GOFEX

IBUPROFEN

SOFT CAPSULE 400 MG

Box Warning

Cardiovascular Risk:

NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

NSAIDs is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Risk:

NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events.

Composition:

Each softgel capsule contains:

Solubilized Ibuprofen Eq to Ibuprofen 400 mg

(present as free acid and potassium salt)

Other ingredients: Polyethylene glycol 600, potassium hydroxide, purified water, gelatin, sorbitol, glycerin, FD&C green no 3.

Description: Clear, colourless, oily liquid filled in 20 minim, oblong, green, transparent soft gelatin shell capsules.

Indications:

For relieving the pain of various etiology: headache, pain after tooth extraction, and postoperative pain, as well as for the treatment of primary dysmenorrhea.

For the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis, as well as for the musculoskeletal and traumatic alterations implying pain and inflammation.

NOTIFIKASI: 03/10/2025 ID: EREG100272VR12500059

Dosage:

Dosage for adults:

The main recommended posology is 1200 mg/day, divided into 3-4 single administrations. Should gastric disturbances appear after drug ingestion, then the administration can be performed by drinking concomitantly some milk or during meals.

In case of rheumatoid arthritis, a higher dosage may be required but, in any case, it is recommended not to exceed 2400 mg Ibuprofen a day, by considering that the lowest possible effective dose is to be administered.

In case of primary dysmenorrhea, the recommended dose is 400 mg every 4 hours up to pain relief, always considering the lowest possible effective dosage.

For elderly patients, the posology is to be established by the physician, as a possible usual dose reduction may be needed, in case of kidney failure, the dosage must be adequately adjusted, being the drug eliminated preferably through renal excretion.

Contraindications:

- Hypersensitivity to the active substance “ibuprofen” or to any of the excipients of this medicinal product. (See List of Excipients).
- History of hypersensitivity reactions (e.g. bronchospasm, asthma, rhinitis or urticaria) in response to acetylsalycilic acid (ASA) or other non-steroidal anti-inflammatory drugs (NSAIDs).
- History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.
- Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding).
- Other active bleeding like cerebrovascular bleedings or colitis ulcerosa.
- Severe kidney and/or liver insufficiency.
- Hemorrhagic diathesis
- Third trimester of pregnancy (see section 4.6 Pregnancy and Lactation).
- Severe heart failure (NYHA Class IV).

Warnings and precautions:

Undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms (see Posology and GI and cardiovascular risk below).

GI Effects:

- The use of ibuprofen with Concomitant NSAIDs, including COX-2 selective inhibitors should be avoided.
- Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation, which may be fatal (See Posology).
- Gastrointestinal bleeding, ulceration and perforation: GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs, at any time during treatment, with or without warning symptoms or previous history of serious GI events. The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with hemorrhage or perforation (See Contraindications), and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for these patients, and also for patients requiring concomitant low dose aspirin, or other drugs likely to increase gastrointestinal risk (See Interactions with other medicinal products and other forms of interaction).
- Patients with a history of GI toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stages of treatment. Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or anti-platelet agents such as acetyl salicylic acid (See Interactions). When GI bleeding or ulceration occurs, the treatment should be withdrawn. NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as their condition may be exacerbated (See Undesirable effects).

Cardiovascular and cerebrovascular effects

- Appropriate monitoring and advice are required for patients with a history of hypertension and or mild to moderate congestive heart failure. Fluid retention, hypertension and oedema have been reported in association with NSAIDs therapy.
- Clinical studies suggest that use of ibuprofen, particularly at a high dose (2400 mg/day) may be associated with a small increased risk of arterial thrombotic event (for example myocardial infarction or stroke). Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g. ≤ 1200 mg/day) is associated with an increased risk of arterial thrombotic events.
- Patients with uncontrolled hypertension, congestive heart failure (NYHA II-III), established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with ibuprofen after careful consideration and high doses (2400 mg/day) should be avoided.
- Careful consideration should also be exercised before initiating long term treatment of patients with risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia,

diabetes mellitus, and smoking), particularly if high doses of ibuprofen (2400 mg/day) are required.

Severe skin reactions

- Serious skin reactions, some of them fatal, including exfoliative dermatitis, Steven-Johnson's syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDSs (see Undesirable effects). Patients appear to be at highest risk of these reactions early in the course of therapy, the onset of the reaction occurring in the majority of cases within the first month of treatment. Ibuprofen-containing products should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Masking of symptoms of underlying infections

- Ibuprofen 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 Ibuprofen 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.

