PACKAGE LEAFLET: INFORMATION FOR THE USER

Ibuprofen Algik 20 mg/ml Oral Suspension
Ibuprofen

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- Ask your doctor in case of worsening or persistence of symptoms.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days (fever) or 7 days (pain).

What is in this leaflet:

1. What Ibuprofen Algik is and what it is used for

Pharmacotherapeutic group
Anti-inflammatory and anti-rheumatic products, non-steroids; propionic acid derivatives

This medicine is available as an oral solution for oral use.
The active substance is ibuprofen, which is a propionic acid derivative with anti-inflammatory, analgesic and antipyretic action.

Ibuprofen Algik is indicated in:
- symptomatology associated with flu and colds (fever and pain);
- odynophagia and pharyngitis;
- mild to moderate migraine (headaches);
- mild to moderate muscular pain;
- bruises;
- fever (not more than 3 days);
- primary dysmenorrhea (period pain).

2. What you need to know before you take Ibuprofen Algik

Do not take Ibuprofen Algik:

- If you are allergic to ibuprofen or any of the other ingredients of this medicine (listed in section 6).
- If you have or ever had asthma, rhinitis, rash, angioneurotic oedema or bronchospasm associated to the use of acetylsalicylic acid or other non-steroidal anti-inflammatory drugs;
- If you suffer or have a history of gastrointestinal bleeding or perforation related with previous NSAIDs therapeutic;
- If you suffer from renal failure, in case of high doses of ibuprofen (higher than 1600 mg/day);
- If you suffer or had suffered from recurring peptic ulcer/bleeding (two or more episodes distinct from ulceration or diagnosed bleeding);
- If you have Severe Heart Failure;
- If you have alterations in coagulation;
- If you have intolerance to some sugars;
- During the last trimester of pregnancy.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ibuprofen Algik.

Signs of an allergic reaction to this medicine, including breathing problems, swelling of the face and neck region (angioedema), chest pain have been reported with ibuprofen. Stop immediately Ibuprofen Algik and contact immediately your doctor or medical emergencies if you notice any of these signs.

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

In the initiation of the treatment, ibuprofen, as other NSAIDs should be administered with caution in patient with considerable dehydration.

The administration of Ibuprofen Algik may reduce the female fertility and it is not recommended to women that are planning to have a baby. In women that have difficulty in becoming pregnant or in which the possibility of infertility is being investigated the interruption of Ibuprofen Algik shall be considered.

<u>Cardiovascular effects:</u>

Ibuprofen should be administered with caution in patients with a history of heart failure or hypertension, since there have been reports of oedemas associated to ibuprofen administration.

Anti-inflammatory/pain-killer medicines like ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

You should talk to your doctor or pharmacist about your treatment before taking Ibuprofen Algik if:

- You have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including 'mini-stroke' or transient ischaemic attack "TIA").
- You have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.
- You have an infection - please see heading "Infections" below.

Infections

Ibuprofen Algik may hide signs of infections such as fever and pain. It is therefore possible that Ibuprofen Algik may delay appropriate treatment of infection, which may lead to an increased risk of complications. This has been observed in pneumonia caused by bacteria and bacterial skin infections related to chickenpox. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.

Cutaneous reactions

Serious skin reactions including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with ibuprofen treatment. Stop taking Ibuprofen Algik and seek medical attention immediately, if you noticeany of the symptoms related to these serious skin reactions described in section 4.

Gastrointestinal effects:

Ibuprofen should be used with caution in patients with a history of gastrointestinal disease.

For all NSAIDs have been reported cases of bleeding, ulceration and gastrointestinal perforation potentially fatal, in several phases of treatment, associated or not with warning symptoms or history of serious gastrointestinal events. The risk of bleeding, ulceration or perforation is higher with increased doses of NSAIDs, in patients with history of peptic ulcer, especially if associated with bleeding or perforation and in elderly patients. In these conditions patients should be instructed to inform their assistant doctor about the occurrence of abdominal symptoms and digestive bleeding, especially in the initial phases of treatment. In these patients the treatment should be initiated with a minimum effective dose. Co-administration of protective agents (e.g. misoprostol or proton pump inhibitors) shall be considered in these patients, as well as those who need to take simultaneously acetylsalicylic acid in lower doses, or other medicines susceptible to increase the risk of ulcer or bleeding, as corticosteroids, anticoagulants (as warfarin), selective serotonin reuptake inhibitors or platelet aggregation inhibitors such as acetylsalicylic acid.

In case of gastrointestinal bleeding or ulceration in patients taking ibuprofen the treatment should be discontinued. NSAIDs should be administered with caution in patients with

history of inflammatory bowel disease (ulcerative colitis, Crohn's disease), since these situations can be exacerbated.

Concomitant use of ibuprofen with corticosteroids or other NSAIDs may increase the risk of ulceration and gastrointestinal bleeding.

