Ibuprofen

INJECTION
100 mg/mL

WARNING : RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

Cardiovascular Risk

- **Non-steroidal anti-inflammatory drugs (NSAIDs) may increase the risk of serious cardiovascular (CV) 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 [*see Warnings and Precautions*].**
- **Ibuprofen is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery [*see Contraindications and Warnings and Precautions*].**

Gastrointestinal Risk

- **NSAIDs increase the risk of serious gastrointestinal (GI) 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 [*see Warnings and Precautions*].**

COMPOSITION
Ibuprofen Injection
Each mL contains :
Ibuprofen 100 mg

PHARMACOLOGY PROPERTIES
Ibuprofen's mechanism of action, like that of other NSAIDs, is not completely understood but may be related to prostaglandin synthetase inhibition. **Ibuprofen** possesses anti-inflammatory, analgesic, and antipyretic activity.

PHARMACOKINETIC PROPERTIES
Ibuprofen is a racemic mixture of [-]R- and [+]S-isomers. In vivo and in vitro studies indicate that the [+]S-isomer is responsible for clinical activity. The [-]R-form, while thought to be pharmacologically inactive, is slowly and incompletely (~60%) interconverted into the active [+]S species in adults. The [-]R-isomer serves as a circulating reservoir to maintain levels of active drug. The pharmacokinetic parameters of **Ibuprofen** injection determined in a published paper study with volunteers are presented below.

Pharmacokinetic Parameters of Intravenous Ibuprofen		
	400 mg* **Ibuprofen** Mean (CV%)	800 mg* **Ibuprofen** Mean (CV%)
Number of Patients	12	12
AUC (mcg.h/mL)	109.3 (26.4)	192.8 (18.5)
Cmax (mcg/mL)	39.2 (15.5)	72.6 (13.2)
KEL (1/h)	0,32 (17.9)	0,29 (12,8)
$T_{1/2}$ (h)	2.22 (20.1)	2.44 (12.9)

AUC = Area-under-the-curve
Cmax = Peak plasma concentration
CV = Coefficient of Variation
KEL = First-order elimination rate constant
$T_{1/2}$ = Elimination half-life
* = 60 minute infusion time

Ibuprofen, like most NSAIDs, is highly protein bound (>99% bound at 20 mcg/mL). Protein binding is saturable, and at concentrations >20 mcg/mL binding is nonlinear. Based on oral dosing data, there is an age- or fever-related change in volume of distribution for **ibuprofen.**

INDICATIONS
Ibuprofen is indicated in adults for the management of acute moderate to severe pain as an adjunct to intravenous opioid analgesics where an intravenous route of administration is considered clinically necessary

DOSAGE AND ADMINISTRATION
Administer 400 mg to 800 mg intravenously every 6 hours as necessary. Infusion time must be at least 30 minutes. The highest recommended dose is 2400 mg daily. Do not exceed 3200 mg. Similarly, going beyond 24 hours must be justified based on benefits over risks assessments.

Preparation and Administration
Concentrated injection **must be diluted** prior to intravenous (IV) infusion.
Dilute to a final concentration of 4 mg/mL or less. Appropriate diluents include 0.9% Sodium Chloride (normal saline) or 5% Glucose.

- 400 mg dose : Dilute 4 mL of Injection in no less than 100 mL of diluent
- 800 mg dose : Dilute 8 mL of Injection in no less than 200 mL of diluent

Visually inspect Injection for particulate matter and discolouration prior to administration, whenever solution and container permit. If visibly opaque particles, discolouration or other foreign particulates are observed, the solution should not be used. Once diluted the solution should be used as soon as possible. It is a sterile solution for single use and contains no antimicrobial preservative. Infusion time is 30 minutes.
Injection should be used in one patient on one occasion only. It contains no antimicrobial preservative. Unused solution should be discarded.