Other effects:

- Caution is required in patients with coagulation disorders and liver, cardiac or kidney insufficiency. Caution should be used when initiating treatment with ibuprofen in patients with considerable dehydration.
- Risks of long-term habitual use of analgesic are headache and analgesic nephropathy.
- Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergic disease.
- Caution is required in patients with systemic lupus erythematosus or other collagen diseases. There is some evidence that drugs which inhibit cyclo-oxygenase/prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation. This is reversible on withdrawal of treatment.
- Patients who experience visual disturbances during ibuprofen therapy should discontinue the treatment and have an ophthalmologic examination. NSAIDs may produce an increase of liver function test results.

Drug Interactions

Acetylsalycilic acid: Concomitant administration of ibuprofen and Acetylsalicylic acid is not generally recommended because of the potential of increased adverse effects. Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose acetylsalicylic acid on platelet aggregation when they are dosed concomitantly. 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 Pharmacodynamic properties).

Diuretics: The efficacy of furosemide and thiazide diuretics can be decreased, probably due to sodium retention related to an inhibition of prostaglandin synthesis in the kidneys. Corticosteroid: increase risk of gastrointestinal ulceration or bleeding (see special warnings and precaution for use).

Anti-coagulants: NSAIDs may enhance the effects of anti-coagulants, such as warfarin (see special warning and precautions for use).

Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs): Increased risk of gastrointestinal bleeding (see special waming and precautions for use).

Anti-hypertensives agents: Ibuprofen may diminish the effects of antihypertensives.

Consequently, the concomitant use of NSAIDs and ACE Inhibitors or beta-blocking agents may be associated with a risk of acute renal failure.

Digoxin, phenytoin, lithium : In the literature individual cases of increase plasma levels of digoxin, phenytoin and lithium due to ibuprofen have been described.

Other non-steroid anti-inflammatory drugs (NSAIDs), including cyclooxygenase-2 selective inhibitors:

Ibuprofen (like other NSAIDS) should be used with caution in combination with acetylsalicylic acid or other NSAIDs and systemic corticosteroids: this may increase the risk of adverse drug reactions in the gastro intestinal tract.

Methotrexate:

Ibuprofen can increase methotrexate plasma levels.

Zidovudine:

Concurrent treatment of zidovudine and ibuprofen can increase the risk of haemarthoses and haematoma in HIV (+) haemophilic patients.

Tacrolimus:

Concurrent use of ibuprofen and tacrolimus can increase the risk of nephrotoxicity, due to the reduction of the renal prostaglandins synthesis.

Hypoglycaemics agent:

Ibuprofen increases hypoglycemic effects of oral hypoglycemic agents and insulin. It may be necessary to adjust the dosage.

Cyclosporine:

Concurrent use of non-steroidal anti-inflammatory drugs (NSAIDs) may result in increased risk of cyclosporine nephrotoxicity effect.

Voriconazole or Fluconazole: Concurrent use of ibuprofen may result in increased ibuprofen exposure and plasma concentration.

Mifepristone:

Concurrent use of non-steroidal anti-inflammatory drugs (NSAIDs) may result in increased exposure to the NSAID. A decrease in the efficacy of mifepristone can theoretically occur due to the antiprostaglandin properties of NSAIDs. Studies on the effect of single or repeated ibuprofen administration starting on the day prostaglandin administration (or as needed) did not find evidence of an adverse influence on the action of mifepristone, nor or the overall clinical efficacy of the pregnancy termination protocol.

Quinolone antibiotics:

Concurrent use of non-steroidal use of non-steroidal anti - inflammatory drugs (NSAIDs) may result in an increased risk of seizures.

Herbal Extract:

Gingko biloba may potentiate the risk of bleeding with NSAIDS.

Aminoglycosides:

NSAIDs may decrease the excretion of aminoglycosides.

Interactions with diagnostic test results:

- Bleeding time (may prolong bleeding time until 1 day after discontinuation of therapy).
- Serum glucose concentration (may decrease).
- Creatinine Clearance (may decrease).
- Haematocrit or haemoglobin (may decrease)
- BUN, serum creatinine concentration and kaliemia (may increase).
- Liver function test (may occur elevation of transaminases).

Pregnancy, Lactation, and Fertility

Pregnancy:

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. During the first and second trimester of pregnancy, GOFEN should not be given unless clearly necessary. If GOFEN 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. Consequently, GOFEN is contraindicated during the third trimester of pregnancy (see contraindications).

Lactation:

Ibuprofen and its products of decomposition/ metabolites are excreted in human milk, but at therapeutic doses of GOFEN no effects on the breastfed newborns/infants are anticipated. As harmful effects on the infant are not yet known, it is not generally necessary to interrupt breast-feeding for short-term treatment with recommended dose for mild to moderate pain and fever.

