For submit in Malaysia
Artwork of insert **"GOFEN LIQUIZ"** code ***RI-I604-H14-00-03***
Size : 132 x 186 mm

GOFEN LIQUIZ

Ibuprofen Suspension 100 mg/5 ml

1. NAME OF THE MEDICINAL PRODUCT
Gofen Liquiz
100 mg of ibuprofen in each 5ml (one teaspoonful) suspension.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 1 teaspoon (5 ml) contains:
Ibuprofen 100mg
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Suspension
Off-white suspension with orange flavor.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Gofen Liquiz is indicated for the relief of fever such as fever associated with cold and flu, and pain such as pain from teething and toothache, earache, sore throats, headache and minor aches and sprains. Also indicated for the relief of inflammation of muscles and joints.

4.2 Posology and method of administration
Undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms.
The daily dosage of Gofen Liquiz is 20-30mg/kg bodyweight in divided doses. Using the spoon or measuring cup provided
this can be achieved as follows:
Infants 3 - 6 months weighing more than 5kg: 2.5ml may be taken 3 times in 24 hours.
Infants 6 - 12 months: 2.5ml may be taken 3 to 4 times in 24 hours.
Children 1 - 3 years: 5.0ml may be taken 3 times in 24 hours.
Children 4 - 6 years: 7.5ml may be taken 3 times in 24 hours.
Children 7 - 9 years: 10.0ml may be taken 3 times in 24 hours.
Children 10-12 years: 15.0ml may be taken 3 times in 24 hours.
The doses should be given approximately every 6-8 hours (or with a minimum of 4 hours between each dose if required). Not suitable for children under 3 months of age unless advised by your doctor.
For post-immunization pyrexia: 2.5ml dose following by a further 2.5ml dose 6 hours later if necessary. No more than 5.0ml in 24 hours. If the fever is not reduced, consult your doctor.
For oral administration.
For short-term use only. If in children (aged 6 months and over), this product is required for more than 3 days, or if symptoms worsen a doctor should be consulted. For infant aged 3-6 months, medical advice should be sought if symptoms worsen or not later than 24 hours if symptoms persist.

4.3 Contraindications
Hypersensitivity to ibuprofen or to any of the excipients in the product. Patients who have previously shown hypersensitivity reactions (e.g asthma, rhinitis, angioedema or urticaria) in response to ibuprofen, acetylsalicylic acid (Aspirin) or other non-steroidal anti-inflammatory drugs (NSAIDs). Active or a history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding). History of gastrointestinal bleeding or perforation, related to previous NSAID therapy. Severe heart failure, renal failure or hepatic failure. Last trimester of pregnancy.

4.4 Special warning and precautions for use
Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see GI and cardiovascular risks below).
The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal.

Respiratory:
Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergic disease.

Other NSAIDs:
The use of ibuprofen with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided (see section Interaction with other medicinal products and other forms of interaction).

SLE and mixed connective tissue disease:
Systemic lupus erythematosus and mixed connective tissue disease, due to increased risk of aseptic meningitis (see section Undesirable effects)
Caution (discussion with doctor or pharmacist) is required prior to starting treatment in patients with a history of hypertension and/or heart failure as fluid retention, hypertension and oedema have been reported in association with NSAID therapy.
Clinical trial and epidemiological data suggest that use of ibuprofen, particularly at high doses (2400 mg daily) and in long- term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g.1200 mg daily) is associated with an increased risk of myocardial infarction.

Cardiovascular and cerebrovascular effects:
Cases of Kounis syndrome have been reported in patients treated with ibuprofen. Kounis syndrome has been defined as cardiovascular symptoms secondary to an allergic or hypersensitive reaction associated with constriction of coronary arteries and potentially leading to myocardial infarction.

