For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Ibuprofen Solution for Infusion 400 mg/100 ml

AMERICAN
BRUFOCAN IV

400 mg / 100 ml Infusion
For IV Infusion Only

AMERICAN REMEDIES©
Care & Cure with Research

COMPOSITION
Each 100 ml contains :

Ibuprofen IP	400 mg
Water for Injections IP	q.s.

PHARMACEUTICAL FORM
Solution for Intravenous Infusion
THERAPEUTIC INDICATION
Ibuprofen is indicated in adults for the short-term symptomatic treatment of acute moderate pain, and for the short-term symptomatic treatment of fever, when administration by intravenous route is clinically justified when other routes of administration are not possible.
DOSAGE AND METHOD OF ADMINISTRATION
Posology
Undesirable effects may be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms
Adequate hydration of the patient should be maintained to minimize the risk of possible adverse reactions at renal level.
Adults
The recommended dose is 400 mg of ibuprofen every 6 to 8 hours as necessary, without exceeding the maximum daily recommended dose of 1200 mg.
This medicinal product is indicated for short-term treatment (a maximum treatment duration of 3 days) and limiting the duration of treatment to the acute symptomatic phase when the oral administration is inappropriate. Patients must switch to oral treatment as soon as this is possible.
Elderly:
No dose reduction is required. However, precautions should be taken when treating elderly patients as they are generally more prone to adverse effects, and are more likely to have renal, hepatic and cardiovascular dysfunction and to be using concomitant medications. Due to the possibility to suffer from adverse reactions. it is recommended to monitor these patients. Treatment should be reviewed at regular intervals and discontinued if no benefit is seen or intolerance occurs. Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals.
Renal impairment:
Precautions should be taken when NSAIDs are used in patients with renal insufficiency.
In patients with mild or moderate renal impairment the initial dose should be reduced and be kept as low as possible for the shortest duration necessary to control symptoms and renal function monitored.
This medicinal product is contraindicated in patients with severe renal insufficiency.
Hepatic impairment:
Precautions should be taken when NSAIDs are used in this population although differences in the pharmacokinetic profile have not been observed.
Patients with mild or moderate hepatic insufficiency should start the treatment with reduced doses, the dose should be kept as low as possible for the shortest duration necessary and they should be carefully monitored.
This medicinal product is contraindicated in patients with severe hepatic insufficiency.
Paediatric population
This medicinal product should not be used in children and adolescents. The use of Ibuprofen has not been studied in children and adolescents. Therefore, the safety and efficacy have not been established.
Method of administration
Intravenous use.
This medicinal product should be administered as an intravenous infusion for 30 minutes.
The remaining solution should be discarded.
Restricted to hospital use only.
CONTRAINDICATIONS
Hypersensitivity to the active substance, to other NSAIDs or to any of the excipients listed.
• Patients who have previously had bronchospasm, asthma, rhinitis, angioedema or urticaria associated with acetylsalicylic acid or other nonsteroidal anti-inflammatory drugs (NSAIDs).
• Patients with a history of gastrointestinal bleeding or perforation related to previous NSAIDs therapy.
• Active or history of recurrent peptic ulcer/gastrointestinal haemorrhage (two or more distinct episodes of proven ulceration or bleeding).
• Severe hepatic impairment
• Severe renal impairment
• Severe heart failure (NYHA Class IV)
• Cerebrovascular bleeding or other active bleeding.
• Conditions involving an increased tendency or active bleeding such as thrombocytopenia.
• Unclarified blood-formation disturbances.
• Severe dehydratation (caused by vomiting, diarrhoea or inadequate liquid intake).
• During the third trimester of pregnancy.
SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see gastrointestinal and cardiovascular risks).
The elderly has an increased frequency of adverse reactions to NSAIDs, especially gastrointestinal bleeding and perforation, which may be fatal.
Respiratory:
Caution is required if this medicinal product is administered to patients suffering from, or with a previous history of, bronchial asthma, chronic rhinitis or allergic diseases since NSAIDs have been reported to cause bronchospasm, urticaria or angioedema in such patients.