Fertility:

If Ibuprofen is used by a woman attempting to conceive the dose should be kept as low and duration of treatment as short as possible.

Effect on ability of driving and operating machine

Dizziness and headache have been reported which may affect the patient's ability to drive or to operate machinery. Single administration or short term use of ibuprofen does not usually warrant the adoption of any special precautions. Therefore, GOFEN has minor influence on these abilities.

Side Effects

- Undesirable effects are primary linked to the pharmacological effect of ibuprofen on prostaglandin synthesis. The most commonly reported adverse events effect the gastrointestinal tract, ranging from nausea and dyspepsia to serious bleeding or activation of peptic ulcer (see special warnings and precautions for use).
- Bullous reaction including Steven-Johnson's syndrome and toxic epidermal Necrolysis where observed very seldom.
- Oedema, hypertension, and cardiac failure have been reported in association with NSAIDS treatment. Clinical studies suggest that use of ibuprofen, particularly at high dose (2400 mg/day) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infraction or stroke) (see Special Warnings and precaution for use).
- In the table below adverse reactions are listed by system organ class, and frequency (very common (more than or equal to 1/10). Common (21/100 to less than 1/10), uncommon (21/1.000 to 1/100), rare (21/10.000 to less than 1/1.000), very rare (less than 1/10.000) and not known (cannot be estimated from the available data) Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

System Organ Class	**Frequency**
Blood and lymphatic system disorders Thrombocytopenia, agranulocytosis, aplastic anaemia Anaemia	 Rare Not known
Immune system disorders Allergic reaction Anaphylaxis Anaphylactic shock	 Uncommon Rare Not known
Nervous system disorders Headache, dizziness Meningitis aseptic	 Common Not known
Eye disorders Visual disturbance Papilloedema	 Rare Not known

Ear and labyrinth disorders Ear disorder	 Rare
Cardiac disorders Cardiac failure	 Not known
Vascular disorders Arterial thrombosis, hypertension, hypotension	 Not known
Respiratory, thoracic and mediastinal disorders Asthma, aggravated asthma, bronchospam, dyspnea Throat irritation	 Uncommon Not known
Gastrointestinal disorders Dyspepsia, diarrhoea Abdominal pain, nausea, flatulence Peptic ulcer, gastrointestinal haemorrhage, vomiting, malaena, gastritis Gastrointestinal perforation, constipation, haematemesis, ulcerative stomatitis, colitis aggravayed, Crohn's disease aggravated Anorexia	 Very common Common Uncommon Rare Not known
Hepato-biliary disorders Hepatic disorders Liver injury, hepatitis, jaundice	 Rare Not known
Skin and subcutaneous tissue disorders Skin disorder, rash Angioedema, purpura, pruritus, urticaria Bullous reaction, erythema multiforme, exfoliative dermatitis,	 Common Uncommon Very rare

Steven Johnson's syndrome, toxic epidermal necrolysis Photosensitivity reaction, skin reaction aggravated Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) Acute generalised exanthematous pustulosis (AGEP)	 Not known Not known Not known
Renal and urinary disorders Hematuria Acute renal failure, interstitial nephritis, papilary necrosis	 Rare Very rare
General disorders and administration site conditions Oedema	 Not known
Investigations Liver function test abnormal Renal function test abnormal	 Rare Not known

Overdose

- Symptoms:
  In general, overdose symptoms include nausea, gastralgia,vomiting (blood) and diarrhoea (blood), dizziness, spasms, nystagmus and diplopia, headache and tinnitus. In case of severe intoxication also renal function disorders, hypotension, decrease of consciousness and coma (it is not clear whether the renal function disorder is caused by the intoxication or by the concurrent hypotension). In serious poisoning metabolic acidosis may occur.
- Management of overdose:
  There is no specific antidote for ibuprofen.
  The stomach should be emptied as soon as possible. If possible, the patient should vomit. If the patient is unconscious, gastric lavage and correction of severe electrolyte abnormalities should be considered.

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. Healthcare professionals are asked to report any suspected adverse reactions to.

Pusat Farmakovigilans Direktorat Pengawasan Keamanan, Mutu dan Ekspor Impor Obat Narkotika, Psikotropika, Prekursor, dan Zat Adiktif Badan Pengawas Obat dan Makanan Republik Indonesia Address:

Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560

Email: pv-center@pom.go.id

Phone: +62-21- 4244691 Ext. 1079

Website: http://e-meso.pom.go.id/

Pharmacological Properties

Pharmacodynamic properties

Pharmacotherapeutic group: Antiinflammatory and anti-rheumatic products, non-steroids, propionic acid derivatives. Ibuprofen is a synthetic analgesic-antiinflammatory drug with a marked antipyretic action.

