1.3.2.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

MYBULEN FORTE 400 mg/10 mg/500 mg film- coated tablets

Ibuprofen, codeine phosphate hemihydrate, paracetamol

Sugar free

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

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

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

1. What MYBULEN FORTE is and what it is used for

MYBULEN FORTE belongs to a group of medicines called analgesics (painkillers) and is indicated for the treatment 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 MYBULEN FORTE

Do not take MYBULEN FORTE if you:

- are hypersensitive (allergic) to the paracetamol, ibuprofen or codeine or any of the other ingredients of MYBULEN FORTE (see What MYBULEN FORTE contains).
- have liver problems.
- have kidney problems.
- have a history of peptic ulcer or stomach (gastrointestinal) perforation, ulceration or bleeding in your stomach or small intestine (duodenum) related to previous use of Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) such as MYBULEN FORTE.
- are allergic to aspirin or other NSAIDs.
- have heart failure or heart disease.
- have bleeding and/or ulcers in your digestive tract.
- have diarrhoea resulting from severe inflammation of the inner lining of the colon (pseudomembranous colitis).
- use medicines to prevent your blood from clotting (coumarin anticoagulants) e.g. warfarin (see Other medicines and MYBULEN FORTE).
- are breastfeeding or in your third trimester of pregnancy (see section Pregnancy, breastfeeding and fertility).
- have difficulty breathing or breathing problems, acute asthma, uncontrolled asthma, head injuries or increased pressure inside the skull.
- have ingested large quantities of alcohol (acute alcoholism).

- have painless growths on the inside of your nose (nasal polyps), associated with aspirin-induced bronchospasm (constriction of air passages which causes difficulty breathing, coughing, wheezing, and chest tightness).
- had an operation on the biliary tract.
- are taking a medicine to treat depression called Monoamine Oxidase Inhibitors (MAOIs) or have taken them in the last 2 weeks. MAOIs are medicines such as moclobemide, phenelzine or tranylcypromine.
- during an asthma attack, while you are having difficulty breathing or if you have heart failure secondary to chronic lung disease.
- are under 18 years of age and have had your tonsils or adenoids removed due to obstructive sleep apnoea syndrome (stop and start breathing during sleep).
- know that you metabolise (break down) codeine into morphine very rapidly.
- have chronic constipation.

MYBULEN FORTE should not be given to children younger than 12 years of age.

Warnings and precautions

Take special care with MYBULEN FORTE:

- do not use MYBULEN FORTE longer than 5 days and if your symptoms continue, consult your doctor. If you suffer from kidney or liver disease, you should only use MYBULEN FORTE under the supervision of your doctor.
- do not take more than what your doctor has prescribed and take care not to use other medicines that contain the same ingredients as MYBULEN FORTE. This includes, for example, cold and flu medicines which may contain paracetamol and other anti-inflammatory medicines like diclofenac, celecoxib.
- MYBULEN FORTE may mask the signs of an infection such as fever and inflammation.

- if you have anaemia (less red blood cells) or other blood disorders.
- if you will be having surgery you may experience excessive bleeding.
- if you are elderly, as adverse effects like bleeding in your digestive tract can become fatal.
- if you are a child or adolescent who is dehydrated as this can lead to damage of the kidney.
- if you have a history of ulcers or bleeding in the stomach.
- if you have a history of asthma.
- MYBULEN FORTE contains codeine, which is an opioid medicine. Repeated use of MYBULEN FORTE may result in you becoming accustomed to it (needing to take higher doses). Repeated use of MYBULEN FORTE may also lead to dependence, abuse and addiction, which may result in life-threatening overdose.
- 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 FORTE.
- if you experience any of the following signs whilst taking MYBULEN FORTE, 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 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 are taking MYBULEN FORTE 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.
- if you have high blood pressure or mild heart problems, high sugar levels, high cholesterol levels or if you smoke, take MYBULEN FORTE only under supervision of your healthcare provider.
- if you have Systemic Lupus Erythematosus (SLE) an autoimmune disease that can affect the joints, skin, kidneys, blood cells, brain, heart and lungs or other connective tissue disorders.
- if you have trouble conceiving a baby.
- you have problems passing water or have prostate problems.
- you have a bowel problem such as colitis, Crohn's disease or a blockage of your bowel.
- you have a disease of the adrenal gland called Addison's disease.
- if you are taking other medicines which cause you to feel sleepy (benzodiazepines) (see Other medicines and MYBULEN FORTE).
- if you have serious skin reactions, including shedding of scaly dead skin, extremely serious allergic skin reactions, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), Steven-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), Drug induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) (may look like round or oval patches and swelling of the skin), blistering (hives), itching. MYBULEN FORTE 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 are taking an antibiotic called flucloxacillin with MYBULEN FORTE, 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 any conditions predisposing to and exacerbated by fluid retention, as MYBULEN FORTE may cause fluid retention and swelling (oedema) (see Do not take MYBULEN FORTE).
- 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 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 are taking antidiarrhoeal medicine as this can lead to severe constipation.