Anaphylactoid Reactions:
As standard practice during intravenous infusion, close patient monitoring is recommended, especially at the beginning of the infusion to detect any anaphylactic reaction caused by the active substance or the excipients.
Severe acute hypersensitivity reactions (e.g. anaphylactic shock) are very rarely observed. At the first signs of a hypersensitivity reaction following the administration of ibuprofen, therapy must be stopped and symptomatic treatment must be established. Medically required measures, in line with the symptoms, must be initiated by specialist personnel.
Other NSAIDs:
The use of Ibuprofen with concomitant NSAIDs, including cyclooxygenase-2 selective inhibitors should be avoided.
SLE and Mixed Connective Tissue Disease (MCTD):
Some cases of aseptic meningitis have been reported with the use of ibuprofen in patients with systemic lupus erythematosus (SLE). Aseptic meningitis is probably more likely to occur in patients with systemic lupus erythematosus and related connective tissue diseases.
Renal and hepatic impairment:
Ibuprofen should be used with caution in patients with history of renal or hepatic disease and specially during concomitant treatment with diuretics as inhibition of prostaglandins may produce fluid retention and renal function deterioration. In case of administration to these patients, the dose of ibuprofen should be keep the lowest as possible and regular monitoring of the renal function should be performed.
In case of dehydratation, suitable liquid intake should be guaranteed, as dehydratation can be a trigger for developing renal failure.
In general, regular use of analgesics, especially combination of differents analgesics agents, may lead to long-lasting renal damage with risk of develop renal failure (analgesic nephropathy). Patients at greatest risk of this reaction are elderly patients and those with impaired renal function, heart failure, hepatic dysfunction, those who are being treated with diuretics or ACE inhibitors.
Discontinuation of NSAID therapy is usually followed by recovery to the pre-treatment state.
As with other NSAIDs, ibuprofen may produce mild transitory increases of some parameters of the hepatic function, as well as significate increases of transaminases. In case an important increase of these parameters occur, the treatment should be discontinued.
Cardiovascular and cerebrovascular effects:
Clinical studies suggest that use of ibuprofen, particularly at a high dose (2400 mg daily), may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). Overall, epidemiological studies do not suggest that low dose ibuprofen (e.g. ≤1200 mg daily) is associated with an increased risk of 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 if the doctor considers the benefit/risk balance is favorable 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, hyperlipidemia, diabetes mellitus, smoking), particularly if high doses of ibuprofen (2400 mg/day) are required.
Female fertility impairment:
The use of ibuprofen may impair female fertility affecting ovulation.
Gastrointestinal:
NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated.
Gastrointestinal bleeding, ulceration or perforations which can be fatal have been reported at any time during the treatment with NSAIDs, 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 NSAID doses, in patients with a history of ulcer, 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, and also for patients requiring concomitant low dose aspirin, or other drugs likely to increase gastrointestinal risk.
Patients with a history of gastrointestinal toxicity, particularly when elderly, should report immediately any unusual abdominal symptoms (especially gastrointestinal 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 gastrointestinal bleeding, such as oral corticoids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors (SSRI) or anti-platelet agents such as acetylsalicylic acid.
When gastrointestinal bleeding or ulceration occurs in patients receiving ibuprofen, the treatment should be withdrawn immediately.
Severe skin reactions:
Serious skin reactions, some of them fatal, including exfoliate 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, the onset of the reaction occurring within the first month of treatment in the majority of cases. Acute generalized exanthematous pustulosis (AGEP) has been reported in relation to ibuprofen-containing products. Ibuprofen should be discontinued immediately at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.
Exceptionally, chicken pox can be the origin of severe skin infections and soft tissue complications. So far, the role of NSAIDs in the worsening of these infections cannot be discarded. So that, in case of chicken pox administration of ibuprofen should be avoided.
Hematological Effects:
Ibuprofen may temporarily inhibit the blood-platelet function (thrombocyte aggregation), increasing the bleeding time and the risk of haemorrhage.
