1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

MYBULEN CAPSULES 200 mg/ 10 mg/ 250 mg

Ibuprofen, codeine phosphate, paracetamol

Sugar free

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share MYBULEN CAPSULES 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 CAPSULES are and what it is used for
2. What you need to know before you take MYBULEN CAPSULES
3. How to take MYBULEN CAPSULES
4. Possible side effects
5. How to store MYBULEN CAPSULES
6. Contents of the pack and other information

1. What MYBULEN CAPSULES are and what it is used for

MYBULEN CAPSULES contains codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. MYBULEN CAPSULES also contains Ibuprofen. Ibuprofen, a non-steroidal anti-inflammatory medicine (NSAID), also acts to reduce swelling (inflammation). MYBULEN CAPSULES also contains paracetamol. Paracetamol, an analgesic, acts to relieve pain.

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

2. What you need to know before you take MYBULEN CAPSULES

Do not take MYBULEN CAPSULES

- if you are hypersensitive (allergic) to ibuprofen, paracetamol, codeine phosphate or any of the other ingredients of MYBULEN CAPSULES (listed in section 6).
- if you have had a history of stomach (gastrointestinal) perforation, ulceration and 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 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 liver or kidney problems.

- if you have had allergic reactions such as runny nose, itchy skin rash or swelling of the lips, face, tongue, or throat after you have taken medicines containing acetylsalicylic acid (such as aspirin) or other medicines for pain and inflammation (NSAIDs) (if you are sensitive to aspirin or NSAIDs).
- if you have uncontrolled asthma or difficulty breathing or breathing problems (bronchospasm).
- if you have nasal polyps associated with aspirin-induced bronchospasm.
- if you have respiratory depression, head injuries or increased pressure inside the skull.
- 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 regularly drink large quantities of alcohol.
- if you have had operations on your biliary tract (for example your liver, gall bladder or bile ducts).
- if you have severe diarrhoea associated with pseudomembranous colitis.
- if you are pregnant, do not use NSAIDs, including MYBULEN CAPSULES 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 CAPSULES

MYBULEN CAPSULES 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.

- if you have a history of hypertension (high blood pressure) and/or heart failure, as fluid retention (oedema) in association with swelling of your limbs may occur with MYBULEN CAPSULES therapy (see section 'Do not take MYBULEN CAPSULES').
- if you have heart problems including angina (chest pain).
- if you are elderly, as you may be more prone to side effects, especially gastrointestinal bleeding and perforation, which may be fatal.
- if you suffer from lupus, mixed connective tissue diseases or a similar condition.
- if you have an inherited disorder of the red blood pigment, haemoglobin (porphyria).
- if you have a disorder of blood coagulation, or a decreased number of red blood cells (anaemia).
- if you have disturbances in the formation of blood cells.
- if you have a history of gastrointestinal disease (e.g. ulcerative colitis or Crohn's disease (inflammatory diseases), hiatus hernia, gastro-oesophageal reflux disease (reflux of gastric contents into the oesophagus), 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 must be stopped.
- if you have serious skin reactions, including exfoliative dermatitis (red and scaly skin), Drug Rash with Eosinophillia and Systemic Symptoms (DRESS), Stevens-Johnson syndrome and toxic epidermal necrolysis (life-threatening conditions causing shedding of the skin).

MYBULEN CAPSULES 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 any allergic condition.
- if you have acute abdominal (stomach) conditions.
- if you suffer from allergies, hay fever, chronic swelling of nasal mucosa, sinusitis, 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 CAPSULES may decrease respiratory drive and increase resistance.
- if you have an infection. MYBULEN CAPSULES may mask signs of infections such as fever and pain. It is therefore possible that MYBULEN CAPSULES 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 have a stiff neck, headache, nausea, vomiting, fever or disorientation, as these may be symptoms of meningitis.
- if you have an irregular heartbeat, as this may be induced or exacerbated.
- if you have convulsions or history thereof, as this may be induced or exacerbated.
- if you are dependent on alcohol or drugs.
- if you have gallbladder disease or gallstones, as this may cause biliary tract spasm.
- if you have 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 prostrate or have had recent urinary tract surgery.
- 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.

Children

MYBULEN CAPSULES are not recommended for children under 12 years of age.

Other medicines and MYBULEN CAPSULES

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:

- Anticoagulants (blood-thinning tablets) such as aspirin, warfarin or heparin since the effect of the anticoagulant may be enhanced.
- Anti-platelets, platelet aggregation inhibitors (medicines used against clotting) such as ticlopidine or clopidogrel as there may be an increased risk of gastrointestinal bleeding.
- Sulfonylureas (medicines used to treat diabetes) since your blood sugar levels can be affected.