WARNINGS AND PRECAUTIONS

1. **Cardiovascular Thrombotic Events**
   Clinical trials of several COX-2 selective and nonselective NSAIDs of up to three years duration have shown an increased risk of serious cardiovascular (CV) thrombotic events, myocardial infarction and stroke, which can be fatal. All NSAIDs, both COX-2 selective and nonselective, may have a similar risk. Patients with known CV disease or risk factors for CV disease may be at greater risk. To minimize the potential risk for an adverse CV event in patients treated with an NSAID, use the lowest effective dose for the shortest duration possible. Physicians and patients should remain alert for the development of such events, even in the absence of previous CV symptoms. Patients should be informed about the signs and/or symptoms of serious CV events and the steps to take if they occur.
   Two large, controlled clinical trials of a COX-2 selective NSAID for the treatment of pain in the first 10-14 days following CABG surgery found an increased incidence of myocardial infarction and stroke [*see Contraindications*].
   There is no consistent evidence that concurrent use of aspirin mitigates the increased risk of serious CV thrombotic events associated with NSAID use. The concurrent use of aspirin and an NSAID does increase the risk of serious gastrointestinal (GI) events [*see Warnings and Precautions*].
2. **Gastrointestinal Effects : Risk of Ulceration, Bleeding, and Perforation**
   NSAIDs, including ibuprofen, can cause serious GI adverse events including inflammation, bleeding, ulceration, and perforation of the stomach, small intestine, or large intestine, which can be fatal. These serious adverse events can occur at any time, with or without warning symptoms, in patients treated with NSAIDs. Only one in five patients who develop a serious upper GI adverse event on NSAID therapy is symptomatic. Upper GI ulcers, gross bleeding, or perforation caused by NSAIDs occur in approximately 1% of patients treated for 3-6 months and in about 2-4% of patients treated for one year. These trends continue with longer duration of use, increasing the likelihood of developing a serious GI event at some time during the course of therapy. However, even short-term therapy is not without risk.
   Prescribe NSAIDs, including **Ibuprofen**, with extreme caution in those with a prior history of ulcer disease or GI bleeding. Patients with a prior history of peptic ulcer disease and/or GI bleeding who use NSAIDs have a greater than 10-fold increased risk for developing a GI bleed compared to treated patients with neither of these risk factors. Other factors that increase the risk of GI bleeding in patients treated with NSAIDs include concomitant use of oral corticosteroids or anticoagulants, longer duration of NSAID therapy, smoking, use of alcohol, older age, and poor general health status. Most reports of spontaneous fatal GI events are in elderly or debilitated patients, and therefore special care should be taken in treating this population.
   To minimize the potential risk for an adverse GI event in patients treated with an NSAID, use the lowest effective dose for the shortest possible duration. Patients and physicians should remain alert for signs and symptoms of GI ulcerations and bleeding during NSAID therapy and promptly initiate additional evaluation and treatment if a serious GI event is suspected. This should include discontinuation of the NSAID until a serious GI adverse event is ruled out. For high-risk patients, alternate therapies that do not involve NSAIDs should be considered.
3. **Hepatic Effects**
   Borderline elevations of one or more liver tests may occur in up to 15% of patients taking NSAIDs, including ibuprofen. These laboratory abnormalities may progress, may remain unchanged, or may be transient with continuing therapy. Notable elevations of ALT or AST (approximately three or more times the upper limit of normal) have been reported in approximately 1% of patients in clinical trials with NSAIDs. In addition, rare cases of severe hepatic reactions have been reported, including jaundice, fulminant hepatitis, liver necrosis and hepatic failure, some with fatal outcomes. A patient with symptoms and/or signs suggesting liver dysfunction, or with abnormal liver test values, should be evaluated for evidence of the development of a more severe hepatic reaction while on therapy with ibuprofen. If clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur (e.g., eosinophilia, rash, etc.), ibuprofen should be discontinued.
4. **Hypertension**
   NSAIDs, including ibuprofen, can lead to onset of new hypertension or worsening of pre-existing hypertension, either of which may contribute to the increased incidence of CV events. Use NSAIDs, including ibuprofen, with caution in patients with hypertension. Monitor blood pressure closely during the initiation of NSAID treatment and throughout the course of therapy. Patients taking ACE inhibitors, thiazides, or loop diuretics may have impaired response to these therapies when taking NSAIDs.
5. **Congestive Heart Failure and Edema**