Renal:
Renal impairment as renal function may further deteriorate (See section Contraindications and Section Undesirable effects)
There is a risk of renal impairment in dehydrated children (See section Contraindications and Section Undesirable effects)

Hepatic:
Hepatic dysfunction (See section Contraindications and Section Undesirable effects)

Impaired female fertility:
There is limited evidence that drugs which inhibit cyclo-oxygenase/ prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation. This is reversible upon withdrawal of treatment.

Risk of GI ulceration, Bleeding and Perforation with NSAID:
Serious GI toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAID therapy. Although minor upper GI problems (e.g. dyspepsia) are common usually developing early in therapy, prescribes should remain alert for ulceration and bleeding in patients treated with NSAIDs even in the absence of previous GI tract symptoms. Studies to date have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Patients with prior history of serious GI events and other risk factors associated with peptic ulcer disease (e.g. alcoholism, smoking, and corticosteroid therapy) are at increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events.

Severe cutaneous adverse reactions (SCARs)
Severe cutaneous adverse reactions (SCARs) including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS syndrome) and acute generalised exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been reported in association with the use of ibuprofen (see section Undesirable effects). Most of these reactions occurred within the first month. If signs and symptoms suggestive of these reactions appear, ibuprofen should be withdrawn immediately, and an alternative treatment considered (as appropriate).
If signs and symptoms suggestive of these reactions appear ibuprofen should be withdrawn immediately and an alternative treatment considered (as appropriate).

Masking of symptoms of underlying infections
This medicine can mask symptoms of infection, which may lead to delayed initiation of appropriate treatment and thereby worsening the outcome of the infection. This has been observed in bacterial community acquired pneumonia and bacterial complications to varicella. When this medicine is administered for fever or pain relief in relation to infection, monitoring of infection is advised. In non- hospital settings, the patient should consult a doctor if symptoms persist or worsen. Exceptionally, varicella can be at the origin of serious cutaneous and soft tissues infectious complications. Thus, it is advisable to avoid use of Gofen Liquiz in case of varicella.
This product contains Maltitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Interactions with other medicinal products and other forms of Interaction
Ibuprofen should be avoided in combination with:
Acetylsalicylic acid (aspirin): Unless low-dose acetylsalicylic acid (aspirin) (not above 75mg daily) has been advised by a doctor, as this may increase the risk of adverse reactions.
Experimental data suggest that ibuprofen may inhibit the effect of low dose acetylsalicylic acid (aspirin) on platelet aggregation when they are dosed concomitantly. However, the limitations of these data and the uncertainties regarding extrapolation of ex vivo data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional ibuprofen use.

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

Ibuprofen should be used with caution in combination with:
Anticoagulants: NSAIDS may enhance the effects of anti- coagulants, such as warfarin.
Antihypertensives (ACE inhibitors and Angiotensin II antagonists) and diuretics: NSAIDs may diminish the effect of these drugs. Diuretics can increase the risk of nephrotoxicity of NSAIDs.
Corticosteroids: Increased the risk of gastrointestinal ulceration or bleeding.
Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs): increased risk of gastrointestinal bleeding.
Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels.
Lithium: There is evidence for potential increases in plasma levels of lithium.
Methotrexate: There is a potential for an increase in plasma levels of methotrexate.
Ciclosporin: Increased risk of nephrotoxicity.
Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.
Tacrolimus: Possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus
Zidovudine: Increased risk of haematological toxicity when NSAIDs are given with zidovudine. There is evidence of an increased risk haemarthroses and haematoma in HIV (positive) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.
Quinolone antibiotics: Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.

4.6 Fertility, pregnancy and lactation
Pregnancy
Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5 %. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period.
During the first and second trimester of pregnancy, Gofen Liquiz should not be given unless clearly necessary. If Gofen Liquiz is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.
During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:
- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);
- renal dysfunction, which may progress to renal failure with oligo-hydroamniosis; the mother and the neonate, at the end of pregnancy, to:
- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.
- inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, Gofen Liquiz is contraindicated during the third trimester of pregnancy.