- Anti-hypertensives (used in lowering blood pressure) (e.g. ACE-inhibitors such as captopril; beta-blockers such as atenolol medicines; angiotensin-II receptor antagonists such as losartan).
- Diuretics (water tablets) since the effect of the diuretics may be weakened.
- Potassium-sparing diuretics may increase the risk of too much potassium in the blood.
- Aminoglycoside antibiotics used in certain infections e.g. amikacin, gentamycin, neomycin, tobramycin, since MYBULEN CAPSULES may decrease excretion of aminoglycosides.
- Lithium (used to treat depression and mania) since the effect of lithium may be enhanced.
- Phenytoin (medicine used to treat epilepsy) since the effect of phenytoin may be enhanced.
- Methotrexate (used for some inflammatory diseases and some cancers).
- Ciclosporin or tacrolimus (used to treat some inflammatory diseases and after transplants) since kidney damage may occur.
- Quinolone antibiotics (used for infections) since the risk of convulsions (fits) may be increased.
- Digoxin, (used to treat heart problems) since the effect of digoxin may be enhanced.
- Oral corticosteroids (an anti-inflammatory medicine) since this may increase the risk of gastrointestinal ulcers or bleeding.
- 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.
- Mifepristone (a medicine used to end pregnancy) since MYBULEN CAPSULES can reduce the effect of mifepristone.
- Zidovudine or ritonavir (medicines used to treat HIV-infection).
- Moclobemide (MAOI), and other medicines used to treat depression.
- Bisphosphonates (medicines used in osteoporosis and to reduce high blood calcium levels) as the risk of gastrointestinal perforation, ulceration and bleeding is increased.

- Oxpentifylline (medicines used to increase blood circulation) as the risk of gastrointestinal perforation, ulceration and bleeding is increased.
- Bone marrow depressants e.g. azathioprine used in the treatment of certain autoimmune diseases and in the management of organ transplants.
- Enzyme-inducing and hepatotoxic medicines (medicines which cause chemical-driven liver damage).
- Metoclopramide (used as an antiemetic).
- Colestyramine (used in reducing cholesterol levels in your blood).
- Probenecid or sulfinpyrazone (used to treat gout) since the excretion of MYBULEN CAPSULES may be delayed.
- Selective serotonin reuptake inhibitors (SSRIs) (medicines used to treat depression) such as paroxetine, sertraline, citalopram as these may increase risk of gastrointestinal bleeding.
- 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.
- Central nervous system depressants such as anaesthetics, hypnotics and sedatives.
- Medicines used to treat diarrhoea.
- Anticholinergics, such as atropine, as there is an increased risk of severe constipation.
- Voriconazole and fluconazole (CYP2C9 inhibitors) (used for fungal infections) since the effect of MYBULEN CAPSULES may increase.
- Baclofen (a muscle relaxant) because of elevated baclofen toxicity.
- Ginkgo biloba (a herbal medicine) as there is a chance you may bleed more easily if you are taking this with MYBULEN CAPSULES.

MYBULEN CAPSULES with alcohol

Do not drink alcohol when taking MYBULEN CAPSULES as the risk of gastrointestinal perforation, ulceration and bleeding 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 CAPSULES when you are pregnant.

Breastfeeding

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

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

Fertility

MYBULEN CAPSULES 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 CAPSULES 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 CAPSULES 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 CAPSULES affects you (see section 4).

3. How to take MYBULEN CAPSULES

Always take MYBULEN CAPSULES 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.

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

Adults (over the age of 12 years)

The usual dose of MYBULEN CAPSULES is one to two capsules 4 hourly.

Do not take more than 6 capsules 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 CAPSULES is too strong or too weak, talk to your doctor or pharmacist.

MYBULEN CAPSULES should not be used in children under 12 years of age.

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

Prolonged use of MYBULEN CAPSULES, may lead to dependency and addiction.

DO NOT EXCEED THE RECOMMENDED DOSE.

If you take more MYBULEN CAPSULES than you should

MYBULEN CAPSULES 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, exacerbation of asthma in asthmatics may occur. 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 CAPSULES

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

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

4. Possible side effects

MYBULEN CAPSULES can have side effects.

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

If any of the following happens, stop taking MYBULEN CAPSULES 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 Eosinophillia 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 MYBULEN CAPSULES. 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 bleeding), such as, black tarry stools, when emptying your bowels (melaena), or vomiting blood (haematemesis) which may be fatal,
- yellowing of your skin or the whites of your eyes (jaundice),
- an unexpected change in the amount, frequency and/or the appearance of urine passed,
- kidney failure or liver failure,
- 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,
- sudden filling of lungs with fluid, resulting in difficulty breathing, 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,
- spinning (vertigo), agitation, irritability,
- blurred vision, decreased pupil size (miosis), other ocular (eye) reactions,
- ringing in the ears,
- bloating, dry mouth, decreased appetite, irritation of the stomach lining,
- 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.

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: 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 MYBULEN CAPSULES.

5. How to store MYBULEN CAPSULES

Store all medicines out of reach of children.

Store at or below 25 °C in airtight containers.

Protect from moisture.

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 MYBULEN CAPSULES contains

The active substances are 200 mg of ibuprofen, 10 mg of codeine phosphate and 250 mg of paracetamol.

The other ingredients are brilliant blue (C.I. 42090), carmoisine (C.I. 14720), colloidal silicon dioxide, gelatin, magnesium stearate, quinoline yellow (C.I. 47005), sodium starch glycollate, titanium dioxide (C.I. 77891)

Sugar free

What MYBULEN CAPSULES looks like and contents of the pack

MYBULEN CAPSULES are a white to off-white, compacted powder, encapsulated in a size “0” capsule with a blue cap and blue body.

10 capsules are packed in a clear polyvinylchloride, polyethylene, polyvinylidene chloride film sealed with an aluminium foil backing. The blister strips are packed into a unit cardboard carton together with a leaflet.

30 capsules are packed in a white polypropylene securitainer and sealed with a red or blue low-density polyethylene cap with a tamper evident seal together with a silica gel sachet or a white desiccant disc and a leaflet.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

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This leaflet was last revised in

23 December 2022

Registration number

A38/2.8/0527

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

Namibia: NS2 10/2.8/0548

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