

BRUFEN[®] 100mg/5ml

IBUPROFEN

Suspension

COMPOSITION

Each 5 ml (1 scoop) contains 100mg ibuprofen.

CLINICAL PHARMACOLOGY

Pharmacodynamic Properties

Ibuprofen is a propionic acid derivative with analgesic, anti-inflammatory and anti-pyretic activity. The drug's therapeutic effects are thought to result from its inhibitory effect on the enzyme cyclooxygenase, which results in a marked reduction in prostaglandin synthesis. Experimental data suggest that ibuprofen may inhibit the effect of low dose acetylsalicylic acid on platelet aggregation when they are dosed concomitantly. In one study, when a single dose of ibuprofen 400mg was taken within 8 hours before or within 30 minutes after immediate release acetylsalicylic acid dosing (81 mg), a decreased effect of acetylsalicylic acid on the formation of thromboxane or platelet aggregation occurred. However, the limitation 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.

Pharmacokinetics Properties

Ibuprofen is rapidly absorbed from the gastrointestinal tract, peak concentrations occurring one to two hours after administration. The elimination half-life is approximately two hours. Ibuprofen is metabolized in the liver into two inactive metabolites and the kidney excretes these, together with unchanged ibuprofen, either as such or as conjugates. Excretion by the kidney is both rapid and complete. Ibuprofen is extensively bound to plasma proteins.

INDICATIONS

- To reduce fever in children.
- To relief mild to moderate pain, such as dental pain or dental extraction pain, headache, postoperative pain, pain in rheumatic conditions of bones and joints, pain in associations with sprains.

DOSAGE AND ADMINISTRATION

Recommended dose for:

Adult

To relief pain: 3 to 4 times of 10 ml a day.

Children

To relief fever and pain:

Age	Dose	Frequency
1 to 2 years	2.5 ml	3 to 4 times a day
3 to 7 years	5 ml	3 to 4 times a day
8 to 12 years	10 ml	3 to 4 times a day

CONTRAINDICATIONS

- Patients with severe and active ulcer pepticum (gastric and duodenal ulceration).
- Patients with history of hypersensitivity to ibuprofen or other non-steroidal anti-inflammatory drugs
- Patients with polyps in the nose, angioedema and patients who develop asthma symptoms, rhinitis or urticaria when taking acetylsalicylic acid or other non-steroidal anti-inflammatory drugs.
- Last trimester in pregnancy.

WARNINGS AND PRECAUTIONS

General precautions

Undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms (see DOSAGE AND ADMINISTRATION). As with other NSAIDs, ibuprofen may mask the signs of infection.

Geriatric Use

Elderly patients have an increased frequency of adverse reactions to NSAIDs, especially gastrointestinal bleeding and perforation, which may be fatal.

Gastrointestinal bleeding, ulceration and perforation

Ibuprofen should be given with care to patients with a history peptic ulceration and other gastrointestinal disease since their conditions may be exacerbated.

Gastrointestinal bleeding, ulceration and perforation has been reported with all NSAIDs at anytime during treatment.

These adverse events can be fatal and may occur with or without warning symptoms or a previous history of serious gastrointestinal events. The risk of gastrointestinal bleeding, ulceration or perforation is higher with increasing ibuprofen in patients with a history of ulcers, particularly if complicated with hemorrhage or perforation, 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, as well as patients requiring concomitant low dose acetylsalicylic acid or for the drugs likely to increase gastrointestinal risk (see DRUG INTERACTIONS).

Patients with a history of gastrointestinal disease, particularly when elderly, should report any unusual abdominal symptoms (especially gastrointestinal bleeding) in the initial stages of treatment.

If gastrointestinal bleeding or ulceration occurs in patients receiving ibuprofen, the treatment should be withdrawn.

Respiratory disorder

Caution is required if ibuprofen is administered to patients suffering from, or with a previous history of, bronchial asthma since ibuprofen has been reported to cause bronchospasm in such patients.

Cardiac, Renal and Hepatic impairment

Caution is required in patients with renal, hepatic or cardiac impairment since use of NSAIDs may result in deterioration of renal function. The dose must be kept as low as possible and renal function should be monitored in these patients.

Cardiovascular and Cerebrovascular effects

Ibuprofen should be given with care to patients with a history of a heart failure or hypertension since edema has been reported in association with ibuprofen administration.