   Fluid retention and edema have been observed in some patients taking NSAIDs. Use **Ibuprofen** with caution in patients with fluid retention or heart failure.
6. **Renal Effects**
   Use caution when initiating treatment with **Ibuprofen** in patients with considerable dehydration.
   Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury. Renal toxicity has also been seen in patients in whom renal prostaglandins have a compensatory role in the maintenance of renal perfusion. In these patients, administration of an NSAID may cause a dose dependent reduction in prostaglandin formation and, secondarily, in renal blood flow, which may precipitate overt renal decompensation. Patients at greatest risk of this reaction are those with impaired renal function, heart failure, liver dysfunction, those taking diuretics or ACE inhibitors, and the elderly. Discontinuation of NSAID therapy is usually followed by recovery to the pretreatment state.
   No information is available from controlled clinical studies regarding the use of **Ibuprofen** in patients with advanced renal disease. If **Ibuprofen** therapy must be initiated in patients with advanced renal disease, closely monitor the patient's renal function.
7. **Anaphylactoid Reactions**
   As with other NSAIDs, anaphylactoid reactions may occur in patients without known prior exposure to ibuprofen. **Ibuprofen** is contraindicated in patients with the aspirin triad. This symptom complex typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially fatal bronchospasm after taking aspirin or other NSAIDs [see Contraindications].
8. **Serious Skin Reactions**
   NSAIDs, including ibuprofen, can cause serious skin adverse reactions such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. These serious events may occur without warning. Inform patients about the signs and symptoms of serious skin manifestations, and to discontinue **Ibuprofen** at the first appearance of skin rash or any other sign of hypersensitivity.
9. **Pregnancy**
   Starting at 30 weeks gestation, **Ibuprofen**, and other NSAIDs, should be avoided by pregnant women as premature closure of the ductus arteriosus in the fetus may occur [*see Use in Specific Populations*].
10. **Masking Inflammation and Fever**
    The pharmacological activity of ibuprofen in reducing fever and inflammation may diminish the utility of these diagnostic signs in detecting complications of presumed noninfectious, painful conditions.
11. **Hematological Effects**
    Ibuprofen must be diluted prior to use. Infusion of the drug product without dilution can cause hemolysis [*see Dosage and Administration*].
    Anemia may occur in patients receiving NSAIDs, including ibuprofen. This may be due to fluid retention, occult or gross GI blood loss, or an incompletely described effect on erythropoiesis. In patients on long-term treatment with NSAIDs, including **ibuprofen**, check hemoglobin or hematocrit if they exhibit any signs or symptoms of anemia or blood loss.
    NSAIDs inhibit platelet aggregation and have been shown to prolong bleeding time in some patients. Unlike aspirin, their effects on platelet function are less severe quantitatively, of shorter duration, and reversible. Carefully monitor patients who may be adversely affected by alterations in platelet function, such as those with coagulation disorders or patients receiving anticoagulants.
12. **Pre-existing Asthma**
    Patients with asthma may have aspirin-sensitive asthma. The use of aspirin in patients with aspirin-sensitive asthma has been associated with severe bronchospasm, which can be fatal. Since cross-reactivity between aspirin and NSAIDs has been reported in such aspirin-sensitive patients, including bronchospasm, **Ibuprofen** contraindicated in patients with this form of aspirin sensitivity and should be used with caution in all patients with pre-existing asthma.
13. **Ophthalmological Effects**
    Blurred or diminished vision, scotomata, and changes in color vision have been reported with oral ibuprofen. Discontinue ibuprofen if a patient develops such complaints, and refer the patient for an ophthalmologic examination that includes central visual fields and color vision testing.
14. **Aseptic Meningitis**
    Aseptic meningitis with fever and coma has been observed in patients on oral ibuprofen therapy. Although it is probably more likely to occur in patients with systemic lupus erythematosus and related connective tissue diseases, it has been reported in patients who do not have underlying chronic disease. If signs or symptoms of meningitis develop in a patient on ibuprofen, give consideration to whether or not the signs or symptoms are related to ibuprofen therapy.
15. **Monitoring**
    Because serious GI tract ulcerations and bleeding can occur without warning symptoms, physicians should monitor for signs or symptoms of GI bleeding.
    Patients on long-term treatment with NSAIDs should have CBC and chemistry profiles checked periodically. If clinical signs and symptoms consistent with liver or renal disease develop, systemic manifestations occur (e.g., eosinophilia, rash), or abnormal liver tests persist or worsen, discontinue **Ibuprofen.**