Breast-feeding
In limited studies, ibuprofen appears in the breast milk in very low concentration and is unlikely to affect the breast fed infant adversely.

Fertility
See section Warning and precaution regarding female fertility.

4.7 Effects on ability to drive and use machines
None expected at recommended doses and duration of therapy.

4.8 Undesirable effects
The following list of adverse effects relates to those experienced with ibuprofen at OTC doses (maximum 1200 mg ibuprofen per day), in short-term use. In the treatment of chronic conditions, under long- term treatment, additional adverse events may occur.
Adverse events which have been associated with ibuprofen are given below, tabulated by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1000 and <1/100), rare (≥1/10,000 and <1/1000), very rare (< 1/10,000) and not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness. The most commonly observed adverse events are gastrointestinal in nature.

System Organ Class	Frequency	Adverse Events
Blood and Lymphatic System Disorders	Very rare	Haematopoietic disorders, anaemia, leucopenia, thrombocytopenia, pancytopenia and agranulocytosis
Immune System Disorders	Uncommon	Hypersensitivity with urticaria and pruritus
	Very rare	Severe hypersensitivity reactions, including facial, tongue and throat swelling, dyspnoea, tachycardia, and hypotension (anaphylaxis, angioedema or severeshock)
Nervous System Disorders	Uncommon	Headache
	Very rare	Aseptic meningitis
Cardiac Disorders	Not known Not Known	Cardiac failure and oedema Kounis syndrome
Vascular Disorders	Not known	Hypertension
Respiratory, Thoracic and Mediastinal Disorders	Not known	Respiratory tract reactivity comprising asthma, bronchospasm or dyspnoea
Gastrointestinal Disorders	Uncommon	Abdominal pain, nausea and dyspepsia
	Rare	Diarrhoea, flatulence, constipation and vomiting
	Very rare	Peptic ulcer, gastrointestinal perforation or gastrointestinal haemorrhage, melaena, and haematemesis. Mouth ulceration and gastritis. Exacerbation of colitis and Crohn's disease
Hepatobiliary Disorders	Very rare	Liver disorder
Skin and Subcutaneous Tissue Disorders	Uncommon	Skin rash
	Very rare	Severe cutaneous adverse reactions (SCARs) (including Stevens-Johnson Syndrome, erythema multiforme, exfoliative dermatitis and toxic epidermal necrolysis)
	Not known	Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) Acute generalised exanthematous pustulosis (AGEP) Photosensitivity reactions
Renal and Urinary Disorders	Very rare	Acute renal failure, papillary necrosis, especially in long-term use, associated with increased serum urea and oedema
Investigations	Very rare	Haemoglobin decreased
Infections and infestations	Not known	Exacerbation of infections related inflammation has been described, in exceptional cases, severe skin infections and soft-tissue complications may occur during a varicella infection.

Description of Selected Adverse Reactions
1. First signs are fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding and bruising.
2. Hypersensitivity reactions: These may consist of (a) non-specific allergic reactions and anaphylaxis, (b) respiratory tract reactivity, including asthma, aggravated asthma,bronchospasm, and dyspnoea, or (c) various skin reactions, including pruritus, urticaria, purpura, angioedema and, more rarely, exfoliative and bullous dermatoses, including toxic epidermal necrolysis, Stevens- Johnson Syndrome and erythema multiforme.
3. The pathogenic mechanism of drug-induced aseptic meningitis is not fully understood. However, the available data on NSAID-related aseptic meningitis points to a hypersensitivity reaction (due to a temporal relationship with drug intake, and disappearance of symptoms after drug discontinuation). Of note, single cases of symptoms of aseptic meningitis (such as stiff neck, headache, nausea, vomiting, fever or disorientation) have been observed during treatment with ibuprofen in patients with existing auto-immune disorders (such as systemic lupus erythematosus and mixed connective tissue disease).
4. Clinical trial and epidemiological data suggest that use of ibuprofen (particularly at high doses 2400 mg daily) and in long-term treatment may be associated with a small increased risk of arterial thrombotic events (e.g. myocardial infarction or stroke).
5. The adverse events observed most often are gastrointestinal in nature.
6. Sometimes fatal.
7. See section warning and precautions.
8. Especially in long-term use, associated with increased serum urea and oedema. Also includes papillary necrosis.