Patients with coagulation disorders or those undergoing surgery should therefore be monitored. Special medical vigilance is required for use in patients immediately after undergoing major surgery.
Ibuprofen should only be used with particular caution in patients receiving acetylsalicylic acid to inhibit platelet aggregation.
Ophthalmological Effects:
Blurred or diminished vision, scotomata, and changes in colour vision have been reported with oral ibuprofen. Discontinue ibuprofen if the patient develops such complaints, and refer the patient for an ophthalmologic examination that includes central visual fields and colour vision testing.
Other special warnings and precautions for use:
NSAIDs may mask the signs of infection.
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.
In patients in long-term treatment with ibuprofen the renal, hepatic and hematologic function as well as hematic count should be controlled as preventive measure.
Transitory hypoglycaemia has been reported with the use of Trometamol. It is recommended to determinate glucose plasma levels during the treatment.
Prolonged use of painkillers may cause, headache that must not be treated with increased doses of the medicinal product.
Patient should be carefully observed at the beginning of the infusion for anaphylactoid/hypersensitivity reactions to any component of the product. Infusion should be stopped and symptomatic treatment established.
Exceptionally, varicella can cause serious cutaneous and soft tissues infectious complications. To date, the contributing role of NSAIDs in the worsening of these infections cannot be ruled out. Thus, it is advisable to avoid use of Ibuprofen in case of varicella.
Interferences with analytical tests:
• Bleeding time (can be prolongued during 1 day after withdrawn the treatment).
• Blood glucose concentration (may decrease).
• Creatinine clearance (may decrease)
• Hematocrit or hemoglobin (may decrease)
• Blood concentrations of ureic nitrogen and seric concentrations of creatinin and potassium (may increase).
• In hepatic function tests: increase in transaminases values.
Ibuprofen should only be used after strict assessment of the benefit / risk in patients with congenital disorder of porphyrin metabolism (e.g. acute intermittent porphyria).
Through concomitant consumption of alcohol, active substance-related undesirable effects, particularly those that concern the gastrointestinal tract or the central nervous system, may be increased on use of NSAIDs.
Caution is required in patients with certain conditions, which may be made worse:
• In patients who react allergically to other substances, as an increased risk of hypersensitivity reactions occurring also exists for them on use of this medicinal product.
• In patients who suffer from hay fever, nasal polyps or chronic obstructive respiratory disorders as an increased risk exists for them of allergic reaction occurring. These may present as asthma attacks (so-called analgesic asthma), Quincke´s oedema or urticaria.
This medicinal product contains 303 mg sodium per 100 ml, equivalent to 15% of the WHO recommended maximum daily intake of 2 g sodium for an adult.
DRUG INTERACTIONS
Other NSAIDs, including COX-2 inhibitors and salicylates:
As a result of synergist effects, the concurrent administration use of two or more NSAIDs may increase the risk of gastrointestinal ulcers and bleeding. Co-administration of ibuprofen with other NSAIDs should therefore be avoided.
Concomitant use with other NSAIDs should be avoided as it may increase the risk of gastrointestinal ulceration and haemorrhages.
Acetylsalicylic 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.
Cardiac glycosides (Digoxin):
NSAIDs may exacerbate cardiac failure, reduce glomerular filtration rate and increase plasma levels of cardiac glycosides. Monitoring of serum digoxin is recommended.
Corticosteroids:
Corticoids can also increase the risk of suffer adverse reactions, specially those related with gastrointestinal tract (ulceration or gastrointestinal bleeding.
Anti-platelet agents *(e.g. clopidogrel and tioclopidine)*:
Increase the risk of gastrointestinal bleeding. NSAIDs should not be combined with ticlopidine due to the risk of an additive effect in the inhibition of platelet function.
CYP2C9 Inhibitors:
Concomitant administration of ibuprofen with CYP2C9 inhibitors may increase the exposure to ibuprofen (CYP2C9 substrate). In a study with voriconazole and fluconazole (CYP2C9 inhibitors), an increased S(+)- ibuprofen exposure by approximately 80 to 100% has been shown. Reduction of the ibuprofen dose should be considered when potent CYP2C9 inhibitors are administered concomitantly, particularly when high-dose ibuprofen is administered with either voriconazole or fluconazole.