ADVERSE REACTIONS
The following serious adverse reactions are discussed elsewhere in the labeling :

- Cardiovascular thrombotic events [*see Boxed Warning and Warnings and Precautions*]
- Gastrointestinal effects [*see Boxed Warning and Warnings and Precautions*]
- Hepatic effects [*see Warnings and Precautions*]
- Hypertension [*see Warnings and Precautions*]
- Congestive heart failure and edema [*see Warnings and Precautions*]
- Renal effects [*see Warnings and Precautions*]
- Anaphylactoid reactions [*see Warnings and Precautions*]
- Serious skin reactions [*see Warnings and Precautions*]

The most common adverse reactions reported in clinical studies are nausea, flatulence, vomiting, and headache. The most common reason for discontinuation due to adverse events in controlled trials of **Ibuprofen** is pruritus (<1%).

The following adverse reactions possibly related to ibuprofen are displayed by system organ classification.
Blood and lymphatic system disorders: Anemia, leukopenia, thrombocytopenia
Ear and labyrinth disorders: Ear pain
Endocrine disorders: Adrenal insufficiency
Gastrointestinal disorders: Abdominal discomfort, abdominal pain, abdominal pain upper, constipation, dry mouth, dyspepsia, gastroesophageal reflux disease, ileus, nausea, vomitting, flatulence
General disorders and administration site conditions: Chest pain, edema peripheral, inflammation, infusion site bruising, infusion site extravasation, infusion site irritation, infusion site pain, infusion site swelling, multi-organ failure
Immune system disorders: Hypersensitivity
Infections and infestations: Cellulitis, urinary tract infection fungal, vulvovaginal mycotic infection
Injury, poisoning and procedural complications: Anaemia postoperative, postoperative wound infection, procedural pain, wound complication
Investigations: Blood albumin decreased, blood creatinine increased, blood glucose increased, blood pressure increased, blood test abnormal, breath sounds abnormal, hepatic enzyme increased, liver function test abnormal, oxygen saturation decreased, platelet count decreased, urine output decreased, hemoglobin decreased
Metabolism and nutrition disorders: Acidosis, hyperglycemia, hypoglycemia, hypomagnesemia, hyponatremia, hypokalemia
Musculoskeletal and connective tissue disorders: Arthralgia, back pain, neck pain, pain in extremity
Nervous system disorders: Dizziness, headache, hypoesthesia, syncope, tremor, insomia
Psychiatric disorders: Agitation, anxiety, confusional state, disorientation
Renal and urinary disorders: Hematuria, renal failure acute, urinary retention
Respiratory, thoracic and mediastinal disorders: Cough, dyspnea, epistaxis, nasal congestion, pharyngeal edema, pharyngolaryngeal pain, pulmonary embolism, pulmonary edema, respiratory depression, respiratory failure, sleep apnea syndrome, wheezing
Skin and subcutaneous tissue disorders: Cellulitis, decubitus ulcer, dermatitis allergic, hyperhidrosis, rash
Surgical and medical procedures: Wound drainage
Vascular disorders: Deep vein thrombosis, hematoma, wound hemorrhage

CONTRAINDICATIONS

1. **Hypersensitivity**
   Ibuprofen is contraindicated in patients with known hypersensitivity (e.g., anaphylactoid reactions and serious skin reactions) to **ibuprofen** [*see Warnings and Precautions*].
2. **Asthma and Allergic Reactions**
   Ibuprofen is contraindicated in patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe, rarely fatal anaphylactic-like reactions to NSAIDs have been reported in such patients [*see Warnings and Precautions*].
3. **Coronary Artery Bypass Graft (CABG)**
   Ibuprofen is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery [*see Warnings and Precautions*].
4. **Pregnancy**
   Ibuprofen is contraindicated in last trimester in pregnancy.