Mechanism of action:

Ibuprofen is the first phenylpropionic acid derivative. It is a prostaglandin synthetase inhibitor with analgesic, antipyretic and anti-inflammatory properties. It possesses a nonnarcotic analgesic activity. The mechanism of action of ibuprofen (insitu formation of L-arginine salt) is linked to the reversible inhibition of the COX enzyme, responsible for conversion of arachidonic acid into cyclic endoperoxydes, hence reducing the synthesis of thromboxane (TXA2), prostacyclines (PGI2) and prostaglandines (PG).

Pharmacokinetic properties:

On oral application, ibuprofen is partly absorbed in the stomach and then completely in the small intestine. After absorption, ibuprofen is conjugated to plasma-proteins for about 99% and is mainly distributed throughout the plasma compartment. It diffuses slowly into the synovial spaces and is eliminated more slowly from these spaces than it is from the plasma. Ibuprofen is metabolized in the liver mainly by hydroxylation and carboxylation of the isobutyl group. The metabolites have no known pharmacological activity. The plasma half-life is 1-2 hours. Over 90% of dosage can be found in the urine as metabolites and their conjugates. Less than 1% is excreted unchanged in the urine.

Bioequivalence Study Result:

- Bioequivalence study was carried out on Gofen soft capsules 400 mg (produced by Mega Lifesciences Ltd., Thailand) compared with Nurofen 400 caplets (produced by Reckitt Benckiser Healthcare Manufacturing Ltd., Thailand) with an open label balanced, randomized, two-treatment, two-period, two-sequence, single dose, crossover study design, in 28 healthy subjects in fasting conditions. Study results showed that test drug is bioequivalent to reference drug with GMR AUC0-t, AUC0-~ and Cmax value 95.72%, 93.93% and 119.81% respectively with a 90% CI values 90.98-100.71%, 90.02-98.02% and 109.73-130.82%.
- Results of Comparative Dissolution Test (CDT) carried out between test drug (Gofen soft capsules 400 mg) and reference drug (Nurofen caplets 400 mg) at 3 pH (0.1 N HCl medium, pH 4.5 acetate buffer, and phosphate buffer pH 6.8) are 94.95%, 62.77%, and 69.78% respectively. The results at these three pH showed that the two products are similar with F2 value ≥50.0

- Results of Comparative Dissolution Test (CDT) carried out between comparator used in the BE study (Nurofen caplet 400 mg) and innovator approved in Indonesia (Spedifen tablet 400 mg) in 3 pH (medium HCl 0.1 N, acetate buffer pH 4.5, and phosphate buffer pH 6.8) are 79.51%, 56.30% and 64.24% respectively. The results on these three pH levels showed that the two products are similar with F2 value ≥ 50.0

Storage

Store below 30°C in a dry place, away from direct sunlight.

HARUS DENGAN RESEP DOKTER

Shelf Life

Three years from manufacturing date.

Product specification: Manufacturer

Packaging

Box, 5 Catch Cover @ 1 Blister @ 10 Soft Capsules.

Reg No. DKI xxx xxx xxx

Box, 1 Blister @ 10 Soft Capsules

Reg No. DKI xxx xxx xxx

Note:

Read the instruction carefully before use.

Do not use the product after the expiry date.

Do not use the product if there are any significant changes in appearance of the capsules.

Keep out of reach of children.

Manufacturing under license from:
Mega Lifesciences (AUSTRALIA) PTY.LTD.
and Manufactured By:
Mega Lifesciences Public Company Limited
Bangpoo Industrial Estate, Mueng Samutprakarn 10280, Thailand

Registered by:
PT Mega Lifesciences Indonesia
Bogor-Indonesia

INFORMASI PRODUK UNTUK PASIEN

GOFEX

Ibuprofen 400 mg Kapsul Lunak

Bacalah seluruh leaflet ini dengan seksama sebelum Anda memulai penggunaan obat ini.

- Simpanlah leaflet ini di tempat yang aman, agar dapat dibaca kembali jika diperlukan.
- Jika ada pertanyaan lebih lanjut, hubungilah dokter atau apoteker.
- Obat ini diresepkan untuk Anda. Jangan diberikan kepada orang lain. Hal tersebut dikarenakan obat ini dapat saja membahayakan orang lain, walaupun gejala yang dialami sama dengan Anda.
- Jika mengalami efek samping, hubungilah dokter atau apoteker, termasuk kemungkinan efek samping yang tidak tercantum pada leaflet ini.