Epidemiological data suggest that use of ibuprofen, particularly at high dose (2400 mg daily) and in long-term treatment, may be associated with a small increased risk of arterial thrombotic events, such as myocardial infarction or stroke. Epidemiological studies do not suggest that low dose ibuprofen (e.g. <= 1200 mg daily) is associated with an increased risk of arterial thrombotic events, particularly myocardial infarction.

Patients with uncontrolled hypertension, congestive heart failure, established ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease should only be treated with ibuprofen after careful consideration. Similar consideration should be made before initiating longer-term treatment of patients with risk factors for cardiovascular disease (e.g. hypertension, hyperlipidemia, diabetes mellitus and smoking).

Dermatological effects

Serious skin reaction, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs. Patients appear to be at highest risk of these reactions early in the course of therapy. In the majority of cases, the onset of the reaction occurs within the first month of treatment. Ibuprofen should be discontinued at the first appearance of skin rash, mucosal lesions or any other signs of hypersensitivity.

Renal effects

Caution should be used when initiating treatment with ibuprofen in patients with considerable dehydration.

As with other NSAIDs, long-term administration of ibuprofen has resulted in renal papillary necrosis and other renal pathologic changes. 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 a non-steroidal anti-inflammatory drug 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 and ACE inhibitors and the elderly.

Discontinuation of non-steroidal anti-inflammatory drug therapy is usually followed by recovery to the pretreatment state.

Hematological effects

Ibuprofen, like other NSAIDs, can inhibit platelet aggregation and has been shown to prolong bleeding time in normal subject.

Aseptic meningitis

Aseptic meningitis has been observed on rare occasions in patients on ibuprofen therapy. Although it is probably more likely to occur in patients with systemic lupus erythematosus and related connective tissue disease, it has been reported in patients who do not have been underlying chronic disease.

DRUG INTERACTIONS

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

Anti-hypertensives - NSAIDs may reduce the effect of anti-hypertensives, such as ACE inhibitors.

Diuretics - NSAIDs may reduce the diuretic effect. Diuretics can also increase the risk of nephrotoxicity of NSAIDs

Lithium - NSAIDs may decrease elimination of lithium.

Methotrexate - NSAIDs may decrease elimination of methotrexate.

Anti-coagulants - NSAIDs may enhance the effects of anti-coagulants, such as warfarin.

Anti-platelet agents and Selective Serotonin Reuptake Inhibitors (SSRIs) - Increased risk of gastrointestinal bleeding with NSAIDs.

Aminoglycosides - NSAIDs may decrease the excretion of aminoglycosides.

Acetylsalicylic acid - as with other products containing NSAIDs, 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 inhibit the effect of low dose acetylsalicylic acid on platelet aggregation when they are dosed concomitantly. However, the limitations of these data and uncertainties of extrapolation of ex vivo data to the clinical situation imply that no firm conclusion can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional ibuprofen use (see CLINICAL PHARMACOLOGY).

Cardiac glycoside - NSAIDs may exacerbate cardiac failure, reduce glomerular filtration rate and increased plasma cardiac glycoside levels.

Cyclosporine - Increased risk of nephrotoxicity with NSAIDs.

Corticosteroids - Increased risk of gastrointestinal ulceration or bleeding with NSAIDs.

Cox-2 inhibitors and other NSAIDs - Concomitant use with other NSAIDs. Including cyclooxygenase-2 inhibitors, should be avoided due to the potential for additive effects.

Herbal extracts - Ginkgo biloba may potentiate the risk of bleeding with NSAIDs.

Mifepristone - NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.

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.

Tacrolimus - Possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus.

Zidovudine - Increased risk of hematological toxicity when NSAIDs are given with zidovudine. There is evidence of an increased risk of hemarthroses and hematoma in HIV (+) hemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.

PREGNANCY AND LACTATION

While no teratogenic effects have been demonstrated in animal toxicology studies, the use of ibuprofen during pregnancy should be avoided. Congenital abnormalities have been reported in association with ibuprofen administration in man, however these are low in frequency and do not appear to follow any discernible pattern. In view of the known effects of NSAID on the fetal cardiovascular system (closure of ductus arterius) use in late pregnancy should be avoided.

Labor and delivery

Administration of ibuprofen is not recommended during labor and delivery. The onset of labor may be delayed and the duration increased with a greater bleeding tendency in both mother and child.