Children and adolescents

MYBULEN FORTE is not recommended for children under 12 years of age and adolescents (12 to 18 years) who have problems with breathing.

Other medicines and MYBULEN FORTE

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:

- Isoniazid, medicine used to treat tuberculosis (TB).
- Antiepileptics, such as carbamazepine, phenobarbital, phenytoin and primidone: medicines used to treat epilepsy.
- Chloramphenicol: an antibiotic medicine.
- Oral contraceptives: medicines used for birth control.
- Metoclopramide or domperidone: medicines used to treat nausea and vomiting.
- Cholestyramine: medicine used to lower cholesterol.
- Coumarin anticoagulants: medicines used to thin the blood such as warfarin.
- Anti-platelet medicines: medicines that prevent platelets from sticking together and forming blood clots such as clopidogrel and ticlopidine.
- Enzyme-inducing and hepatotoxic (liver toxic) medicines: together with MYBULEN FORTE it may increase the risk of liver toxicity and decrease the effect of MYBULEN FORTE.
- Salicylates e.g., aspirin: medicines used to treat pain due to inflammatory conditions or fever, as it could cause more kidney side effects.
- Antibacterial medicines (such as flucloxacillin).
- Interferon alfa (an antiviral medicine), as paracetamol enhances the antiviral effect of interferon alfa.
- Antihypertensives, beta-blockers and water tablets: medicines used to treat high blood pressure.
- Cardiac glycosides: medicines used to treat heart conditions e.g. digoxin.

- Phenytoin: medicine used to treat epilepsy.
- Lithium: medicine used to treat some mental problems.
- Methotrexate: medicine used to treat some type of cancers as well as a type of arthritis.
- Ciclosporin and tacrolimus: medicines used in organ transplant patients.
- Mifepristone: medicine used to protect the stomach lining especially when using an anti-inflammatory medicine.
- Probenecid and sulfinpyrazone: medicines used to treat gout.
- Other analgesics and COX-2 inhibitors: medicines use to treat pain and inflammation e.g. aspirin, diclofenac, celecoxib.
- Corticosteroids: medicines used in the treatment of inflammatory conditions e.g. prednisone, dexamethasone.
- Quinolone antibiotics: medicines used to treat infection e.g. ciprofloxacin.
- Sulfonylureas: medicines used to treat diabetes.
- Antidepressants (e.g. selective serotonin reuptake inhibitors such as citalopram, fluoxetine, paroxetine, monoamine oxidase inhibitors such as phenelzine, selegiline, tricyclic antidepressants such as amitriptyline): medicines used to treat depression.
- Zidovudine or ritonavir: medicines used to treat HIV.
- Baclofen: medicines used to relax muscles.
- Captopril: medicine used for high blood pressure.
- Bone marrow depressants: medicines that decrease the amount of blood cells produced by your bone marrow.
- Aminoglycosides: medicines used to treat infection (type of antibiotic).
- Herbal extracts e.g. ginkgo biloba: herbal medicine used to enhance memory.
- Voriconazole and fluconazole: medicines use to treat fungal infections.
- Analgesics, tranquilisers, sedative hypnotics and alcohol: medicines which make you

drowsy or sleepy (CNS depressants).