1. Nama Obat
   GOFEX
2. Bentuk sediaan
   Kapsul Lunak
3. Pemerian obat
   Cairan bening, tidak berwarna, berminyak yang diisi dengan cangkang kapsul gelatin lunak, lonjong, hijau, transparan.
4. Komposisi zat aktif
   Ibuprofen
5. Kekuatan obat
   400 mg
6. Indikasi/ untuk apa obat digunakan? Dan seberapa banyak dan seberapa sering obat ini boleh digunakan?
   - Obat ini digunakan untuk menghilangkan rasa sakit dari berbagai etiologi: sakit kepala, nyeri setelah pencabutan gigi, dan nyeri pasca operasi, serta untuk pengobatan nyeri haid.
   - Obat ini digunakan untuk menghilangkan tanda dan gejala peradangan sendi dan pengapuran tulang, serta untuk perubahan sistem jaringan otot, tulang dan sendi, dan traumatis yang menimbulkan rasa sakit dan peradangan.
7. Seberapa banyak dan seberapa sering obat ini boleh digunakan?
   Dosis untuk orang dewasa:
   Dosis utama yang direkomendasikan adalah 1200 mg/hari, dibagi menjadi 3-4 pemberian tunggal. Jika gangguan lambung muncul setelah konsumsi obat, maka pemberian dapat dilakukan dengan minum susu atau selama makan.
   Dalam kasus peradangan sendi, dosis yang lebih tinggi mungkin diperlukan tetapi, bagaimanapun, dianjurkan untuk tidak melebihi 2400 mg Ibuprofen sehari, dengan mempertimbangkan bahwa dosis efektif serendah mungkin harus diberikan. Dalam kasus nyeri haid, dosis yang dianjurkan adalah 400 mg setiap 4 jam hingga menghilangkan rasa sakit, selalu mempertimbangkan dosis efektif serendah mungkin.
   Untuk pasien lanjut usia, posologi harus ditetapkan oleh dokter, karena mungkin diperlukan pengurangan dosis yang biasa, dalam kasus gagal ginjal, dosis harus disesuaikan secara memadai, karena obat sebaiknya dieliminasi melalui ekskresi ginjal.

8. Kontraindikasi/pada keadaan apa anda tidak diperbolehkan menggunakan obat ini?
   - Hipersensitif terhadap zat aktif "ibuprofen" atau salah satu eksipien dari produk obat ini. (Lihat Daftar Bahan Tambahan).
   - Riwayat reaksi hipersensitivitas (misalnya penyempitan saluran pernafasan, asma, hidung tersumbat, rinitis, atau gatal-gatal) sebagai respons terhadap asam asetilsalisilat (ASA) atau obat antiinflamasi nonsteroid (OAINS) lainnya.
   - Riwayat perdarahan atau robekan pada saluran cerna, berhubungan dengan terapi OAINS sebelumnya.
   -Aktif, atau riwayat tukak/perdarahan peptik berulang (dua atau lebih episode sariawan atau perdarahan yang terbukti).
   - Perdarahan aktif lainnya seperti perdarahan pembuluh darah otak atau radang usus.
   - Gangguan fungsi ginjal dan/atau hati yang parah.
   - Kelainan darah
   - Trimester ketiga kehamilan (lihat bagian 4.6 Kehamilan dan Laktasi).
   - Gagal jantung berat (NYHA Kelas IV).
9. Apa yang perlu diperhatikan bila menggunakan obat ini? Penggunaan ibuprofen harus hati-hati pada penderita:
   - Efek yang tidak diinginkan dapat diminimalkan dengan menggunakan dosis efektif terendah untuk durasi terpendek yang diperlukan untuk mengontrol gejala (lihat Posologi dan Saluran cerna dan risiko jantung dan pembuluh darah di bawah).
   - Efek Saluran cerna:
     - ✓ Penggunaan ibuprofen dengan NSAID bersamaan, termasuk penghambat selektif COX-2 harus dihindari.
     - ✓ Lansia: Lansia mengalami peningkatan frekuensi reaksi merugikan terhadap NSAID terutama perdarahan saluran cerna dan robekan saluran cerna, yang dapat berakibat fatal (Lihat Posologi).
     - ✓ Perdarahan saluran cerna, sariawan dan robekan saluran cerna: perdarahan saluran cerna, sariawan atau robekan saluran cerna, yang dapat berakibat fatal, telah dilaporkan dengan semua OAINS, setiap saat selama pengobatan, dengan atau tanpa gejala peringatan atau riwayat kejadian saluran cerna serius sebelumnya. Risiko perdarahan saluran cerna, sariawan atau robekan saluran cerna lebih tinggi dengan peningkatan dosis OAINS, pada pasien dengan riwayat ulkus, terutama jika disertai perdarahan atau robekan saluran cerna (Lihat Kontraindikasi), dan pada orang tua. Pasien-pasien ini harus memulai pengobatan dengan dosis terendah yang tersedia. Terapi kombinasi dengan agen pelindung (misalnya misoprostol atau penghambat pompa proton) harus dipertimbangkan untuk pasien ini, dan juga untuk pasien yang membutuhkan asetosal dosis rendah secara bersamaan, atau obat lain yang cenderung meningkatkan risiko gastrointestinal (Lihat Interaksi dengan produk obat lain dan bentuk interaksi lainnya).
     - ✓ Pasien dengan riwayat toksisitas saluran cerna, terutama saat lanjut usia, harus melaporkan gejala perut yang tidak biasa (terutama perdarahan saluran cerna) terutama pada tahap awal pengobatan. Perhatian harus disarankan pada pasien yang menerima obat bersamaan yang dapat meningkatkan risiko sariawan atau perdarahan, seperti kortikosteroid oral, antikoagulan seperti warfarin, obat-obatan anti depressan atau agen anti-platelet seperti asam asetil salisilat (Lihat Interaksi).