As with the other products containing NSAIDs, concomitant administration of ibuprofen with acetylsalicylic acid is not recommended due to a potential increase of adverse effects.

The concomitant administration of Ibuprofen Algik with other NSAIDs, including selective ciclooxigenase-2 inhibitors, should be avoided.

The elderly have an increased frequency of adverse reactions with NSAIDs, especially of gastrointestinal bleedings and perforation that may be fatal.

Renal and urinary effects:
As with other NSAIDs, the long-term administration of ibuprofen has resulted in renal papillary necrosis and other pathologic renal reactions. Cases of renal toxicity have also been seen in patients in whom prostaglandins have a compensatory role in the maintenance of renal perfusion. In these patients, the administration of NSAIDs may cause a decrease in dose-dependent prostaglandins formation and, secondarily, in renal blood flow, who may precipitate an evident renal decompensation. Patients at greatest risk for this reaction are those with renal dysfunction, heart failure, hepatic dysfunction those who take diuretics and ACE inhibitors and the elderly patients. Discontinuation of therapy with NSAIDs is generally followed by a recovery to a pre-treatment state.

In patients with renal, hepatic or cardiac failure predisposed to hydrosaline retention, caution should be exercised since the use of NSAIDs may result in deterioration of renal function. In these patients the dose should be as low as possible and renal function should be monitored.

Effects on respiratory system:
In asthmatic patients or with a previous history of bronchial asthma, special caution should be exercised since ibuprofen may trigger a clinical picture of bronchospasm in those patients.

Hepatic effects:
Hepatic function should be carefully monitored in patients treated with ibuprofen presenting symptoms compatible with hepatic lesion (anorexia, nausea, vomiting, jaundice) and/or developing hepatic function changes (transaminases, bilirubin, alkaline phosphatase, gamma-GT). In the presence of values higher than 2 times the upper normal value, the medicine should be discontinued immediately and an investigation should be initiated in order to clarify the situation. The re-exposure to ibuprofen should be avoided.

Ibuprofen, as other NSAIDs, may inhibit platelets aggregation and extend the bleeding time. Caution is recommended when administering ibuprofen concomitantly with oral anticoagulants.

Immune system effects:
Ibuprofen should be used with caution in patients with systemic lupus erythematosus or other autoimmune diseases, due to the risk of aseptic meningitis and/or renal failure.

Eye effects:
Patients presenting vision disorders during the treatment with ibuprofen should suspend the therapy and should be submitted to an ophthalmological examination.

Other medicines and Ibuprofen Algik
Ibuprofen Algik may affect or be affected by some other medicines. For example:

- Medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine).
- Medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan).

Some other medicines may also affect or be affected by the treatment of Ibuprofen Algik. You should therefore always seek the advice of your doctor or pharmacist before you use Ibuprofen Algik with other medicines.

NSAIDs may reduce the renal clearance of lithium resulting in increased plasma levels and toxicity. If ibuprofen is prescribed to a patient on therapy with lithium, a close monitoring of lithium levels should be performed.

Co-administration of ibuprofen and methotrexate can increase the plasma level of the latter and, consequently, their toxic effects. NSAIDs can exacerbate heart failure, reduce glomerular filtration rate and increase plasma levels of cardiac glycosides.

The administration of NSAIDs and cyclosporine have an increased risk of nephrotoxicity.

The action of certain medicines such as anticoagulants (that prevent blood clotting) (e.g. acetylsalicylic acid, warfarin, ticlopidine.), some medicines for high blood pressure (ACE-inhibitors such as captopril, beta-blockers, angiotensin-II receptor antagonists), among other medicines may affect or be affected by ibuprofen treatment. Consequently, you should always get medical advice before taking ibuprofen with other medicines.

Concomitant administration with oral anticoagulants or antiplatelet agents, including acetylsalicylic acid, can produce additive effects.
In literature there are references to the possibility of acute renal failure occur with concomitant use of ACE-inhibitors. Ibuprofen Algik, similarly to what happens with other non-steroidal anti-inflammatory steroids can interact with other drugs, namely antihypertensives (diuretics, blockers, converting-enzyme inhibitors). Once ibuprofen, like

other anti-inflammatory drugs, has antiplatelet effect, its use may demand the reduction of oral hypocoagulant doses.

Anticoagulants: NSAIDs may increase the effects of anticoagulants, such as warfarin.

Diuretics, angiotensin-converting-enzyme inhibitors (ACE-inhibitors) and angiotensin-II receptor antagonists: Nonsteroidal anti-inflammatory drugs may reduce the efficacy of diuretics as well as other antihypertensive medicines.
In some patients with decreased renal function, concomitant administration of ibuprofen with ACE-inhibitors and angiotensin-II receptor antagonists may cause a worsening of renal function.

