SPEDIFEN® 400MG GRANULES

Ibuprofen (as L-arginine salt) 400mg

What is in this leaflet

What Spedifen® is used for

- Pain: headache including migraine, toothache, dysmenorrhea (period pain), neuralgia (nerve pain), inflammation, swelling and pain in the joints and muscles, episiotomy and after-birth pain, pain following tooth extraction, post-operative pain, soft tissues injuries and traumatisms.
- Rheumatic inflammatory diseases: rheumatoid arthritis (systemic inflammatory disorder that affects joints), ankylosing spondylitis (chronic inflammatory disease of the skeleton), Still's Disease.
- Degenerative rheumatic disease: osteoarthritis (joint disease characterized by joint pain and stiffness of neck, back and lower back, hips, knees, five or more joints, etc)
- Non-articular rheumatic conditions: inflammation of tendon, fibrous tissue, bursa, spinal nerves, muscle pain, lower back pain, frozen shoulder, pain of the leg/ back.

How Spedifen® works

Spedifen® contains the active ingredient ibuprofen in the form of arginine salt. Ibuprofen is an anti-inflammatory drug with analgesic, antipyretic and anti-rheumatic activities. It works by reducing prostaglandin that cause inflammation and pain in the body.

Before you use Spedifen®

When you must not use it

- If you are
  - hypersensitive to ibuprofen or one of the ingredients in this product.
  - in the last trimester of pregnancy
  - breastfeeding
  - with the treatment of postoperative pain following coronary bypass surgery (incl. use of a heart-lung machine)
- If you have
  - a history of breathing difficulty or allergy-like skin reactions after taking acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs)
  - a history of gastrointestinal bleeding or perforation after taking other non-steroidal anti-inflammatory drugs (NSAIDs)
  - active stomach/intestinal ulcer or bleeding
  - inflammatory bowel disease (such as Crohn's disease, colitis ulcerosa).
  - bleeding in the brain
  - an increased tendency to bleeding
  - severe impaired liver function (cirrhosis and ascites).
  - severe kidney problems (creatinine clearance <30 ml/min)
  - severe heart failure (NYHA III-IV)
  - rare hereditary problems of fructose intolerance, glucose-galactose, malabsorption or sucrase-isomaltase insufficiency.

Before you start to use it

Always ask your doctor or pharmacist before using this product if you have any doubts.

If you are pregnant or trying to pregnant, seek advices from your doctor or pharmacist before taking this medicine.

Tell your doctor if you have risk factors for heart disease (eg: high blood pressure, diabetes, high blood lipid levels, smoking). Your doctor will decide whether you can use Spedifen® as long term treatment.

Taking other medicines

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Other non-steroidal anti-inflammatory drugs (NSAIDs) including COX-2 inhibitors and/or glucocorticoids and alcohol
- Acetylsalicylic acid, medicine for the treatment of pain and fever
- Probenecid, Sulfinpyrazone, medicines used to treat gout
- Oral anticoagulants, blood thinning agents
- Platelet aggregation inhibitors and selective serotonin reuptake inhibitors
- Anti-diabetic medicinal products
- Aminoglycosides, antibiotic used to treat bacterial infections
- Diuretics, medicine to increase urination
- Anti-hypertensive agents, medicine to treat high blood pressure
- Histamine H2-receptor antagonists, medicine to treat conditions that cause excess stomach acid.
- Digoxin, medicine for heart disease
- Phenytoin, medicine used to treat epilepsy and prevent seizures
- Lithium, medicine for depression
- Methotrexate, medicine used to treat rheumatoid arthritis, as well as some types of cancer
- Zidovudine, medicine that treat HIV/ AIDS
- Tacrolimus, used as an immunosuppressant
- Voriconazole and Fluconazole, medicines that treat fungal infections
- Mifepristone, medicines used for abortion during pregnancy
- Baclofen, medicines that treat muscle symptoms
- Quinolones, medicines for infection
- Cyclosporine, used as an immunosuppressant
- Herbal extracts, Ginkgo biloba

How to use Spedifen®

How much to use

Adults: Initial dose: 400 mg sachets:2-4 /day according to medical advice. The maximum daily dose should not exceed 1600mg.