Ketika perdarahan saluran cerna atau sariawan terjadi, pengobatan harus dihentikan. OAINS harus diberikan dengan hati-hati kepada pasien dengan riwayat penyakit saluran cerna (radang usus, radang kronis saluran cerna) karena kondisinya dapat memburuk (Lihat Efek yang tidak diinginkan).

Efek jantung dan pembuluh darah otak: ibuprofen dosis rendah (misalnya).

- Pemantauan dan saran yang tepat diperlukan untuk pasien dengan riwayat hipertensi dan atau gagal jantung kongestif ringan sampai sedang. Retensi cairan, hipertensi dan edema telah dilaporkan berhubungan dengan terapi OAINS.
- Studi klinis menunjukkan bahwa penggunaan ibuprofen, terutama pada dosis tinggi (2400 mg/hari) dapat dikaitkan dengan sedikit peningkatan risiko kejadian gumpalan (misalnya serangan jantung atau stroke). Secara keseluruhan, studi epidemiologi tidak menunjukkan bahwa ibuprofen dosis rendah (≤ 1200 mg/hari) dikaitkan dengan peningkatan risiko kejadian gumpalan pembuluh darah arteri.
- Pasien dengan hipertensi yang tidak terkontrol, gagal jantung kongestif (NYHA II-III), penyakit jantung iskemik, penyakit penyumbatan aliran darah ke tungkai, dan/atau penyakit pembuluh darah otak hanya boleh diobati dengan ibuprofen setelah pertimbangan hati-hati dan dosis tinggi (2400 mg/hari) harus diberikan dihindari.
- Pertimbangan hati-hati juga harus dilakukan sebelum memulai pengobatan jangka panjang pasien dengan faktor risiko kejadian penyakit jantung dan pembuluh darah (misalnya tekanan darah tinggi, kolesterol tinggi, diabetes mellitus, dan merokok), terutama jika ibuprofen dosis tinggi (2400 mg/hari) diperlukan.

Reaksi kulit yang parah

- Reaksi kulit yang serius, beberapa di antaranya fatal, termasuk reaksi kemerahan dan pengelupasan kulit, sindrom Stevens-Johnson, dan hipersensitivitas pada kulit, telah dilaporkan sangat jarang terkait dengan penggunaan OAINS (lihat Efek yang tidak diinginkan). Pasien tampaknya berada pada risiko tertinggi dari reaksi ini di awal terapi, timbulnya reaksi terjadi pada sebagian besar kasus dalam bulan pertama pengobatan. Produk yang mengandung ibuprofen harus dihentikan saat pertama kali muncul ruam kulit, lesi mukosa, atau tanda hipersensitivitas lainnya.

Menutupi gejala infeksi yang mendasarinya

- Ibuprofen dapat menutupi gejala infeksi, yang dapat menyebabkan penundaan pengobatan yang tepat dan dengan demikian memperburuk hasil infeksi. Ini telah diamati pada radang paru-paru yang didapat komunitas bakteri dan komplikasi bakteri pada varicella. Ketika Ibuprofen diberikan untuk meredakan demam atau nyeri sehubungan dengan infeksi, disarankan untuk memantau infeksi. Di tempat non-rumah sakit, pasien harus berkonsultasi dengan dokter jika gejala terus berlanjut atau memburuk.