- Anticholinergics or antimuscarinics (e.g. atropine): medicines which are used as premedication before operations and after heart attacks.
- Cimetidine: medicine used to treat heartburn and ulcers.
- Antihistamines: medicines used to treat allergies.
- Neuromuscular blocking agents: medicines used during anaesthesia.
- Anti-dysrhythmics: medicines used to prevent abnormal cardiac rhythms such as atrial fibrillation, atrial flutter, ventricular tachycardia, and ventricular fibrillation (e.g. mexiletine, quinidine).
- Naloxone and naltrexone: medicines used in addictions and overdose.

MYBULEN FORTE with alcohol

You should not drink alcohol while taking MYBULEN FORTE. Alcohol may increase the side effects of MYBULEN FORTE.

Pregnancy, breastfeeding and fertility

You should not take MYBULEN FORTE if you are breastfeeding your baby or if you are in your third trimester of pregnancy.

The active ingredient can pass into breastmilk. There is a risk of side effects in breastfed babies, such as serious breathing problems that could result in death of the 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.

MYBULEN FORTE may impair female fertility and is not recommended in women attempting to fall pregnant.

Driving and using machines

Since adverse reactions such as dizziness, drowsiness (feeling sleepy) and difficulty in seeing (visual disturbance) have been reported in patients receiving MYBULEN FORTE, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that MYBULEN FORTE does not adversely affect your ability to do so (see Possible side effects).

It is not always possible to predict to what extent MYBULEN FORTE 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 FORTE affects you (see section 4).

3. How to take MYBULEN FORTE

Do not share medicines prescribed for you with any other person. Always take MYBULEN FORTE 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.

Do not use continuously for more than 5 days without consulting your doctor. Consult your doctor if pain or fever persists or gets worse, if new symptoms occur or if redness and swelling is present, as these could be signs of a serious condition. Consult a doctor if no relief is obtained from the recommended dosage.

The usual dose of MYBULEN FORTE is one tablet three times a day when necessary. The maximum dose is 3 (three) tablets per 24 hours.

Not recommended for children under 12 years of age.

Care should be taken in adolescents (12 to 18 years) (see Do not take MYBULEN FORTE).

Patients suffering from liver and kidney disease should take MYBULEN FORTE under medical supervision.

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

DO NOT EXCEED THE RECOMMENDED DOSE.

If you take more MYBULEN FORTE 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.

Symptoms of overdose for paracetamol:

Prompt treatment is essential. In the event of an overdosage, consult a doctor immediately, or take the person to a hospital directly even if there are no symptoms.

A delay in starting treatment may mean that the antidote (substance to reverse the effect of another agent) is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed. Symptoms of paracetamol overdosage in the first 24 hours, is abnormal paleness of the skin, nausea, vomiting, lack of appetite and possibly abdominal pain.

Symptoms of overdose for ibuprofen:

The most likely symptoms of overdosage are gastrointestinal such as pain in upper, middle region of stomach, nausea, vomiting or rarely diarrhoea.

Symptoms of overdose for codeine phosphate:

Respiratory depression is the most important feature of overdosage. Pin-point pupils, nausea and vomiting are common.

If you forget to take MYBULEN FORTE

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

DO NOT EXCEED THE RECOMMENDED DOSE (see How to take MYBULEN FORTE).

4. Possible side effects

MYBULEN FORTE can have side effects.