Anticoagulants:
NSAIDs may enhance the effects of anticoagulants, such as warfarin and heparin. In case of concomitant use, it is recommended to monitor the coagulation levels.
Phenytoin:
Plasmatic levels of phenytoin may be increased in the concomitant treatment with ibuprofen and therefore the risk of toxicity may increase.
Captopril:
Experimental studies indicate that ibuprofen counteracts the effect of captopril of increased sodium excretion.
Selective serotonin reuptake inhibitors (SSRIs):
Can increase the risk of gastrointestinal bleeding.
Lithium:
Co-administration of ibuprofen with lithium preparations can increase the serum level of these medicinal products. Cheking the serum lithium level is necessary.
Probenecid and sulfinpyrazone:
Medicines which contains probenecid or sulfinpyrazone may retard the excretion of ibuprofen.
Diuretics, ACE inhibitors, beta-blockers and angiotensin II antagonists:
Diuretics and ACE-inhibitors may increase the nephrotoxicity of NSAIDs. NSAIDs may reduce the effect of diuretics and other anti-hypertensives. In patients with renal impairment (e.g. dehydrated patients or elderly patients with renal funtion impaired) concomitant treatment with ACE inhibitors, beta-blockers or angiotensin II antagonists and cyclooxigenase inhibitors may be associated to a deterioration of the renal function, including an acute renal failure which is normally reversible. So that concomitant administration should be done with caution, specially in elderly. Patients should be hydrated and a renal monitorization after starting the concomitant treatment should be considered as well as a periodic monitorization right after.
The concomitant administration of ibuprofen ACE-inhibitors may lead to hyperkalaemia.
Potassium-sparing diuretics:
Concomitant use of ibuprofen and potassium-sparing diuretics may be associated with an increase in the potassium levels, so that it is recommended to control plasmatic levels of this ion.
Methotrexate:
NSAIDs inhibit the tubular secretion of methotrexate and certain metabolic interactions may occur resulting in decreased clearance of methotrexate. Administration of ibuprofen 24 hours before or after administration of methotrexate, it may occur an increase of the methotrexate plasmatic level with the consequent increase in its toxic effect. Therefore, concomitant use of NSAIDs and high doses of methotrexate should be avoided. Also, the potential risk of interactions in low dose treatment with methotrexate should be considered, especially in patients with impaired renal funcion. In combined treatment, renal function should be monitored.
Ciclosporin:
The risk of renal impairment is increased due to concomitant administration with certain NSAIDs. This effect also cannot be ruled out for a combination of ciclosporin with ibuprofen.
Zidovudine:
Increased risk of haematological toxicity when NSAIDs are given with zidovudine. There is evidence of an increased risk of haemarthroses and haematoma in HIV(+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen. Blood counts 1-2 weeks after starting use together are recommended.
Sulfonylureas:
Clinical investigations have demonstrated interactions between NSAIDs and sulfonylureas.
NSAIDs can increase the hypoglycemic effect of sulfonylureas. In the case of simultaneous treatment, monitoring of blood glucosa levels is recommended.
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.
Mifepristone:
NSAIDs should not be administered within 8-12 days after the administration of mifepristone as the effecs of this drug can be reduced.
Baclofen:
Ibuprofen may enhance baclofen toxicity by means of a possible accumulation due to the renal failure caused by ibuprofen.
Pentoxifylline:
In patients receiving treatment with ibuprofen in combination with pentoxifylline it may increase the risk of bleeding, so it is recommended to monitor bleeding time.
Tacrolimus:
Concomitant administration with ibuprofen may increase the risk of nephrotoxicity-
Aminoglycosides:
NSAIDs may enhance nephrotoxicity of aminoglycosides, even more if aminoglycosides have been administered at high doses for long period of time.