DRUG INTERACTIONS

1. **Aspirin**
   When **ibuprofen** is administered with aspirin, ibuprofen's protein binding is reduced, although the clearance of free **ibuprofen** is not altered. The clinical significance of this interaction is not known; however, as with other NSAIDs, concomitant administration of **Ibuprofen** and aspirin is not generally recommended because of the potential for increased adverse effects.
2. **Anticoagulants**
   The effects of warfarin and NSAIDs on GI bleeding are synergistic, such that the users of both drugs together have a higher risk of serious GI bleeding than users of either drug alone [*see Warnings and Precautions*].
3. **ACE Inhibitors**
   Combination use of ACE inhibitors or angiotensin receptor antagonists, anti-inflammatory drugs and thiazide diuretics.
   NSAIDs may diminish the antihypertensive effect of ACE inhibitors. This interaction should be given consideration in patients taking NSAIDs concomitantly with ACE inhibitors. **Ibuprofen** like other NSAIDs can reduce the antihypertensive effect of ACE inhibitors and beta-blockers with possible loss of blood pressure control and can attenuate the natriuretic effects of thiazide diuretics and furosemide. Diuretics can also increase the risk of nephrotoxicity of NSAIDs. The combined use of the three classes of drugs, thiazides, an ACE inhibiting drug (ACE-inhibitor or angiotensin reseptor antagonist) and an antiinflammatory drug (NSAID or COX-2 inhibitor) all at the same time increases the risk of renal impairment.
4. **Diuretics**
   Clinical studies and postmarketing observations have shown that ibuprofen can reduce the natriuretic effects of furosemide and thiazides in some patients. This response has been attributed to inhibition of renal prostaglandin synthesis. During concomitant therapy with NSAIDs, observe patients closely for signs of renal failure, as well as to assure diuretic efficacy [*see Warnings and Precautions*].
5. **Lithium**
   Ibuprofen should be avoided in patients taking lithium as NSAIDs have produced elevations of plasma lithium levels and a reduction in renal lithium clearance.
6. **Methotrexate**
   NSAIDs have been reported to competitively inhibit methotrexate accumulation in rabbit kidney slices. This indicates that NSAIDs may enhance the toxicity of methotrexate. Use caution when NSAIDs are administered concomitantly with methotrexate.
7. **H-2 Antagonists**
   In studies of human volunteers, co-administration of cimetidine or ranitidine with **ibuprofen** had no substantive effect on **ibuprofen** serum concentrations.
8. **Aminoglycosides**
   NSAIDs may decrease the excretion of aminoglycosides.
9. **Cardiac Glycosides**
   NSAIDs may exacerbate cardiac failure, reduce glomerular filtration rate and increase plasma cardiac glycoside levels. Care should therefore be taken in patients treated with cardiac glycosides.
10. **Corticosteroids**
    Increased risk of gastrointestinal bleeding.
11. **Cyclosporin or Tacrolimus**
    Increased risk of nephrotoxicity when used with NSAIDs.
12. **Mifepristone**
    NSAIDs should not be used for 8-12 days after mifepristone administrations NSAIDs can reduce the effects of mifepristone.
13. **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.
14. **Zidovudine**
    Increased risk of haematological toxicity when NSAIDs are given with zidovudine. There is evidence of an increased risk of haemarthroses and hematoma in HIV (+) haemophiliacs receiving concurrent treatment with zidovudine and **ibuprofen.**
15. **Selective Serotonin Reuptake Inhibitors (SSRIs)**
    Concomitant administration of NSAIDs and SSRIs may increase the risk of gastrointestinal ulceration and bleeding.

USE IN SPECIFIC POPULATIONS

1. **Pregnancy**
   Ibuprofen is contraindicated for use during the third trimester of pregnancy because of risk of premature closure of the ductus arteriosus and the potential to prolong parturition.
   There are no adequate, well-controlled studies in pregnant women. Prior to the third trimester of pregnancy, should be used only if the potential benefit to the mother justifies the potential risk to the fetus.
   Inhibition of prostaglandin synthesis may adversely affect pregnancy and/or the embryofetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation after use of a prostaglandin synthesis inhibitor in early pregnancy.
2. **Labor and Delivery**
   The effects of **Ibuprofen** on labor and delivery in pregnant women are unknown. In rat studies, maternal exposure to NSAIDs, as with other drugs known to inhibit prostaglandin synthesis, increased the incidence of dystocia and delayed parturition, and decreased pup survival.
3. **Nursing Mothers**
   It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from **Ibuprofen**, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.
4. **Pediatric Use**
   Safety and efficacy of **Ibuprofen** for the treatment of pain has not been established in pediatric patients below the age of 18 years.
5. **Geriatric Use**
   Clinical studies of **Ibuprofen** did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. Elderly patients are at increased risk for serious GI adverse events.
6. **Hepatic Impairment**
   Ibuprofen has not been studied in patients with hepatic impairment. **Ibuprofen** is extensively metabolized in the liver via the CYP isoenzymes.
7. **Renal Impairment**
   Ibuprofen has not been studied in patients with renal impairment. **Ibuprofen** and its metabolites are eliminated via the kidney. **Ibuprofen's** action on inhibiting the renal prostaglandin production may increase the risk of renal adverse events.

