

Applicant: Unimed Healthcare (Pty) Ltd
Product name: FLAMARET
Dosage Form: Capsules

Professional Information Leaflet (PIL)
for Medicines for Human Use
FLAMARET (capsules)

SCHEDULING STATUS:

S3

FLAMARET capsules
Indomethacin
Contains lactose monohydrate 95,00 mg

Read all of this leaflet carefully before you start taking FLAMARET

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- FLAMARET has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

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

Applicant: Unimed Healthcare (Pty) Ltd
Product name: FLAMARET
Dosage Form: Capsules

1. What FLAMARET is and what it is used for

FLAMARET contains the active ingredient, indomethacin which belongs to a group of medicines known as non-steroidal anti-inflammatory medicines or NSAIDs. FLAMARET reduces fever, pain and inflammation.

FLAMARET is used for:

- rheumatoid arthritis (autoimmune and inflammatory disease that may cause joint pain, inflammation and damage throughout your body);
- osteoarthritis (disease of the joints, causing pain and stiffness of your joints);
- ankylosing spondylitis (pain and stiffness in your back);
- deterioration of the cartilage that serves as a cushion in the joints of your hip (degenerative joint disease of your hip);
- acute gouty arthritis (a form of arthritis in which crystals build up in your joints);
- musculoskeletal disorders (such as bursitis, tendonitis, synovitis, tenosynovitis, capsulitis of the shoulder, sprains and strains);
- low back pain;
- fever;
- period pain;
- pain, inflammation, swelling and difficulty opening your mouth following dental surgical procedures.

2. What you need to know before you take FLAMARET

Do not take FLAMARET

- if you are hypersensitive (allergic) to indomethacin, aspirin or to any of the ingredients of FLAMARET (listed in section 6),

Applicant: Unimed Healthcare (Pty) Ltd

Product name: FLAMARET

Dosage Form: Capsules

- if you previously suffered from any of the following after taking aspirin or other NSAIDs:
 - asthma attack (wheezing, chest tightness, breathlessness);
 - skin hives (skin rash/raised red patches on your skin with severe itching);
 - runny nose (rhinitis);
 - nasal polyps (nasal blockage due to swellings in the linings of your nose).
- if you are taking a medicine called diflunisal for pain, swelling, stiffness or joint pain;
- if you are operating machinery;
- if you suffer from any psychiatric disorder, epilepsy (fits) or you have been diagnosed with Parkinsonism (trouble moving or walking, stiffness, tremor, shakiness);
- if you have severe liver and/or kidney failure;
- if you have a peptic ulcer (sore in your stomach or duodenum) or you suffer from bleeding in your stomach, or have had (history of) peptic ulcers, stomach bleeding or bursting of an ulcer (perforation) after taking NSAIDs, including FLAMARET;
- if you have inflammation of your stomach and/or intestines (gastritis, regional enteritis, ulcerative colitis) or a history of recurring ulcers (sores) in your stomach or intestines;
- if you currently have or previously had stomach and/or intestinal lesions, including ulcers, bleeding or perforations;
- if you have previously experienced an allergic reaction (sensitivity) that caused swelling of your face and mouth (angioedema) after taking NSAIDs and/or aspirin;
- if you are having heart surgery (for narrowed or blocked arteries), since FLAMARET should not be used to treat pain during such an operation;
- if you have a heart condition such as heart failure or ischaemic heart disease, you have suffered a stroke, or you suffer from peripheral arterial disease (a condition in which narrowed arteries reduce blood flow to your arms or legs);
- if you are pregnant or breastfeeding your baby (see **Pregnancy, breastfeeding and fertility**).

Applicant: Unimed Healthcare (Pty) Ltd
Product name: FLAMARET
Dosage Form: Capsules

The safety of FLAMARET in children has not been established.

Warnings and precautions

Take special care with FLAMARET:

FLAMARET may lead to serious heart and/or blood vessel problems, stomach and/or intestinal problems, or skin reactions which lead to death.

If you are taking FLAMARET for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harm to the kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).