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

If any of the following happens, stop taking MYBULEN FORTE 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 Reaction 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 reaction to MYBULEN FORTE. 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:

- changes in the way your heart beats, for example, if you notice it beating faster or slower (palpitations, bradycardia).
- increase in blood pressure (hypertension).
- difficulty in breathing (dyspnoea, comprising asthma, aggravated asthma) or wheezing due to airway spasms (bronchospasm).
- pain in the upper area of the stomach, being and feeling sick (nausea and vomiting) as these may be symptoms of inflammation of the pancreas (pancreatitis).
- less urine than is normal for you.
- black stools (melaena) and/or vomiting blood (haematemesis), which may be signs of bleeding ulcers in your digestive tract.
- pain in the digestive tract directly after eating or for a time period after you have eaten as this may be a sign of an ulcer in your digestive tract.
- impaired vision and/or eye pain.
- impaired hearing.
- yellow pigmentation of skin and eyes, nausea, vomiting, loss of appetite, fever, pain or swelling in the upper right abdomen, fatigue, dark-coloured urine which may be signs of liver problems or hepatotoxicity.
- a stiff neck, headache, nausea, vomiting, fever or disorientation as these may be symptoms of inflammation of the membrane in the brain (aseptic meningitis).
- shortness of breath, fatigue, swollen legs and rapid heartbeat as these could be signs of heart failure, a heart attack or stroke.
- dull pain in the middle to upper right area of the stomach (biliary spasm).
- prolonged use can lead to addiction and tolerance which means you no longer respond to a medicine in the way you did at first.

- breathing difficulty, wheezing, and dry coughs that appear to shake the entire body. Chills, sweating, aching, discomfort and/or fatigue as these are symptoms of alveolitis.
- ringing or buzzing sounds in ears (tinnitus), dizziness/loss of balance, change in hearing as these are signs of ototoxicity which can lead to sensorineural hearing loss.
- 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).

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:

- Abnormal blood laboratory results such as reduction in blood platelets (which increases bleeding or bruising), white blood cells (which makes infections more likely) and red blood cells (which may cause weakness or breathlessness),
- unable to pass stool (constipation), nausea, vomiting, flatulence (gas), dyspepsia (heartburn), loose, watery stool (diarrhoea), stomach-ache,
- tiredness (fatigue),
- drowsiness,
- dizziness,
- nervousness,
- inability to sleep (insomnia), low mood (depression),
- headache.

Less frequent side effects:

- Inflammation of the skin (dermatitis),
- runny nose (rhinitis),
- itching, red bumps (urticaria); itching (pruritus), small purple coloured spots caused by bleeding into the skin (purpura), increased sensitivity of skin to sun (photosensitivity reaction),
- confusion, restlessness, changes of mood, unrealistic feeling of well-being (euphoria); feeling of unease such as worry or fear (anxiety),
- feeling of pins-and-needles (paraesthesia),
- somnolence (sleepiness),
- blurred or double vision, miosis (decrease in pupil size), other ocular (eye) reactions, hearing/visual impairment,
- tinnitus (ringing sound in the ear), vertigo (internal or external spinning sensation),
- cough suppression,
- dry mouth,
- sweating, facial flushing, lowered body temperature (hypothermia),
- inability to urinate.

Side effects with an unknown frequency:

- Increase in severity of colitis (inflammation of the colon) and Crohn's disease (inflammation of the digestive tract),
- difficulty swallowing (dysphagia), food getting stuck in the oesophagus after swallowing (impaction), chest pain that is often centrally located and does not respond to antacids, backflow of undigested food (regurgitation) as these are symptoms of Pulmonary eosinophilia,
- you have blood in your urine as this is a sign of haematuria,

- fluid retention,
- light-headedness,
- irritability,
- 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.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

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

5. How to store MYBULEN FORTE

Store all medicines out of reach of children.

Store at or below 25 °C.

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 FORTE contains

The active substances are 400 mg ibuprofen, 10 mg codeine phosphate hemihydrate, 500 mg paracetamol.

The other ingredients are hypromellose (E464), macrogol, magnesium stearate, microcrystalline cellulose, povidone, pregelatinised starch, titanium dioxide (E171).

Sugar free.

What MYBULEN FORTE looks like and contents of the pack

MYBULEN FORTE is a white to off-white capsule shaped film-coated tablet debossed with "E19" on one side and breakline on the other side.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

15 tablets are packed into a white round high density polyethylene (HDPE) bottle with polypropylene cap with induction seal wad. The bottle may be packed in an outer carton.

Holder of Certificate of Registration

PHARMACARE LIMITED

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Woodmead 2191

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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

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