SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

GENERIC: Ibuprofen Oral Suspension BP 100 mg / 5ml

DESCRIPTION: Light orange coloured, homogeneous suspension with characteristic odour and sweet taste.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen 100 mg/5 ml

Excipients with known effect

Also contains sodium Methylhydroxybenzoate, sodium propylhydroxybenzoate.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

Oral Suspension

4. CLINICAL PARTICULARS

4.1.Therapeutic Indication:

Ibuprofen oral Suspension is indicated for its analgesic and anti-inflammatory effects in the treatment of rheumatoid arthritis (including juvenile rheumatoid arthritis or Still's disease), ankylosing spondylitis, osteoarthritis and other non-rheumatoid (seronegative) arthropathies.

In the treatment of non-articular rheumatic conditions, Ibuprofen Suspension is indicated in periarticular conditions such as frozen shoulder (capsulitis), bursitis, tendonitis, tenosynovitis and low back pain; Ibuprofen Suspension can also be used in soft tissue injuries such as sprains and strains.

Ibuprofen Suspension is also indicated for its analgesic effect in the relief of mild to moderate pain such as dysmenorrhoea, dental and post-operative pain and for symptomatic relief of headache, including migraine headache.

Ibuprofen oral suspension is indicated in short term use for the treatment of pyrexia in children over one year of age.

4.2.Posology and method of administration:

The recommended dosage of ibuprofen is 1200-1800 mg daily in divided doses. Some patients can be maintained on 600-1200 mg daily. Total daily dose should not exceed 2400mg.

Children: the daily dosage of ibuprofen is 20 mg/kg of body weight in divided doses. This can be achieved as follows:

1-2 years: one 2.5 ml spoonful (50 mg) three to four times in a day.

3-7 years: one 5 ml spoonful (100 mg) three to four times in a day.

8-12 years: two 5 ml spoonfuls (200 mg) three to four times in a day.

Not recommended for children weighing less than 7 kg. in juvenile rheumatoid arthritis, up to 40 mg/kg of body weight daily in divided doses may be taken.

Elderly: the elderly are at increased risk of serious consequences of adverse reactions if an NSAID is considered necessary, the lowes effective dose should be monitored regularly for GI bleeding during NSAID therapy. If rental of hepatic function is impaired, dosage should be assessed individually.

For oral administration, it is recommended that patients with sensitive stomachs take ibuprofen with food. If taken shortly after eating, the onset of action of ibuprofen may be delayed. To be taken preferably with or after food.

4.3.Contraindications:

Avoid in case of

- Pregnancy, 4 months
- Hypersensitivity to parabens
- Hypersensitivity to arylcorboxylic
- Hypersensitivity to non steroidal anti-inflmmatory
- Hypersensitivity to salicylates
- Asthama attack associated with aspirin
- Active peptic ulcer disease
- Severe renal impairment: creatinine clearance <30 ml/min
- Severe hepatic impairment
- Severe heart failure uncontrolled
- Lupus erythematosus
- Genetics of galactose intolerance
- Malansorption of glucose and galactose syndrome
- Lactase deficiency

Ibuprofen Suspension is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients.

Ibuprofen Suspension is contraindicated during the last trimester of pregnancy.

4.4.Warning and precautions for use

- Asthma: Patients with asthma associated with chronic rhinitis, chronic sinusitis with and / or nasal polyposis, may have an allergic reaction when taking aspirin and / or anti-inflammatory drugs, higher than the rest of the population.

The administration of this specialty can cause an asthma attack, especially in certain individuals allergic to aspirin or an NSAID (see Contraindications).

- Risk of gastrointestinal bleeding: The Gastrointestinal bleeding can occur at any time during treatment without necessarily warning signs or history. The relative risk increases in the elderly, low body weight, the patient undergoing anticoagulation or antiplatelet.

In case of gastrointestinal bleeding, discontinue treatment immediately.

- Risk of peptic ulcer: ulcers / perforation can occur at any time during treatment without necessarily warning signs or history. The relative risk increases in the elderly, frail, low body weight, the patient undergoing anticoagulation or antiplatelet. In cases of ulcer, discontinue treatment immediately.
- Chickenpox: Chickenpox can cause unusually severe infectious complications skin and soft tissue. To date, promoting the role of NSAIDs in the worsening of these infections can not be excluded. It is therefore prudent to avoid using this medicine for chickenpox.
- Prolonged treatment: When prescribing, the physician should consider the fact that secondary anovulatory infertility by not breaking the Graafian follicle, reversible upon discontinuation of treatment have been described in patients treated with long-term with some prostaglandin synthesis inhibitors.

During prolonged treatment, it is recommended to check the blood count, liver and kidney functions.

- Digestive pathology, previous: Ibuprofen should be administered with caution and under special surveillance in patients with history of gastrointestinal disorders (peptic ulcer, hiatal hernia, gastrointestinal bleeding).
- Elderly: Age does not alter the kinetics of ibuprofen, the dose should not have to be modified according to this parameter.