- use the lowest effective dose for the shortest period necessary to control symptoms;
- if you are taking other NSAIDs, including cyclooxygenase-2-selective inhibitors (used to treat pain and inflammation);
- if you have any heart, liver or kidney problems. Your liver and/or kidney function should be closely monitored by your doctor;
- if you have a bleeding disorder;
- if you have high blood pressure, as FLAMARET may cause fluid retention and swelling, and worsen the condition;
- if you are taking a diuretic (water tablet) (used reduce water retention in your body);
- if you have any risk factors for heart disease, such as high blood pressure, high cholesterol levels, diabetes (high blood sugar levels) or if you are a smoker;
- if you have an infection, as FLAMARET may mask the signs and symptoms of an infection (e.g. fever). Tell your doctor as soon as possible in order to receive the correct treatment for the infection;

Applicant: Unimed Healthcare (Pty) Ltd

Product name: FLAMARET

Dosage Form: Capsules

- if you experience any difficulties with your eyes while taking FLAMARET. If you have rheumatoid arthritis your doctor may want to examine your eyes at intervals during your treatment with FLAMARET. You should see your doctor if you notice any change in your vision;
- if you are an elderly patient, you may be more likely to experience the side effects of FLAMARET;
- if you suffer from asthma;
- if you develop a fever, severe skin rash or skin reaction, swollen glands, blistering of the skin, mouth or eyes, scaling of the skin, or any unusual reaction such as facial swelling when starting treatment with FLAMARET, stop taking FLAMARET and tell your doctor immediately. These serious events may occur without warning and may be fatal. They include DRESS (drug reaction with eosinophilia and systemic symptoms), exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis (TEN);
- if you have difficulty in ovulation and fertility or becoming pregnant;
- if you experience any symptoms of either stomach ulcer or bleeding while taking FLAMARET, stop taking FLAMARET and consult your doctor immediately;
- if you are taking other medicines which could increase your risk for ulcers or bleeding, such as corticosteroids, anticoagulants or antiplatelet medicines (used to thin blood), such as warfarin and aspirin, and selective serotonin reuptake inhibitors (SSRIs) (used to treat depression);
- if you experience high levels of potassium in your blood (hyperkalaemia), anaemia or any liver problems while taking FLAMARET;
- if you just had an operation as FLAMARET can increase your bleeding time;
- if you have been taking FLAMARET for a long time and have frequent headaches, you should stop taking FLAMARET and tell your doctor;

Applicant: Unimed Healthcare (Pty) Ltd

Product name: FLAMARET

Dosage Form: Capsules

- if you experience headaches, dizziness or light-headedness while taking FLAMARET, you may need to reduce the dose and if your headache continues despite the dose reduction, stop taking FLAMARET;
- do not use aspirin as a preventative treatment for heart disease;
- if you suffer from systemic lupus erythematosus (SLE), an autoimmune disorder or mixed connective tissue disorders
- if you are taking other medicines which could increase your risk for ulcers or bleeding, such as corticosteroids (used to treat inflamed areas of your body), anticoagulants or antiplatelet medicines (used to thin your blood), such as warfarin and aspirin, and selective serotonin reuptake inhibitors (SSRIs) (used to treat depression);

Paediatric population

The safe use of FLAMARET in children has not been established. Children should not take FLAMARET.

Other medicines and FLAMARET

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking or have been given the following medicines as they are known to interact with FLAMARET:

- aspirin or other salicylates;
- other nonsteroidal anti-inflammatory drugs (NSAIDs), including diflunisal. Diflunisal should not be taken with FLAMARET (see **Do not take FLAMARET**);
- medicines used to treat high blood pressure such as diuretics or water tablets (e.g. furosemide and triamterene), angiotensin-converting enzyme (ACE) inhibitors,

Applicant: Unimed Healthcare (Pty) Ltd

Product name: FLAMARET

Dosage Form: Capsules

angiotensin-II antagonists, alpha-blockers or beta-blockers. Triamterene and FLAMARET should not be taken together;