Nursing mothers

In the limited studies so far available, ibuprofen appears in the breast milk in very low concentrations. Ibuprofen is not recommended for use in nursing mothers.

ADVERSE REACTIONS

The pattern of adverse events reported for ibuprofen is similar to that of other NSAIDs.

Immune system disorders

Hypersensitivity reaction has been reported following treatment with ibuprofen. These may consist of (a) non-specific allergic reaction and anaphylaxis, (b) respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnea, or (c) assorted skin disorders, including rash of various types, pruritus, urticaria, purpura, angioedema and, very rarely, bullous dermatoses (including Stevens-Johnson syndrome, toxic epidermal necrolysis and erythema multiforme).

Gastrointestinal disorders

The most commonly observed adverse events are gastrointestinal in nature. Nausea, vomiting, diarrhea, flatulence, constipation, dyspepsia, abdominal pain, melena, hematemesis, ulcerative stomatitis, gastrointestinal hemorrhage and exacerbation of colitis and Crohn's disease (see **CONTRAINDICATIONS**) have been reported following ibuprofen administration. Less frequently, gastritis, duodenal ulcer and gastric ulcer have been observed.

Pancreatitis has been reported very rarely.

General disorders and administration site conditions

Edema has been reported in association with ibuprofen treatment.

Other adverse events reported less commonly and for which causality has not necessarily been established include:

Blood and lymphatic system disorders - Thrombocytopenia, neutropenia, agranulocytosis, aplastic anemia and hemolytic anemia.

Psychiatric disorders - Depression, confusional state.

Nervous system disorders - Headache, paresthesia, dizziness, somnolence, optic neuritis.

Eye disorders - Visual disturbance.

Ear and labyrinth disorders - Vertigo, tinnitus.

Hepatobiliary disorders - Hepatic function abnormal, hepatic failure, hepatitis, jaundice.

Skin and subcutaneous tissue disorders - Photosensitivity reaction.

Renal and urinary disorders - Toxic nephropathy in various forms, including interstitial nephritis, nephrotic syndrome and renal failure.

OVERDOSAGE

Symptoms

The symptoms of overdose include nausea, vomiting, dizziness, convulsion, loss of consciousness and depression of the CNS and respiratory system. Large overdoses are generally well tolerated when no other drugs are being taken.

Treatment

There is no specific antidote to ibuprofen.

STORAGE

Do not store above 30°C.

Shelf-life: 3 years

<p>P. No. 1 Awas Obat Keras Bacalah aturan memakainya</p>
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PRESENTATION

Box, bottle of 60 ml

Reg. No. DTL0400203033A1

Manufactured by

PT. Abbott Indonesia

Jl. Raya Jakarta Bogor Km. 37, Cimanggis

Depok 16415, Indonesia

Underlicense and controlled by

Abbott Laboratories, Chicago, ILL., USA

BRUFEN[®] 100mg/5ml Suspensi

IBUPROFEN

INFORMASI PENTING

Bacalah seluruh isi leaflet sebelum anda mulai menggunakan obat ini.

- Simpan leaflet ini karena anda mungkin perlu untuk membacanya kembali.
- Leaflet ini menyediakan ringkasan informasi yang tersedia saat ini mengenai BRUFEN[®] 100 mg/5 ml Suspensi.
- Untuk informasi lebih lanjut atau bantuan mintalah kepada dokter anda atau apoteker.
- Obat ini hanya untuk anda dan tidak boleh diberikan kepada orang lain, sekalipun mereka memperlihatkan gejala-gejala seperti yang anda alami.
- Beritahukan dokter anda atau apoteker apabila anda mengalami efek-efek samping.

Informasi yang terdapat pada leaflet:

1. Apakah BRUFEN[®] 100 mg/5 ml Suspensi dan apakah kegunaanya?
2. Apa yang harus anda ketahui sebelum menggunakan BRUFEN[®] 100 mg/5 ml Suspensi?
3. Bagaimana anda harus menggunakan BRUFEN[®] 100 mg/5 ml Suspensi?
4. Efek-efek samping yang mungkin ditimbulkan oleh BRUFEN[®] 100 mg/5 ml Suspensi.
5. Bagaimana anda harus menyimpan BRUFEN[®] 100 mg/5 ml Suspensi?
6. Informasi lebih lanjut mengenai BRUFEN[®] 100 mg/5 ml Suspensi.