Corticosteroids: increased risk of gastrointestinal ulceration or bleeding.

Anti-platelet agents and selective serotonin reuptake inhibitors: increased risk of gastrointestinal bleeding.

Pregnancy, breast-feeding and fertility
Talk to your doctor or pharmacist before taking any medicine.

Do not take Ibuprofen Algik if you are in the last 3 months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take Ibuprofen Algik during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, Ibuprofen Algik can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

Administration of Ibuprofeno Algik is contraindicated during the third trimester of pregnancy.

Due to lack of clinical studies, the use of Ibuprofen Algik in breast-feeding women is not recommended.

Driving and using machines
Due to the possibility of occurrence of certain side effects such as dizziness and confusion after ibuprofen administration, the ability to drive and use machines may be conditioned.
Generally, ibuprofen does not affect the ability to drive or to use machines in single or short-term treatments.

Ibuprofen Algik contains glycerol, which can be harmful in high doses. It may cause headaches, stomach pains and diarrhoea.
Ibuprofen Algik also contains azorubine (E 122) as colorant. It may cause allergic-like reactions, including asthma especially in patients allergic to acetylsalicylic acid.
Ibuprofen Algik also contains maltitol liquid. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
Ibuprofen Algik contains 0.156 mmol (or 3.590 mg) sodium per ml. This information should be taken into consideration by patients on a controlled sodium diet.

3. How to take Ibuprofen Algik

Always take this medicine exactly as described in this leaflet or as your doctor has told you. Talk to your doctor or pharmacist if you are not sure.

The dose varies according to the patient, his/her age and his/her medical condition.
The daily recommended doses are as follows:

Children (20 mg/kg/day):

- Children from 6 months to 1 year:

½ measuring spoon (50 mg), 3 to 4 times per day, every 6 to 8 hours;

- Children from 1 to 6 years:

1 measuring spoon (100 mg), 3 to 4 times per day, every 6 to 8 hours;

- Children from 6 to 12 years:

2 measuring spoons (200 mg), 3 to 4 times per day, every 6 to 8 hours.

It should not be used in children under 6 months of age.

Adults:
Although ibuprofen 200, 400 or 600 is usually used in adults, when there is difficulty in swallowing, Ibuprofen Algik can be administered at a dose of 3 measuring spoons (5 ml), 4 times per day.

Renal failure:
Cautions should be exercised when a NSAIDs is administrated in patients with renal failure.
In patients with mild to moderate renal dysfunction the initial dose should be reduced.
Ibuprofen should not be administered in patients with severe renal failure. (see “Warnings and precautions”).

Use the lowest effective dose for the shortest time period necessary to control the symptoms. If you have an infection, consult a doctor without delay if symptoms (such as fever and pain) persist or worsen (see section 2).

Route of administration
Oral use.

Duration of average treatment
It varies according to the patient and his/her clinical situation.

If you take more Ibuprofen Algik than you should:
If you take more Ibuprofen Algik than you should or if your children take this medicine by accident, always contact a doctor or go to the nearest hospital to obtain an opinion of the risk and advice on the measures to take.
The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.
General common measures to other intoxication should be proceeded, such as gastric lavage and activated charcoal administration and special measures, such as administration of antacids (and/or H2 antagonists), proper hydration and correction of the acidosis (if any) with sodium bicarbonate.

If you forget to take Ibuprofen Algik:
Take the medicine as soon as possible. If it is almost time for the next dose, wait until then and continue normally. Do not take a double dose to make up for a dose that you forgot to take.

If you stop taking Ibuprofen Algik:
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Ibuprofen Algik can cause side effects although not everybody gets them.

Stop using ibuprofen and seek medical attention immediately if you notice any of the following symptoms:
• reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms [exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis].
• Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome).
• A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis)

Infections and infestations: Aseptic meningitis (fever or coma); Rhinitis.

Blood and lymphatic system disorders: Thrombocytopenia; Agranulocytosis; Eosinophilia; Coagulopathy (coagulation changes); Aplastic anaemia; Haemolytic anaemia; Neutropenia.

Immune System disorders: Anaphylactic reactions (anaphylaxis); Serum sickness (serum syndrome).

Metabolism and nutrition disorders: Acidosis; Fluid retention; Hypoglycaemia; Hyponatremia; Decreased appetite.

Psychiatric disorders: Hallucinations, Confusional state; Depression; Insomnia; Nervousness; Influence on the lability (emotional lability).

Nervous system disorders: Dizziness; Headache; Drowsiness; Paraesthesia; Benign intracranial hypertension (pseudotumor cerebri).

Eye disorders: Visual disturbance; Conjunctivitis; Diplopia; Chromatopsia (chromatic vision changes); Amblyopia; Cataracts; Optic neuritis; Scotomas.