In early treatment, careful monitoring of the volume of diuresis and renal function is necessary particularly in the elderly.

- Heart failure: When starting therapy, careful monitoring of the volume of urine output and renal function is necessary in patients with heart failure.
- Hepatic impairment: In the beginning of treatment, careful monitoring of the volume of urine output and renal function is necessary in patients with hepatic impairment.
- Chronic renal failure: the beginning of treatment, careful monitoring of the volume of urine output and renal function is necessary in patients with chronic renal failure.

- Surgery, history: the beginning of treatment, careful monitoring of the volume of urine output and renal function is necessary for patients after major surgery resulting hypovolemia.
- Risk of eye condition: If vision problems emerging during the treatment, a complete eye examination should be performed.

Breastfeeding: NSAIDs passing into breast milk, as a precaution, should be avoided to administer them in a nursing woman.

4.5.Drug Interactions

Care should be taken in patients treated with any of the following drugs as interactions have been reported in some patients.

Antihypertensives, beta-blockers and diuretics: NSAIDs may reduce the effect of anti-hypertensives, such as ACE inhibitors, beta-blockers and diuretics.

Diuretics can also increase the risk of nephrotoxicity of NSAIDs.

Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma cardiac glycoside levels.

Cholestyramine; The concomitant administration of ibuprofen and cholestyramine may reduce the absorption of ibuprofen in the gastrointestinal tract. However, the clinical significance is unknown.

Lithium: Decreased elimination of lithium.

Methotrexate: NSAIDs may inhibit the tubular secretion of methotrexate and reduce clearance of methotrexate.

Ciclosporin: Increased risk of nephrotoxicity.

Mifepristone: A decrease in the efficacy of the medicinal product can theoretically occur due to the antiprostaglandin properties of NSAIDs. Limited evidence suggests that coadministration of NSAIDs on the day of prostaglandin administration does not adversely influence the effects of mifepristone or the prostaglandin on cervical ripening or uterine contractility and does not reduce the clinical efficacy of medicinal termination of pregnancy.

Other analgesics and cyclooxygenase-2 selective inhibitors: Avoid concomitant use of two or more NSAIDs, including Cox-2 inhibitors, as this may increase the risk of adverse effects.

Aspirin: As with other products containing NSAIDs, concomitant administration of ibuprofen and aspirin is not generally recommended because of the potential of increased adverse effects.

4.6.Pregnancy & Lactation

Pregnancy: Appearance malformation: first quarter

Studies in animals have not shown teratogenic effects.

In the absence of teratogenic effects in animals, a malformation in humans is not expected.

In humans, no particular malformative effect, related to administration during the first trimester of pregnancy, have been reported. However, epidemiological studies are needed to confirm the absence of risk.

Fetotoxic and neonatal appearance: the second and third quarter

It is a toxicity class for all prostaglandin synthesis inhibitors.

Administration during the second and third quarter subject to:

- An impairment of renal function:
- As may occur in uterus at 12 weeks of gestation (initiation of fetal diuresis): oligohydramnios (usually reversible upon discontinuation), or anamnios especially during prolonged exposure.
- At birth, renal failure (reversible or not) may persist especially in case of late and prolonged exposure (with a risk of severe hyperkalemia delayed).
- Cardiopulmonary risk of harm:

Partial or complete constriction of the ductus arteriosus in utero.

Constriction of the ductus arteriosus can occur from 5 months of age and can lead to right heart failure or fetal or neonatal fetal death in utero. This risk is particularly important that the outlet is near term (less reversibility). This effect exists even for a timely decision.

- A risk of prolonged bleeding time for mother and child.

Accordingly:

- Up to 12 weeks gestation: the use of Ibuprofen should only be considered if necessary.
- Between 12 and 24 weeks gestation (between the onset of fetal diuresis and 5 months of age): a brief decision should only be prescribed if necessary. A long-term use is strongly discouraged.
- Beyond 24 weeks of gestation (5 months old): any point is well taken against inappropriate.
- Inadvertently taking beyond 24 weeks of gestation (5 months of age) warrants monitoring cardiac and renal, and fetal / neonatal or by term exposure. The duration of this monitoring will be adapted to the half-life of the molecule.

4.7.Effects on ability to drive and use machines:

None expected at recommended doses and duration of therapy.

4.8.Adverse Effects

Hypersensitivity reactions have been reported and these may consist of:

a) non-specific allergic reactions and anaphylaxis,

b) respiratory tract reactivity e.g. asthma, aggravated asthma, bronchospasm or dyspnoea,

c) various skin reactions, e.g. pruritus, urticaria, angioedema and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme).

The following list of adverse effects relates to those experienced with Ibuprofen at OTC doses, for short-term use. In the treatment of chronic conditions, under long-term treatment, additional adverse effects may occur.