In elderly the posology must be carefully assessed by the physician since a reduction of the above mentioned dosage may be needed.

When to use it
The administration of the first daily dose on awakening (with food). The following daily doses should be taken during or after meals.

How long to use it
Take this medicine exactly as your doctor has told you.

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen.

If you forget to use it
Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

If you use too much (overdose)
Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Prolonged use at doses higher than recommended may cause severe hypokalaemia (low levels of potassium in your blood).

Common symptoms of overdose include nausea, vomiting, dizziness, drowsiness, tremors (involuntary shaking of one or more parts of your body).
Less common are headache, ringing in the ears, uncoordinated movement, a fast heart rate, constriction of the pupil and reversible increases in transaminases, bilirubin, and thrombocytopenia.
Severe symptoms are rare and include unconsciousness (coma), metabolic acidosis (condition that occurs when the body produces excessive quantities of acid), seizures, and acute renal failure; also, apnea (slow breathing or short period of time without breathing) in children < 2 years.

While you are using it
Things you must do
- You must strictly comply with your doctor's prescription or your pharmacist's advice.
- You must dissolve the granules in a glass of water (not carbonated mineral water) and take immediately.
- If you feel that the medicine is too weak or too strong, you must tell your doctor or pharmacist.

Things you must not do
- Do not change the prescribed dosage on your own.
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give this medicine to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of
- Stomach/intestinal ulcer, bleeding or perforation may occur during treatment with Spedifen®. Stop taking Spedifen® if any of the above happen.
- Be cautious when taking Spedifen® if you have
  - uncontrolled high blood pressure, heart failure (NYHA II), heart disease and/or stroke. High doses (2,400 mg/day) should be avoided.
  - risk factors for cardiovascular events (e.g. high blood pressure, high cholesterol, diabetes mellitus and smoking).
  - systemic lupus erythematosus (SLE, an autoimmune disease) or collagenosis (a rare skin disorder), due to an increased risk of inflammation of the meninges (the protective membranes covering the brain and spinal cord).
  - impaired heart or kidney function as it can cause an increase in blood pressure and / or fluid retention (oedema).
  - an infection as ibuprofen may mask its symptoms when relieving fever or pain. Please consult a doctor if symptoms persist or worsen.
  - a history of asthma, chronic nasal inflammation or allergy as ibuprofen may cause breathing difficulties, hives or swelling of the face or throat.
  - Prior history of serious GI events and other risk factors associated with peptic ulcer disease (e.g. alcoholism, smoking and corticosteroid therapy)
- Severe skin reactions have been reported in association with ibuprofen treatment. Stop taking Spedifen® and seek medical attention immediately if you develop any skin rash, mucous membrane lesions, blisters or other signs of allergy within the first month of treatment, as these could be early signs of a very serious skin reaction.
- Allergic reactions to this medicine, such as trouble breathing, swelling of the face or neck (angioedema), and chest pain (Kounis syndrome), have been reported with ibuprofen. If you experience any of these symptoms, stop using Spedifen® immediately and contact a doctor right away.
- Discontinue the treatment and seek for ophthalmologic examination if you are suffering from visual disturbances during ibuprofen therapy.
- NSAIDs may cause an increase in liver function test results.
- Spedifen® may affect the results of diagnostic tests (eg: bleeding time, serum glucose concentration, creatinine clearance, haematocrit or haemoglobin, Blood Urea Nitrogen (BUN), serum creatinine concentrations and kaliemia)
- Each Spedifen® 400mg granules sachet contains 60mg aspartame, which is a source of phenylalanine. If you have phenylketonuria (a rare genetic disorder that causes a build-up of phenylalanine), consuming this medicine may be harmful to you.
- Each Spedifen® 400mg granules sachet contains 57 mg sodium per sachet, equivalent to 2.85% of the WHO's recommended maximum daily intake of 2 g sodium for an adult.