Efek lainnya

- Perhatian diperlukan pada pasien dengan gangguan penggumpalan dan insufisiensi hati, jantung atau ginjal. Perhatian harus digunakan saat memulai pengobatan dengan ibuprofen pada pasien dengan dehidrasi berat.
- Risiko penggunaan analgesik kebiasaan jangka panjang adalah sakit kepala dan kerusakan ginjal akibat penggunaan analgesik.
- Penyempitan saluran napas dapat terjadi pada pasien yang menderita atau dengan riwayat asma bronkial atau penyakit alergi sebelumnya.
- Perhatian diperlukan pada pasien dengan penyakit autoimun kronis atau penyakit

kolagen lainnya. Ada beberapa bukti bahwa obat yang menghambat sintesis siklooksigenase/prostaglandin dapat menyebabkan gangguan kesuburan wanita dengan efek pada ovulasi. Ini reversibel pada penarikan pengobatan.

- Pasien yang mengalami gangguan penglihatan selama terapi ibuprofen harus menghentikan pengobatan dan melakukan pemeriksaan oftalmologis. OAIN S dapat menghasilkan peningkatan hasil tes fungsi hati.

10. Obat yang harus dihindari saat mengkomsumsi obat ini?
    Hindari penggunaan ibuprofen dengan obat berikut:
    - Asam asetilsalisilat : Tidak dapat dikesampingkan bahwa penggunaan ibuprofen jangka panjang dapat mengurangi efek pelindung jantung dari asam asetilsalisilat dosis rendah.
    - Diuretik : Efikasi dari furosemid dan diuretik tiazid dapat berkurang.
    - Antikoagulan : OAINS dapat meningkatkan efek antikoagulan, seperti warfarin.
    - Antiplatelet dan Selective serotonin reuptake inhibitors (SSRIs) : Meningkatkan resiko dari pendarahan gastrointestinal.
    - Antihipertensi : Ibuprofen dapat mengurangi efek antihipertensi
    - Digoxin, fenitoin, lithium : Dalam literatur kasus individu ditemukan peningkatan kadar plasma digoksin, fenitoin dan lithium karena ibuprofen.
    - Golongan obat antiinflamasi non steroid (OAINS), termasuk inhibitor selektif siklooksigenasi-2 : Ibuprofen (sama seperti OAINS lainnya) harus digunakan dengan hati-hati pada kombinasi dengan asam asetilsalisilat atau OAINS lainnya dan kortikosteroid sistemik, karena dapat meningkatkan resiko obat yang merugikan pada saluran pencernaan.
    - Metrotrexate : Ibuprofen dapat meningkatkan level plasma metrotexate.
    - Zidovudine : Penggunaan zidovudine dan ibuprofen secara bersamaan dapat meningkatkan resiko darah masuk ke sendi dan memar pada pasien hemofilia HIV (+)
    - Tacrolimus : Penggunaan bersamaan ibuprofen dan tacrolimus dapat meingkatkan resiko keracunan pada ginjal, karena pengurangan sintesis prostaglandin ginjal.
    - Agen hipoglikemia : Ibuprofen meningkatkan efek agen hipoglikemik dan insulin. Mungkin diperlukan penyesuaian dosis.
    - Siklosporin : Penggunaan bersamaan dengan antiinflamasi non steroid (OAINS) dapat meningkatkan resiko dari efek keracunan siklosporin pada ginjal.
    - Voriconazole atau fluconazole : Penggunaan bersamaan dengan ibuprofen dapat menyebabkan peningkatan paparan ibuprofen dan konsentrasi plasma.
    - Mifepristone : Penurunan efek mifepristone secara teoritis dapat terjadi karena sifat antiprostaglandin dari OAINS.
    - Antibiotik quinolone : Penggunaan bersamaan dengan antiinflamasi non steroid (OAINS) dapat menyebabkan peningkatan resiko kejang.
    - Ekstrak herbal Gingko Biloba : Dapat mempotensiasi resiko perdarahan dengan OAINS
    - Aminoglikosida : OAINS dapat menurunkan ekskresi aminoglikosida.
    - Interaksi dengan hasil tes diagnostik:
        - ✓ Waktu perdarahan
        - ✓ Konsentrasi glukosa serum
        - ✓ Klirens Kreatinin
        - ✓ Hematokrit atau hemoglobin
        - ✓ BUN, konsentrasi kreatinin serum dan kaliemia.
        - ✓ Tes fungsi hati.