1. Apakah BRUFEN[®] 100 mg/5 ml Suspensi dan apakah kegunaanya?

BRUFEN[®] 100 mg/5 ml Suspensi termasuk ke dalam kelompok obat yang disebut penghilang rasa nyeri antiinflamasi. BRUFEN[®] 100 mg/5 ml Suspensi dapat digunakan untuk mengatasi rasa nyeri ringan sampai sedang, seperti nyeri gigi atau nyeri setelah pencabutan gigi, sakit kepala, nyeri paska pembedahan, nyeri dalam kondisi-kondisi rematik pada tulang dan sendi, nyeri akibat terkilir. Obat ini juga dapat digunakan untuk menurunkan demam pada anak-anak.

Zat berkhasiat yang terkandung dalam BRUFEN[®] 100 mg/5 ml Suspensi adalah ibuprofen. Tiap 5 ml (satu sendok takar) BRUFEN[®] 100 mg/5 ml Suspensi mengandung 100 mg ibuprofen.

2. Apa yang harus anda ketahui sebelum menggunakan BRUFEN[®] 100 mg/5 ml Suspensi?

Apabila jawaban terhadap salah satu dari pertanyaan di bawah ini adalah 'YA', harap beritahukan dokter anda atau apoteker SEBELUM menggunakan BRUFEN[®] 100 mg/5 ml Suspensi.

- Apakah anda mempunyai, atau pernah mempunyai, ulkus lambung atau keluhan pencernaan lainnya? Jangan menggunakan BRUFEN[®] 100 mg/5 ml Suspensi apabila anda sedang menderita ulkus peptik (ulkus pada lambung atau usus dua belas jari) atau pendarahan pada lambung, atau pernah mengalami dua kali atau lebih kejadian ulkus peptik, pendarahan atau perforasi lambung di masa lalu.
- Apakah mempunyai kondisi yang meningkatkan kecenderungan untuk mengalami pendarahan?
- Apakah anda menderita asma atau apakah anda pernah mengalami reaksi alergi atau menderita mengi setelah menggunakan produk-produk yang mengandung ibuprofen, aspirin atau penghilang nyeri antiinflamasi lainnya?
- Apakah anda menderita penyakit ginjal atau hati?
- Apakah anda menderita penyakit jantung?
Obat-obatan seperti BRUFEN[®] 100 mg/5 ml Suspensi mungkin terkait dengan peningkatan kecil pada resiko serangan jantung (infark miokard) atau stroke. Resiko cenderung terjadi pada penggunaan dosis tinggi dan pengobatan jangka panjang. Jangan melebihi dosis atau durasi pengobatan yang direkomendasikan. Apabila anda memiliki masalah dengan jantung, pernah mengalami stroke atau merasa anda mungkin beresiko untuk mengalami kondisi-kondisi tersebut (misal: apabila anda memiliki tekanan darah tinggi, diabetes, kolesterol tinggi atau perokok) anda harus mendiskusikan pengobatan anda dengan dokter atau apoteker.
- Apakah anda memiliki lupus erythematosus sistemik (SLE, kadang dikenal sebagai lupus) atau penyakit jaringan penghubung (penyakit otoimun yang mempengaruhi jaringan penghubung)?
- Apakah anda pernah diberitahukan oleh dokter bahwa anda memiliki intoleransi terhadap jenis gula tertentu? Sehubungan dengan kandungan sorbitol dan sukrosanya, produk ini tidak direkomendasikan untuk individu yang memiliki intoleransi terhadap fruktosa, sindrom gangguan penyerapan glukosa atau kekurangan enzim sucraseisomaltase.

Bolehkah anda menggunakan BRUFEN® 100 mg/5 ml Suspensi bersama obat-obatan lain?