- Each Spedifen® 400mg granules sachet contains sucrose. If you have an intolerance to certain sugars, contact your doctor before taking this medicine.
- Be careful when driving or operating machinery due to the possible side effects of Spedifen®.

Side effects
The following undesirable effects have been observed:

Blood and lymphatic system disorders
Rare: Haematological effects such as low granulocytes count (a type of white blood cell), low platelet count, low neutrophils count (a type of white blood cell), aplastic anaemia, haemolytic anaemia.
Unknown: Anaemia (low red blood cell count).

Immune system disorders
Uncommon: Allergic reaction.
Rare: Lupus erythematosus syndrome, inflammation of the meninges in patients suffering from an autoimmune disease, such as lupus erythematosus, autoimmune haemolytic anaemia, anaphylaxis (a serious, life-threatening allergic reaction).
Unknown: Anaphylactic shock (life-threatening allergic reaction).

Psychiatric disorders
Uncommon to common: Depression, anxiety, confusional state.
Very rare: Psychotic state (abnormal thinking and perceptions).

Nervous system disorders
Common: Headache, dizziness.
Uncommon to common: Central nervous system side effects such as impaired responsiveness (especially if you are taking alcohol), sleepiness.
Rare: Abnormal sensation of the skin (tingling, burning, numbness).

Eye disorders
Uncommon to common: Visual disturbances, which are usually reversible when treatment is discontinued.
Rare: Damage to the optic nerve, inflammation of the optic nerve.
Unknown: Swelling of the optic nerve.

Ear and labyrinth disorders
Uncommon to common: Ear disorder, hearing difficulties.

Cardiac disorders
Unknown: Heart failure, Kounis syndrome (an allergic reaction that causes cardiovascular symptoms).

Vascular disorders
Unknown: Blood clot in artery, high blood pressure, low blood pressure.

Respiratory, thoracic and mediastinal disorders
Uncommon: Tightness of airways, asthma, shortness of breath.
Rare: Risk of build-up of fluid in the lung in patients with heart failure.
Unknown: Throat irritation.

Gastrointestinal disorders
Very common: Indigestion, diarrhoea.
Common: Gastrointestinal side effects such as nausea, bloating, heartburn, abdominal pain, anorexia (eating disorder), constipation, passing wind, vomiting, inflammation and erosion of the stomach lining, bloody stools (resulting in anaemia).
Uncommon: Stomach ulcer, gastrointestinal bleeding, black tarry stools, inflammation of the stomach lining.
Rare: Ulcerations or perforations in the gastrointestinal tract with bleeding, vomiting blood, mouth ulcer, worsening of colitis or Crohn's disease.

Hepatobiliary disorders
Rare: Liver disorder, liver failure.
Unknown: Liver injury, hepatitis, yellowing of the skin and/or eyes (jaundice).

Skin and subcutaneous tissue disorders
Common: Hypersensitivity reactions such as urticaria, purpura, itching, rash.
Uncommon: Skin swelling (angioedema).
Very rare: Bullous rashes, erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, photosensitivity reaction.
Unknown: Aggravation of skin reactions, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), acute generalised exanthematous pustulosis (AGEP).

Kidney and urinary tract diseases
Rare: Blood in the urine, kidney disorder, kidney dysfunction with water retention in the body.
Very rare: Acute kidney failure.

Systemic disorders and conditions related to the site of administration
Unknown: Swelling (oedema).

Investigations
Rare: Abnormal liver function test.
Unknown: Abnormal kidney function test.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Spedifen®
Storage
Store at temperature not exceeding 30°C, away from moisture and out of reach of children.

Disposal
Medicines should not be disposed of via wastewater or household waste. Ask your doctor or pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description
What it looks like
Spedifen® 400mg granules sachets containing white granules with a characteristic apricot odour.

Ingredients
Active ingredient: Ibuprofen (as L-arginine salt)
Inactive ingredients: L-arginine, Aspartame (E951), Saccharin Sodium (E954), Sucrose, Apricot Flavouring, Sodium Bicarbonate

MAL number
MAL20013750AZ

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