11. Apakah boleh digunakan pada wanita hamil dan menyusui?

Kehamilan

Penghambatan sintesis prostaglandin dapat berdampak buruk pada kehamilan dan/atau perkembangan embrio/janin. Selama trimester pertama dan kedua kehamilan, GOFEX tidak boleh diberikan kecuali benar-benar diperlukan. Jika GOFEX digunakan oleh wanita yang mencoba untuk hamil atau selama trimester pertama dan kedua kehamilan, dosis harus dijaga serendah mungkin dan durasi pengobatan sesingkat mungkin. Akibatnya, GOFEX dikontraindikasikan selama trimester ketiga kehamilan (lihat kontraindikasi)

Menyusui

Ibuprofen dan produk dekomposisi/metabolitnya diekskresikan dalam ASI, tetapi pada dosis terapeutik GOFEX tidak ada efek pada bayi baru lahir/bayi yang disusui. Karena efek berbahaya pada bayi belum diketahui, umumnya tidak perlu menghentikan pemberian ASI untuk pengobatan jangka pendek dengan dosis yang dianjurkan untuk nyeri dan demam ringan hingga sedang.

12. Efek samping yang mungkin terjadi?
    - Efek samping yang paling sering dilaporkan mempengaruhi saluran pencernaan, mulai dari mual dan kembung hingga perdarahan serius atau aktivasi tukak lambung (lihat peringatan dan tindakan pencegahan khusus untuk penggunaan).
    - Reaksi bulosa termasuk sindrom Steven-Johnson's dan hipersensitivitas pada kulit yang sangat jarang diamati.
    - Pembengkakan, hipertensi, dan gagal jantung telah dilaporkan berhubungan dengan pengobatan obat antiinflamasi non steroid. Studi klinis menunjukkan bahwa penggunaan ibuprofen, terutama pada dosis tinggi (2400 mg/hari) dapat dikaitkan dengan sedikit peningkatan risiko kejadian trombotik arteri (misalnya infark miokard atau stroke) (lihat Peringatan Khusus dan pencegahan penggunaan).
    - Berdasarkan frekuensi yang sering terjadi (umum, tidak umum, jarang, tidak diketahui)
        - Umum : Sakit kepala, pusing, gangguan ruam pada kulit
        - Tidak umum: Reaksi alergi, asma, perburukan asma, penyempitan saluran napas, sesak napas, tukak lambung, pendarahan saluran cerna, muntah, tinja berwaran hitam/gelap, radang lambung, pembengkakan dibawah kulit, ruam kulit, gatal-gatal.
        - Jarang : Trombosit rendah, penyakit sumsum tulang tidak memproduksi sel darah putih, kondisi kekurangan sel darah merah, reaksi alergi berat, gangguan penglihatan, gangguan pendengaran, robekan saluran pencernaan, sembelit, perdarahan internal, peradangan pada mukosa usus, peradangan yang memburuk, perburukan *Chron's disease*, penyakit hati, kencing berdarah, tes fungsi hati abnormal
        - Tidak diketahui: Kekurangan darah sel darah merah, reaksi alergi berat, infeksi bakteri pada cairan serebrosinal, pembengkakan pada saraf optik mata, gagal jantung, gumpalan pembuluh darah arteri, hipertensi, hipotensi, iritasi tenggorokan, anoreksia, gangguan liver, hepatitis, penyakit kuning, reaksi fotosensitif, perburukan reaksi kulit, DRESS sindrom, pembengkakan, tes fungsi hati abnormal.

13. Bagaimana cara menyimpan obat ini?

Simpan pada suhu dibawah 30^{o}C dan terlindung dari cahaya.

14. Informasi Overdosis dan penanganannya
    - Secara umum, gejala overdosis meliputi mual, nyeri lambung, muntah (darah) dan diare (darah), pusing, sesak, gangguan pada bola mata dan penglihatan berbayang, sakit kepala, dan telinga berdenging. Dalam kasus keracunan parah juga gangguan fungsi ginjal, hipotensi, penurunan kesadaran dan koma (tidak jelas apakah gangguan fungsi ginjal disebabkan oleh keracunan atau hipotensi bersamaan). Pada keracunan yang serius kadar asam dalam tubuh tinggi dapat terjadi.
    - Penanganan overdosis:
      Tidak ada penawar khusus untuk ibuprofen. Perut harus dikosongkan sesegera mungkin. Jika memungkinkan, pasien harus muntah. Jika pasien tidak sadar, bilas lambung dan koreksi kelainan elektrolit berat harus dipertimbangkan

HARUS DENGAN RESEP DOKTER

Shelf life: 3 tahun

Kemasan
Dus, 5 catchcover @ 1 Blister @10 Kapsul Lunak
Reg No. DKI2360600202A1
Dus, 1 Blister @ 10 Kapsul Lunak
Reg No. DKI2360600202A1

Produsen dibawah lisensi dari:
Mega Lifesciences (AUSTRALIA) PTY.LTD.
Diproduksi oleh:
Mega Lifesciences Public Company Limited Bangpoo industrial estate,
Samutprakarn 10280, Thailand

Didaftarkan oleh:
PT Mega Lifesciences Indonesia Bogor-Indonesia