- certain antacids used to relieve heartburn, indigestion or an upset stomach;
- anticoagulants such as warfarin, used to prevent blood clots;
- antiplatelet medicines used to thin your blood;
- antidepressants used to treat depression and mood disorders, such as selective serotonin reuptake inhibitors (SSRIs);
- antidiabetic medicines, such as sulfonylureas, used to treat high blood sugar levels;
- probenecid used to treat gout;
- methotrexate a medicine used to treat cancer, severe skin disease and rheumatoid arthritis;
- ciclosporin or tacrolimus, calcineurin inhibitors or immunosuppressive medicines, medicines used to prevent the body from rejecting a recent organ or bone marrow transplant;
- lithium used to treat mood disorders;
- antipsychotics such as haloperidol, used to treat mental health conditions;
- antiviral medicines used to treat viral infections such as HIV;
- digoxin used to treat heart failure and a fast heartbeat;
- phenylpropanolamine found in over-the-counter cold relief preparations to provide relief for a blocked nose;
- corticosteroids used to treat inflammation;
- desmopressin medicine used for the treatment of excessive urine conditions including bedwetting, nocturia and diabetes insipidus;
- mifepristone treatment used in emergency for termination of pregnancy in early stages;
- quinolone antibiotics used to treat certain bacterial infections;

Applicant: Unimed Healthcare (Pty) Ltd

Product name: FLAMARET

Dosage Form: Capsules

- muscle relaxants such as baclofen, used to relieve muscle spasms;
- pentoxifylline medicine used to improve blood flow;
- tiludronic acid used to treat Pagets disease (broken and deformed bones and pain in the affected area);
- laboratory tests can result in false-negative results.

Taking FLAMARET with food and drink

It is recommended that FLAMARET be taken with food, milk or an antacid to reduce potential side effects.

Pregnancy and 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 health care provider for advice before taking FLAMARET.

Do not take FLAMARET if you are pregnant or breastfeeding your baby (see **Do not take FLAMARET**).

Driving and using machines

FLAMARET may cause visual disturbances, dizziness, drowsiness, and headaches and affect your ability to drive a vehicle or use machinery. You should not take FLAMARET if you operate machinery.

FLAMARET contains lactose monohydrate

Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take FLAMARET.

Applicant: Unimed Healthcare (Pty) Ltd
Product name: FLAMARET
Dosage Form: Capsules

3. How to take FLAMARET

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

Always take FLAMARET exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended dosage of FLAMARET is 50 mg to 200 mg daily in divided doses. Do not exceed 200 mg daily of FLAMARET capsules.

Use the lowest effective dose for the shortest possible duration necessary to control symptoms, as this may help to reduce side effects.

The dose depends on the medical condition which is being treated. Your doctor will let you know how much you should take.

Your doctor will tell you how long your treatment with FLAMARET will last. If you have the impression that the effect of FLAMARET is too strong or too weak, tell your doctor or pharmacist.

If you take more FLAMARET than you should

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

Symptoms of overdosage include headache, nausea, vomiting, epigastric pain, gastrointestinal bleeding, runny tummy, disorientation, excitation, coma, drowsiness, dizziness, ringing of your ears, fainting, occasional convulsions, abdominal pain, loss of appetite, restlessness and agitation. Significant poisoning kidney injury and liver damage are possible.

If you forget to take FLAMARET

Applicant: Unimed Healthcare (Pty) Ltd
Product name: FLAMARET
Dosage Form: Capsules

Take it when you remember and carry on as before unless it is time for the next dose. Do not take a double dose to make up for forgotten individual doses.

If you stop taking FLAMARET

Do not stop taking FLAMARET without talking to your doctor first, because you may experience a worsening of your condition and unpleasant side effects.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

FLAMARET can have side effects.

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

If any of the following happens, stop taking FLAMARET 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 serious allergic reaction known as Stevens Johnson Syndrome;
- eruption of lesions on the skin known as erythema multiforme;
- fever, flu-like symptoms, a painful red rash (may include purplish spots) that spreads, and blisters follows where the top part of the skin dies and peels off known as toxic epidermal necrolysis (TEN).

Applicant: Unimed Healthcare (Pty) Ltd
Product name: FLAMARET
Dosage Form: Capsules

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to FLAMARET. You may need urgent medical attention or hospitalisation.