OVERDOSAGE
The following signs and symptoms have occurred in individuals following an overdose of oral ibuprofen : abdominal pain, nausea, vomiting, drowsiness, and dizziness. There are no specific measures to treat acute overdosage with **Ibuprofen.** There is no known antidote to ibuprofen. In case of an overdosage, discontinue **Ibuprofen** therapy.

SHELF LIFE
24 months

STORAGE
Store below 25°C

PRESENTATION
Box of 5 vials @ 4 mL
Reg. No. GKL1831540643A1

ON MEDICAL PRESCRIPTION ONLY

Manufactured by :
PT. PRATAPA NIRMALA
Tangerang - Indonesia

LPPOM 00140079931116
I001598-AKM-10719

Insert Ibuprofen

FAHRENHEIT
PT. PRATAPA NIRMALA

Tanggal :	18 Juli 2019
Material :	HVS 60 gr
Size :	105 X 320 mm
Eyemark :	36-47 mm
Color :	Black
Revisi :	04

DISETUJUI OLEH BPOM : 04/03/2024

ID : EREG10019112300303

Informasi Produk untuk Pasien

Ibuprofen

INJEKSI
100 mg/mL

Baca informasi ini secara lengkap dan seksama sebelum Anda mulai menggunakan obat ini.
- Informasi produk ini menjawab pertanyaan umum tentang **Ibuprofen** Injeksi.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter atau apoteker Anda.
- Baca informasi produk ini dengan hati-hati dan seksama.
- Simpan informasi produk ini. Anda mungkin perlu untuk membacanya lagi.

Apa yang ada di dalam informasi produk ini

1. Apakah Ibuprofen itu dan digunakan untuk apa

Apakah Ibuprofen itu
- **Ibuprofen** termasuk ke dalam kelompok obat Anti-Inflamasi Non Steroid (AINS).
- **Ibuprofen** adalah larutan steril yang diberikan melalui infus ke dalam pembuluh darah setelah dilarutkan. **Ibuprofen** hanya boleh diberikan oleh dokter atau perawat.

Digunakan untuk apa Ibuprofen
- **Ibuprofen** diberikan pada pasien dewasa untuk penanganan nyeri akut yang sedang sampai berat sebagai tambahan pada pemberian analgesik opioid jika pemberian intravena dianggap perlu.

2. Apa saja yang harus Anda ketahui sebelum menggunakan Ibuprofen

Ibuprofen termasuk obat AINS
- Obat ini mengandung Ibuprofen. Beritahu dokter Anda jika Anda memiliki riwayat alergi terhadap Ibuprofen.
- Jangan menggunakan **Ibuprofen** jika Anda memiliki serangan asma, gatal-gatal, atau reaksi alergi dengan aspirin atau obat AINS lainnya.
- Jangan menggunakan **Ibuprofen** tepat sebelum atau setelah Anda menjalani operasi bypass jantung (CABG – *Coronary Artery Bypass Graft*).
- Jika Anda atau pasangan Anda dalam kondisi hamil trimester akhir, hindari menggunakan **Ibuprofen**.

Peringatan dan Perhatian

Beritahu dokter atau apoteker Anda sebelum menggunakan **Ibuprofen** tentang semua kondisi medis Anda, termasuk jika :
- Anda memiliki gangguan pada jantung
- Anda memiliki gangguan pencernaan
- Anda memiliki masalah hati
- Anda memiliki tekanan darah tinggi
- Anda memiliki masalah ginjal
- Anda memiliki asma
- Anda memiliki reaksi/alergi pada kulit
- Anda atau pasangan Anda sedang hamil atau merencanakan kehamilan. Jangan menggunakan **Ibuprofen** saat usia kehamilan 30 minggu.

