

1.3.2 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/use 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 peptic ulcer or bleeding in your stomach related to previous use of Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) such as MYBULEN FORTE.
- Are allergic to aspirin.
- Have heart failure.
- Have bleeding and/or ulcers in your digestive tract especially because of taking medicines like MYBULEN FORTE (anti-inflammatory medicines).
- Use medicines to prevent your blood from clotting e.g. warfarin.
- Are pregnant or breastfeeding (see section Pregnancy, breastfeeding and fertility),
- Have severe asthma attacks, severe breathing problems or have any lung conditions (respiratory depression, chronic obstructive lung disease),
- Have recently had a head injury.
- Have been told by your doctor that you have increased pressure in your head. Signs of this include: headaches, being sick (vomiting) and blurred eyesight.
- Consume excessive amounts of alcohol on a regular basis (acute alcoholism).
- 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.

- 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.

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 included 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 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.
- If you have high blood pressure or mild heart problems or heart failure, 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 develop a very serious skin disease like Stevens Johnson Syndrome after using MYBULEN FORTE (see Possible side effects).
- 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 section Other medicines and MYBULEN FORTE).
- If you have suffered from Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome).

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.
- Coumarins: medicines used to thin the blood such as warfarin.
- Antihypertensives, beta-blockers and water tablets: medicines used to treat high blood pressure.
- Cardiac glycosides: medicines used to treat heart conditions e.g. digoxin.
- 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.
- 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: medicine used to treat HIV.
- 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 (e.g. atropine): medicines which are used as premedication before operations and after heart attacks.

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 pregnant or breastfeeding your baby.

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 the daily activities of a patient. Patients should ensure that they do not engage in the above

activities until they are aware of the measure to which MYBULEN FORTE affects them (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 overdose, 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 and vomiting.

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. Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome),
- Acute generalised exanthematous pustulosis (AGEP).

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 responds to a drug 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.

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);
- tinnitus (ringing sound in the ear), vertigo (internal or external spinning sensation);
- 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to: SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

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.

High density polyethylene bottle which may be packed into a carton. Pack size of 15 tablets.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

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Access to the corresponding Professional Information

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E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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