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

- necrotising fasciitis (NF) is a rare but fatal rapidly progressive soft tissue infection, which is characterised by widespread necrosis of the superficial fascia and the subcutaneous fat;
- blood disorders that can cause you to bleed or bruise easily;
- constriction of the air passages as in asthma;
- coma;
- aseptic meningitis especially in patients with existing autoimmune disorders, such as systemic lupus erythematosus or mixed connective tissue disease (symptoms include stiff neck, headache, nausea, vomiting, fever or disorientation);
- seizures/fit;
- pancreatitis which is inflammation of pancreas;
- stroke (loss of sensation in one side of the body, difficulty speaking or moving);
- heart attack, heart failure or chest pain;
- changes in the way your heart beats, beating faster than normal or skipping a beat;
- yellowing of your skin and eyes, dark urine, and tiredness which may be symptoms of liver problems, including jaundice or hepatitis;
- pulmonary oedema (fluid accumulation in the lungs) which may cause respiratory distress or cardiac arrest due to hypoxia;

Applicant: Unimed Healthcare (Pty) Ltd

Product name: FLAMARET

Dosage Form: Capsules

- pulmonary eosinophilia the infiltration of eosinophils into the lung compartments constituting airways, interstitium, and alveoli, increased eosinophils in the lungs presents with chest pain, dry cough, fever;
- blood clot in your veins causing inflammation in the affected areas;
- stomach ulcer, bleeding or perforation (include stomach pain, nausea, vomiting, dark stools, unexplained weight loss);
- dark tarry stools (melaena) indicating bleeding in the gastrointestinal tract;
- cholestasis which is the blockage of flow of bile from the liver with symptoms such as severe pain in the stomach and back;
- kidney problems such as less urine than normal, blood in your urine, frequent urination, increase in blood urea levels indicating that your kidneys are not working well;
- exacerbation of colitis and Crohn's disease.

These are all very serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- confusion, feeling anxious (anxiety), a state in which one's thoughts and feelings seem unreal or not to belong to oneself;
- psychotic episodes, mental disorders and aggravation of these disorders;
- headache, dizziness and light-headedness;
- inflammation of the optic nerve (nerve in your eye);
- ringing in your ears (tinnitus);
- redness of the skin, inflammation of small blood vessels, increase sensitivity of your skin to light.

Less frequent side effects

Applicant: Unimed Healthcare (Pty) Ltd

Product name: FLAMARET

Dosage Form: Capsules

- increase in blood sugar levels, excess sugar in your urine;
- increase in potassium levels in your blood;
- vertigo (loss of balance), feeling tired, drowsiness, listlessness, coma, fitting;
- involuntary muscle movement; muscle weakness, feeling of numbness in fingers and toes;
- parkinsonism (neurological disorder causing movement problems such as tremors, slow movement and stiffness);
- difficulty speaking;
- blurred vision, double vision, pain in your eyes, disturbances of your eyesight;
- flushing;
- nosebleeds;
- feeling like you need to pass stool even though your bowels are empty, anal bleeding, burning, pain, discomfort, itching, irritation;
- loss of appetite.

Frequency unknown:

- feeling depressed, inability to sleep;
- weight gain;
- hallucinations;
- retinal disturbances, deposits in cornea of your eye (feeling something in your eye, watery eyes, pain);
- problem with your hearing, deafness;
- high blood pressure, low blood pressure;
- nausea, vomiting, runny tummy, passing wind, difficulty passing stool, indigestion, abdominal pain;
- hair loss, sweating;

Applicant: Unimed Healthcare (Pty) Ltd

Product name: FLAMARET

Dosage Form: Capsules

- aggravation of psoriasis (scales and red patches that are itchy and sometimes painful);
- increase protein in your urine;
- muscle weakness, acceleration of cartilage degeneration;
- breast changes (include tenderness and enlargement, increase of breast tissue in men);
- vaginal bleeding.

FLAMARET, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness.

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

5. How to store FLAMARET

- Store in a dry place at or below 25 °C. Protect from light
- Store in the original package.

Applicant: Unimed Healthcare (Pty) Ltd

Product name: FLAMARET

Dosage Form: Capsules

- Do not use after the expiry date stated on the pack.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
- Store all medicines out of reach of children.

6. Contents of the pack and other information

What FLAMARET contains

- The active substance is indomethacin. Each tablet contains 25 mg indomethacin.
- The other ingredients are: maize starch, sodium starch glycollate, microcrystalline cellulose, lactose monohydrate.

What FLAMARET looks like and contents of the pack

Size 3 yellow gelatine capsules containing a white to off-white powder imprinted with 'GS'.

Round white polypropylene securitainer containing 100 and 500 capsules.

Holder of Certificate of Registration

Unimed Healthcare (Pty) Ltd

Corner Birch Road & Bluegum Avenue

Anchorville,

Lenasia

1827, South Africa

This leaflet was last revised in

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