4.9 Overdose
In children ingestion of more than 400 mg/kg may cause symptoms. In adults the dose response effect is less clear cut. The half-life in overdose in 1.5-3 hours.
Symptoms: Most patients who have ingested clinically important amounts of NSAIDs will develop no more than nausea, vomiting, epigastric pain, or more rarely diarrhea. Tinnitus, headache and gastrointestinal bleeding are also possible. In more serious poisoning, toxicity is seen in the central nervous system, manifesting as drowsiness, occasionally excitation and disorientation or coma. Occasionally patients develop convulsions. In serious poisoning metabolic acidosis may occur and the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulation clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics.
Management: Management should be symptomatic and supportive and include the maintenance of a clear airway and monitoring of cardiac and vital signs until stable. Consider oral administration of activated charcoal if the patients presents within 1 hour of ingestion of a potentially toxic amount. If frequent or prolonged, convulsions should be treated with intravenous diazepam or lorazepam. Give bronchodilators for asthma.

5. PHARMACOLOGICAL PROPERTIES
Chemical name: 2-[4-(2-methylpropyl)phenyl]propanoic acid.
5.1 Pharmacodynamics Properties
Pharmacotherapeutic Group: Anti-inflammatory and antirheumatic products, non-steroids; Propionic acid derivatives.
ATC Code: M01AE01
Pharmacodynamic effects
Ibuprofen is a non-steroidal analgesic, antipyretic and anti-inflammatory agent and is effective in the relief of pain, fever and inflammation. It acts by inhibiting prostaglandin-synthetized enzymes, which are known to be associated with inflammation, pain and fever.
5.2 Pharmacokinetic Properties
Ibuprofen is rapidly absorbed following administration and is rapidly distributed throughout the whole body. The excretion is rapid and complete via the kidneys. Maximum plasma concentrations are reached 45 minutes after ingestion if taken on an empty stomach. When taken with food, peak levels are observed after 1 to 2 hours. These times may vary with different dosage forms. The half-life of ibuprofen is about 2 hours.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients:
Potassium sorbate, Citric acid anhydrous, Trisodium citrate dihydrate, Saccharin sodium, Sodium chloride, Xanthan gum, Hypromellose. Maltitol syrup, Glycerin, Polysorbate 80, Orange flavor, Purified water.
6.2 Incompatibilities:
None Known
6.3 Shelf Life
Before first opening: 2 years, After first opening: 6 months.
6.4 Special Precautions for storage
Store below 30ºC in a dry place, away from direct sunlight.
6.5 Nature and contents of container
100 ml suspension in amber PET bottle with HDPE screw cap and 15 ml measuring cup.
Pack of 1 bottle.
6.6 Special precautions for disposal and other handling
Any unused Gofen Liquiz should be disposed of in accordance with local requirements.

7. MANUFACTURER'S NAME AND ADDRESS
MEGA LIFESCIENCES Public Company Limited
515/1 Soi 8, Bangpoo Industrial Estate,
Pattana 3 Road, Moo 4, Phraeksa, Mueang,
Samutprakarn 10280, Thailand

8. PRODUCT REGISTRATION HOLDER
MEGA LIFESCIENCES SDN BHD
B-28-02, The Ascent, Paradigm,
No.1, Jalan SS7/26A, Kelana Jaya,
47301 Petaling Jaya, Selangor, Malaysia

9. DATE OF REVISION
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Artwork Check / Layout Check

PC TEAM		*PRODUCTION*		*RA*
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		Production Check 2 :	☐ Pass : …… ☐ Not pass : ……	
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