Beberapa obat yang merupakan antikoagulan (yaitu mengencerkan darah/mencegah pembekuan darah, misal: aspirin/acetysalicylic acid, warfarin, ticlodipine), beberapa obat yang menurunkan tekanan darah tinggi (ACE-inhibitor seperti captopril, beta-blocker seperti atenolol, atau antagonis reseptor angiotensin-II seperti losartan) dan obat-obatan lain yang mungkin mempengaruhi atau terpengaruhi oleh pengobatan dengan ibuprofen. Oleh karena itu, anda harus selalu meminta saran dari dokter atau apoteker sebelum menggunakan ibuprofen dengan obat-obatan lain. Anda juga wajib memberitahukan dokter anda atau apoteker apabila anda sedang menggunakan obat-obatan berikut ini:

- Obat-obat diuretik
- Glikosida jantung, seperti digoxin, digunakan untuk mengobati masalah-masalah jantung
- Lithium
- Zidovudin (obat antivirus)
- Steroid (digunakan pada pengobatan keadaan-keadaan inflamasi)
- Methotrexate (digunakan untuk mengobati jenis kanker tertentu)
- Obat-obatan yang diketahui merupakan immunosuppressant seperti ciclosporin dan tacrolimus (digunakan untuk meredam respon imun anda)
- Obat-obatan yang diketahui sebagai *Selective Serotonin Reuptake Inhibitor* (SSRIs), digunakan untuk pengobatan depresi
- Antibiotik-antibiotik yang termasuk golongan quinolones seperti ciprofloxacin
- Aminoglycoside (salah satu jenis antibiotik)
- Mifepristone
- Produk-produk lain yang mengandung ibuprofen, seperti yang dapat anda beli tanpa resep dokter
- Produk-produk penghilang rasa nyeri antiinflamasi lainnya, termasuk aspirin
- Obat herbal Ginkgo biloba (ada kemungkinan anda akan lebih mudah berdarah apabila anda menggunakannya bersama dengan ibuprofen)

Informasi lain mengenai BRUFEN® 100 mg/5 ml Suspensi

Suspensi ini mengandung sejumlah kecil glycerin. Pada dosis tinggi, glycerin terkadang dapat menyebabkan sakit kepala, gangguan perut dan diare. Oleh karena itu, anda tidak diperbolehkan untuk menggunakan BRUFEN® 100 mg/5 ml Suspensi melebihi dosis yang ditetapkan, kecuali dokter anda menganjurkan anda demikian.

Kehamilan dan menyusui:

Penggunaan BRUFEN® 100 mg/5 ml Suspensi pada saat kehamilan atau menyusui harus dihindari. BRUFEN® 100 mg/5 ml Suspensi tidak boleh digunakan pada masa kehamilan akhir (tiga bulan terakhir) dan penggunaan pada enam bulan pertama kehamilan hanya diperbolehkan apabila dianjurkan oleh dokter anda.

3. Bagaimana anda harus menggunakan BRUFEN® 100 mg/5 ml Suspensi?

SELALU gunakan BRUFEN® 100 mg/5 ml Suspensi seperti yang telah diberitahukan oleh dokter anda. Apabila anda kebingungan periksalah informasi yang terdapat pada kemasan obat atau tanyakan kembali kepada dokter anda atau apoteker. Pastikan botol dikocok dengan seksama sebelum digunakan. Gunakanlah bersama makanan atau setelah makan.

DOSIS:

Dewasa - Untuk meredakan nyeri : 3 sampai 4 kali 10 ml (2 sendok takar) sehari

Anak-anak - Untuk meredakan demam dan nyeri:

Umur	Dosis	Frekuensi
1 - 2 tahun	2.5 ml	3 - 4 kali sehari
3 - 7 tahun	5 ml	3 - 4 kali sehari
8 - 12 tahun	10 ml	3 - 4 kali sehari

APABILA ANDA MENGGUNAKAN BRUFEN® 100 mg/5 ml Suspensi MELEBIHI JUMLAH YANG DIRESEPKAN (KELEBIHAN DOSIS) anda harus **SEGERA** menghubungi dokter anda atau mengunjungi rumah sakit terdekat, bawalah serta BRUFEN® 100 mg/5 ml Suspensi anda.

APABILA ANDA LUPA MENGGUNAKAN BRUFEN® 100 mg/ 5 ml Suspensi gunakanlah obat ini segera ketika anda teringat, kecuali apabila sudah hampir waktu penggunaan dosis berikutnya. Apabila demikian, jangan gunakan dosis yang sudah terlewatkan tersebut. Jangan pernah menggandakan dosis dengan tujuan untuk menggantikan dosis yang terlewatkan.

