurred vision, ringing in the ears, confusion, shaky eye movement and exacerbation of asthma in asthmatics. At high doses, drowsiness, excitation, disorientation, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), vertigo, weakness and dizziness, blood in urine, low blood pressure, hyperkalaemia, metabolic acidosis, increased prothrombin time/INR, acute renal failure, liver damage, respiratory depression, cyanosis, cold body feeling, and breathing problems have been reported.

If you forget to take MYBULEN

Take your missed dose as soon as you remember, if 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 forgotten individual doses.

4. Possible side effects

MYBULEN can have side effects.

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

If any of the following happens, stop taking MYBULEN 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), Drug-induced hypersensitivity syndrome (DIHS), Acute Generalised Exanthematous Pustulosis (AGEP), or Fixed Drug Eruption (FDE).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MYBULEN. 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,
- yellowing of skin or the whites of your eyes (jaundice).
- an unexpected change in the amount of urine passed, its frequency and/or its appearance,
- 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 lightheaded or have weakness of your muscles,
- very low levels of sodium in your blood,
- 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,
- brain injury or increasing pressure inside your skull,
- aseptic meningitis with symptoms of stiff neck, headache, nausea, vomiting, fever or disorientation.

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:

- Inflammation of the mucous members in the nose, which may cause a stuffy or runny nose (rhinitis),
- mouth ulcers and inflammation,
- feeling tired and weak,
- blood disorders such as decrease in white blood cells, decrease in red blood cells. The first symptoms may include fever, sore throat, surface mouth ulcers, flu-like symptoms, severe tiredness, nasal and skin bleeding or unexplained bruising,
- confusional state, nervousness, sleeplessness, depression, restlessness, anxiety, changes in mood, hallucination, drowsiness, headache,
- a feeling of intense excitement and happiness,
- spinning (vertigo), agitation, irritability,
- blurred vision, small pupil of the eye (miosis), other ocular (eye) reactions,
- ringing in the ears,
- bloating, dry mouth, decreased appetite,
- abnormalities of liver function tests, inflammation of the liver,
- impairment of kidney function, kidney pain,
- inflammation of the pancreas with symptoms of nausea, vomiting and stomach pain,
- sweating, facial flushing, difficulties in passing urine, ureteric or biliary spasm,
- drop in body temperature (hypothermia),
- increased sensitivity to sunlight (photosensitivity),
- butterfly-shaped rash on the face (lupus erythematosus syndrome),
- hair loss,

- 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.

Side effects with an unknown frequency:

- Tingling of the hands and feet,
- fluid retention
- hearing problems,
- general feeling of being unwell,
- inflammation of the optic (eye) nerve which may cause eye problems,
- headache, nausea, vomiting, confusion, dizziness, feeling weak or tired, loss of appetite and increased heartbeat due to high acid levels in the body (metabolic acidosis or pyroglutamic aciduria).

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

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 MYBULEN.

5. How to store MYBULEN

Store all medicines out of reach of children.

Store at or below 25 °C, in a well closed container.

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 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 MYBULEN contains

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

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

Sugar free

What MYBULEN looks like and contents of the pack

MYBULEN is a blue, capsule-shaped, film-coated tablet with a break score on one side and debossed with C25 on the other side.

30 tablets are packed into a white polypropylene securitainer together with a desiccant disc or silica gel sachet, rayon and a leaflet, and sealed with a dark blue low density polyethylene cap.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912/ +27 (0)11 239-6200

This leaflet was last revised in

18 November 2024

Registration number

30/2.8/0138

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

Botswana: BOT1001619 S3

Namibia: NS2 04/2.8/0225

Zambia: 145/009 POM

ZA_MYBUTAB_2411_00