The adverse drug reactions (ADRs) observed in patients treated with ibuprofen are listed below by System Organ Class. Frequencies are defined in accordance with current guidance as: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known frequency (cannot be estimated from the available data).

ADRs are presented by frequency category based on 1) incidence in adequately designed clinical trials or epidemiology studies, when available, or 2) when incidence is unavailable, frequency category is listed as 'Not Known'.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9.Overdose

Toxicity

Signs and symptoms of toxicity have generally not been observed at doses below 100 mg/kg in children or adults. However, supportive care may be needed in some cases. Children have been observed to manifest signs and symptoms of toxicity after ingestion of 400 mg/kg or greater.

Symptoms

Most patients who have ingested significant amounts of ibuprofen will manifest symptoms within 4 to 6 hours.

The most frequently reported symptoms of overdose include nausea, vomiting, abdominal pain, lethargy and drowsiness. Central nervous system (CNS) effects include headache, tinnitus, dizziness, convulsion, and loss of consciousness. Nystagmus, metabolic acidosis, hypothermia, renal effects, gastrointestinal bleeding, coma, apnoea, diarrhoea and depression of the CNS and respiratory system have also been rarely reported. Disorientation, excitation, fainting and cardiovascular toxicity, including hypotension, bradycardia and tachycardia have

been reported. In cases of significant overdose, renal failure and liver damage are possible. Large overdoses are generally well tolerated when no other drugs are being taken.

Therapeutic measures

Patients should be treated symptomatically as required. Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within one hour of ingestion of a potentially life-threatening overdose.

Good urine output should be ensured.

Renal and liver function should be closely monitored.

Patients should be observed for at least four hours after ingestion of potentially toxic amounts. Frequent or prolonged convulsions should be treated with intravenous diazepam. Other measures may be indicated by the patient's clinical condition.

5. PHARMACOLOGICAL PROPERTIES:

5.1. Pharmacodynamic properties:

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, non-steroids; propionic acid derivative

ATC Code: M01AE01

Ibuprofen is a propionic acid derivative NSAID that has demonstrated its efficacy by inhibition of prostaglandin synthesis. In humans Ibuprofen reduces inflammatory pain, swellings and fever. Furthermore, Ibuprofen reversibly inhibits platelet aggregation.

Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose acetylsalicylic acid on platelet aggregation when they are dosed concomitantly. Some pharmacodynamic studies show that when single doses of ibuprofen 400 mg were taken within 8 h before or within 30 min after immediate release acetylsalicylic acid dosing (81 mg), a decreased effect of acetylsalicylic acid on the formation of thromboxane or platelet aggregation occurred. Although there are uncertainties regarding extrapolation of these data to the clinical situation, the possibility that regular, long-term use of ibuprofen may reduce the cardioprotective effect of low-dose acetylsalicylic acid cannot be excluded. No clinically relevant effect is considered to be likely for occasional ibuprofen use (see section 4.5).

5.2. Pharmacokinetic properties

Ibuprofen is rapidly absorbed from the gastro-intestinal tract and rapidly distributed throughout the whole body. Peak plasma concentrations occur about 1 to 2 hours after ingestion with food or in 45 minutes if taken on an empty stomach. These times may vary with different dosage forms.

The excretion is rapid and complete via the kidneys.

The elimination half-life is about 2 hours.

It is metabolized to two inactive metabolites and these are rapidly excreted in urine. About 1 percent is excreted in urine as unchanged Ibuprofen and about 14 percent as conjugated Ibuprofen.

Ibuprofen is extensively bound to plasma proteins.

In limited studies, Ibuprofen appears in breast milk in very low concentrations.

5.3.Preclinical safety data

No relevant information additional to that contained elsewhere in the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1.List of excipients

Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Citric Acid Monohydrate, Sucrose, Saccharin Sodium, Glycerol, Microcrystalline Cellulose and Carmellose Sodium (Avicel RC 591), Aluminum Magnesium Silicate (Veegum K R2CG2), Polysorbate 80, Colour Sunset Yellow FCF, Flavor Essence vanilla, Flavor Sweet orange, Flavor Pineapple, Purified Water.

6.2.Incompatibilities

Not Applicable

6.3.Shelf Life

36 Months

6.4.Special precautions for storage:

Store at temperature not exceeding 30°C. Protect from light.

The shelf life after opening the bottle when stored under temperature conditions mentioned above (not exceeding 30°C) in 30 days.

Keep the medicine out of reach of children.

6.5.Nature and contents of container

Amber colored PET bottle100 ml with 25mm cap, label in a carton along with the Insert.

6.6.Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements

7. MARKETING AUTHORIZATION NUMBER (S)

Not applicable.

8. MANUFACTURER NAME

Manufactured by:

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9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

Not applicable.

10. DATE OF REVISION OF THE TEXT

Not applicable.