4. Efek-efek samping yang mungkin ditimbulkan oleh BRUFEN® 100 mg/5 ml Suspensi.

Sama halnya dengan obat-obatan lain, BRUFEN® 100 mg/5 ml Suspensi dapat memberikan efek samping, walaupun biasanya efek samping tersebut ringan dan tidak semua orang akan mengalaminya. Apabila salah satu efek samping bertambah serius, atau apabila anda mengalami efek samping yang tidak terdaftar dalam leaflet ini, mohon memberitahukan kepada dokter anda atau apoteker. Anda dapat mengurangi resiko efek samping dengan menggunakan jumlah dosis terendah dan frekuensi penggunaan tersingkat yang diperlukan untuk mengendalikan gejala-gejala yang anda alami.

Apabila anda mengalami salah satu kondisi di bawah ini kapan pun selama masa pengobatan anda BERHENTILAH MENGGUNAKAN BRUFEN® 100 mg/5 ml Suspensi dan segeralah mencari pertolongan medis:

- Sakit kepala berat, suhu tinggi, kekakuan pada leher atau intoleransi pada cahaya terang
- Mengeluarkan darah bersama feses
- Mengeluarkan kotoran berwarna hitam
- Memuntahkan darah atau gumpalan-gumpalan gelap yang terlihat seperti kopi giling

BERITAHUKAN DOKTER ANDA DAN BERHENTILAH MENGGUNAKAN BRUFEN® 100 mg/5 ml Suspensi APABILA ANDA MENGALAMI :

- Nyeri lambung yang tidak dapat dijelaskan atau gejala-gejala tidak normal lainnya pada lambung, gangguan pencernaan, heartburn, rasa mual dan/atau muntah.
- Bunyi mengi yang tidak dapat dijelaskan, tarikan napas yang pendek, ruam kulit, gatal dan luka memar.
- Mata dan/atau kulit berwarna kuning.
- Radang tenggorokan yang parah disertai demam tinggi.
- Gangguan penglihatan (buram) atau melihat/mendengar hal-hal asing.
- Retensi cairan (misal pembengkakan pada pergelangan kaki).

Obat-obatan seperti BRUFEN® 100 mg/5 ml Suspensi diketahui terkait dengan peningkatan kecil pada resiko serangan jantung (infark miokard) atau stroke.

Gangguan darah, masalah ginjal, masalah hati atau reaksi kulit yang parah dapat muncul sesekali pada penggunaan ibuprofen.

Secara jarang sekali BRUFEN® 100 mg/5 ml Suspensi dapat mengakibatkan meningitis aseptic (peradangan pada selaput pelindung yang menyelimuti otak).

Efek samping lainnya dapat berupa sakit kepala, halusinasi, pusing, rasa kesemutan pada tangan dan kaki, telinga berdenging, depresi, kebingungan, kesulitan tidur, kegelisahan, gangguan pendengaran, rasa terbakar sementara pada mulut atau kerongkongan, diare, konstipasi, kembung, sensitifitas kulit terhadap sinar matahari yang tidak diharapkan, kelelahan, rasa tidak enak badan, suasana hati yang tidak menentu dan pembengkakan dan iritasi pada bagian dalam hidung.

BRUFEN® 100 mg/5 ml Suspensi telah diketahui juga terkadang memperburuk gejala-gejala penyakit Crohn's atau kolitis.

5. Bagaimana anda harus menyimpan BRUFEN® 100 mg/5 ml Suspensi?

BRUFEN® 100 mg/5 ml Suspensi harus disimpan pada suhu tidak lebih dari 30°C. Obat ini harus disimpan di tempat yang aman, terhindar dari penglihatan dan jangkauan anak-anak, obat-obatan anda dapat membahayakan mereka.

Obat ini harus disimpan pada kemasan aslinya, **JANGAN** menggunakan BRUFEN® 100 mg/5 ml Suspensi setelah lewat masa kadaluarsa yang tercantum pada label botolnya.

6. Informasi lebih lanjut mengenai BRUFEN® 100 mg/5 ml Suspensi.

Zat berkhasiat yang terkandung dalam BRUFEN® 100 mg/5 ml Suspensi adalah ibuprofen. Tiap botol mengandung 60 ml suspensi. Reg. No. DTL0400203033A1

Dibuat oleh

PT. Abbott Indonesia

Jl. Raya Jakarta Bogor Km. 37, Cimanggis

Depok 16415, Indonesia

Di bawah pengawasan

Abbott Laboratories, Chicago, ILL., USA