Ear and labyrinth Disorders: Tinnitus; Vertigo; Hypoacusis (hearing impairment).

Cardiac disorders: Palpitations; Arrhythmias; Congestive heart failure (patients with marginal cardiac function); Sinus bradycardia; Sinus tachycardia.

Vascular disorders: Hypertension.

Respiratory, thoracic and mediastinal disorders: Asthma; Dyspnoea; Bronchospasm; Epistaxis; Eosinophilic pneumonia (pneumopathy to eosinophils).

Gastrointestinal disorders: Haematemesis; Gastrointestinal bleeding; Melaena; Nausea; Abdominal pain; Diarrhoea; Dyspepsia (heartburn); Gastrointestinal ulcer; Gastritis; Vomiting; Mouth ulceration (stomatitis ulcerative); Upper abdominal pain (epigastric pain); Constipation; Duodenal ulcer; Oesophagitis; Pancreatitis; Abdominal distension (fullness feeling sensation); Flatulence

Hepatobiliary disorders: Hepatitis; Jaundice; Cholestatic hepatitis (severe and sometimes fatal); Cytolytic hepatitis.

Skin and subcutaneous tissue disorders: Exanthema; Urticaria; Angioneurotic oedema; Stevens-Johnson syndrome; Pruritus; Bullous dermatitis (Vesicular-bullous eruptions); Rash maculo-papular (maculopapular-type cutaneous rash); Alopecia; Purpura; Erythema nodosum; Toxic epidermal necrolysis (Lyell syndrome); Erythema multiforme; Acne; Henoch-Schonlein purpura (vasculitis).

A severe skin reaction known as DRESS syndrome can occur. Symptoms of DRESS include: skin rash, fever, swelling of lymph nodes and an increase of eosinophils (a type of white blood cells).

Frequency "Not known"
A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Photosensitivity reaction (skin becomes sensitive to light). Stop using Ibuprofen Algik if you develop these symptoms and seek medical attention immediately. See also section 2.
Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

Renal and urinary disorders: Acute renal failure; Renal failure; Nephrotic syndrome; Haematuria; Dysuria; Renal papillary necrosis; Interstitial nephritis; Tubulointerstitial nephritis (acute tubulointerstitial nephropathy); Azotaemia; Polyuria; Chronic renal failure.

Reproductive system and breast disorders: Gynaecomastia; Menorrhagia.

General disorders and administration site conditions: Pyrexia (fever); Oedema.

Investigations: Alanine aminotransferase (ALT) increased; Aspartate aminotransferase (AST) increased; Blood alkaline phosphatase increased; Gamma-glutamyltransferase (γ-GT) increased; Creatinine clearance decreased; Haemoglobin decreased.

Side effects seen with NSAIDs:
Gastrointestinal: The most frequently observed adverse events are from gastrointestinal nature. It may occur, particularly in the elderly, peptic ulcers, gastrointestinal perforation or bleeding potentially fatal. Nausea, dyspepsia, vomiting, haematemesis, flatulence, abdominal pain, diarrhoea, constipation, melaena, aphthous stomatitis, exacerbation of colitis and Crohn's disease have been reported following administration of these drugs. Cases of gastritis have been observed less often.

Oedema, arterial hypertension, and heart failure in association with NSAIDs treatment have been reported.

Patients with uncontrolled arterial hypertension, uncontrolled failure, non-congestive heart failure, established ischaemic heart disease, peripheral arterial disease and/or cerebrovascular disease should only be treated with naproxen after careful consideration.
The same cautions should be taken before starting the long-term treatment of patients with cardiovascular risk factors (e.g.: arterial hypertension, hyperlipidaemia, diabetes mellitus e smoking habits).

Bullous reactions including Stevens-Johnson's syndrome and toxic epidermal necrolysis (very rare).

If any side effect becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly ADR Reporting Website www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ibuprofen Algik

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

The stability of the product does not change after opening the package since maintained under normal storage conditions.

Shake before use.
The double spoon and/or syringe must be removed, cleaned and dried after each use.

Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ibuprofen Algik contains

- The Active Substance is ibuprofen. Each 200 ml bottle contains 20 mg per ml of suspension.
- The other ingredients are: sodium benzoate (E 211), citric acid anhydrous, sodium citrate, saccharin sodium, sodium chloride, hypromellose, xanthan gum, liquid maltitol, strawberry aroma, colorant azorubine (E 122), glycerol and purified water.

What Ibuprofen Algik looks like and contents of the pack
It is a viscous suspension, pink coloured with a characteristic strawberry flavour. The suspension is contained in amber bottle sealed with safety cap (pilfer), accompanied by an

auxiliary device for medicine intake (measurer). The bottle is inserted in a printed cardboard package accompanied by the respective information leaflet.

Marketing Authorisation Holder and manufacturer

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