3. Bagaimana cara menggunakan Ibuprofen

Penggunaan Ibuprofen
- Dosis **Ibuprofen** yang dianjurkan adalah 400 mg sampai 800 mg yang disuntikkan setiap 6 jam.
- **Ibuprofen** hanya dapat disuntikkan oleh dokter atau perawat.
- Lama penyuntikkan tidak boleh kurang dari 30 menit.
- Dosis terbesar adalah 2400 mg per hari. Total dosis yang diberikan dalam sehari tidak boleh melebihi 3200 mg.

Penyiapan dan Pemberian Ibuprofen
- **Ibuprofen** harus dilarutkan terlebih dahulu sebelum diberikan kepada pasien.
- Pelarut yang digunakan adalah sodium klorida (garam) 0,9 % atau glukosa 5%.
- Periksa larutan **Ibuprofen** secara visual perihal partikel dan perubahan warna sebelum disuntikkan. Jika ada partikel buram, terjadi perubahan warna, atau terlihat partikel asing lainnya, larutan **Ibuprofen** jangan digunakan.
- Larutan **Ibuprofen** harus langsung segera diberikan kepada pasien setelah dilarutkan.
- **Ibuprofen** hanya diberikan pada satu pasien saja untuk satu kali pemakaian.
- **Ibuprofen** merupakan larutan steril dan tidak mengandung pengawet sehingga sisa larutan **Ibuprofen** yang tidak terpakai, harus dibuang.

4. Efek samping apa saja yang mungkin terjadi

Efek samping obat paling umum adalah mual, perut kembung, muntah, dan sakit kepala.

Efek samping obat yang merugikan, antara lain :
- Anemia, leukopenia, trombositopenia
- Nyeri di telinga
- Gangguan pada saluran cerna (nyeri perut, konstipasi, mulut kering)
- Gangguan pada hati
- Kelainan pada sistem kekebalan tubuh (hipersensitif)
- Hipertensi (tekanan darah tinggi)
- Gagal jantung kongestif dan edema
- Gangguan pada ginjal
- Reaksi anafilaktoid
- Reaksi kulit
- Gangguan metabolisme dan nutrisi

Jika Anda mengalami efek samping, segera beritahu dokter atau apoteker Anda, termasuk efek samping yang tidak tercantum di dalam informasi produk ini.
Jika Anda mengalami gejala-gejala atau tanda-tanda dikarenakan menggunakan **Ibuprofen** terlalu banyak (berlebihan), segera hentikan penggunaan **Ibuprofen**.

5. Bagaimana cara menyimpan Ibuprofen

- **Ibuprofen** biasanya disimpan di rumah sakit.
- Jauhkan obat ini dari pandangan dan jangkauan anak-anak.
- Simpan pada suhu AC (<25°C) dan di dalam kemasan asli sampai waktunya obat digunakan.
- Jangan gunakan **Ibuprofen** setelah tanggal kadaluarsa yang tertera pada dus dan label vial. Tanggal kadaluarsa mengacu pada hari terakhir dari bulan tersebut.

6. Isi produk dan informasi lainnya

Apa isi Ibuprofen
- Zat aktif adalah ibuprofen.

Seperti apa Ibuprofen dan isi kemasan
- **Ibuprofen** adalah larutan jernih, tidak berwarna hingga kekuningan, tidak berbau, dan bebas dari kotoran yang terlihat
- **Ibuprofen** dikemas dalam vial yang ditutup dengan *flip off* dan dilindungi dengan *rubber stopper.*
- **Ibuprofen** tersedia dalam kemasan dengan volume 4 mL dan 8 mL.

No. Reg. GKL1831540643A1

HARUS DENGAN RESEP DOKTER

Diproduksi oleh :
PT. PRATAPA NIRMALA
Tangerang - Indonesia

LPPOM 00140079931116
O001598-AKM-10719

PIL Ibuprofen	
FAHRENHEIT PT. PRATAPA NIRMALA	Tanggal : 18 - 07 - 2019
	Material : HVS 60 gr
	Size : 105 X 320 mm
	Eyemark : 50-62 mm
	Color : Black
	Revisi : 00