Alcohol
The use of ibuprofen in individuals with chronic alcohol consumption (14-20 drinks/week or more) should be avoided due to increased risk of significant GI adverse effects, including bleeding.
Herbal extracts:
Ginkgo biloba may potentiate the risk of bleeding with NSAIDs.
FERTILITY, PREGNANCY AND LACTATION
Pregnancy
Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after the use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk of cardiac malformations was increased from less than 1% to 1.5% approximately. It seems that the risk increases with the dose and duration of the treatment.
In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period.
During the first and second trimester of pregnancy, this medicine should not be given unless clearly necessary. If Ibuprofen is used by a woman attempting to conceive, or during the first or second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.
During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:
• Cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension)
• Renal dysfunction, which may progress to renal failure with oligohydramniosis.
the mother and the neonate, at the end of pregnancy to:
• Possible prolongation of bleeding time due to an anti-aggregating effect, which may occur even at very low doses.
• Inhibition of uterine contractions, resulting in delayed or prolonged labour.
Consequently, ibuprofen is contraindicated during the third trimester of pregnancy.
Breastfeeding
Ibuprofen and its metabolites can pass in low concentrations into the breast milk. No harmful effects to infants are known to date, so for short-term treatment with lower doses interruption of breastfeeding would generally not be necessary. However, it is recommended to interrupt breastfeeding when using higher doses than 1200 mg daily or longer treatment periods due to the potential to inhibit prostaglandin synthesis in the neonate.
Fertility
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.
EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
The influence of Ibuprofen on the ability to drive and use machines is minor. Some isolated patients may experience dizziness and fatigue, so that the ability to drive a vehicle and/or use machines can be affected. This applies to a greater extent in combination with alcohol.
UNDESIRABLE EFFECTS
Ibuprofen induced Stevens - Johnson syndrome (SJS)/ toxic epidermal necrolysis (TEN) and fixed dose eruption (FDE)
Tabulated list of adverse reactions
The undesirable effects possibly related to ibuprofen are listed by organ system classes and frequencies according to the following categories: Very common (≥1/10), Common (≥1/100 to <1/10), Uncommon (≥1/1,000 to <1/100), Rare (≥1/10,000 to < 1/1,000), Very rare (<1/10,000), Not known (frequency cannot be estimated from the available data). The most commonly observed adverse events are gastrointestinal in nature. Peptic ulcers, GI perforation or bleeding, sometimes fatal, may occur particularly in the elderly. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease have been reported following administration. Less frequently, gastritis has been observed. Particularly the risk of gastrointestinal bleeding occurring is dependent on the dose range and the duration of use.
Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment.
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 events (for example myocardial infarction or stroke).
Infections and infestations:
Very rare: Exacerbations of infection related inflammations (e.g. development necrotising fasciitis) coinciding with the use of non-steroidal anti-inflammatory drugs has been described. This is possibly associated with the mechanism of action of the non-steroidal anti-inflammatory drugs.
Blood and lymphatic system disorder:
Very rare: Disturbances to blood formation (anaemia, agranulocytosis, leucopoenia, thrombocytopenia, and pancytopenia,). First symptoms are: fever, sore throat, superficial mouth wounds, influenza-like complaints, severe lassitude, nosebleeds and skin bleeding.
Immune system disorders Uncommon: Hypersensitivity reactions with skin rashes and itching, as well as asthma attacks (possibly with drop in blood pressure),
Very rare: Systemic lupus erythematosus, severe hypersensitivity reactions, face oedema, swelling of the tongue, swelling of the internal larynx with constriction of the airways, difficulty breathing, palpitations, hypotension and life threatening shock).
Psychiatric disorders
Uncommon: Anxiety, restlessness
Rare: Psychotic reactions, nervousness, irritability, confusion or disorientation and depression
Nervous system disorders
Very common: Fatigue or sleeplessness, headache, dizziness
Uncommon: Insomnia, agitation, irritability or tiredness, *very rare:* Aseptic meningitis (stiff neck, headache, nausea, vomiting, fever or confusion). Patients with autoimmune disorders (SLE, mixed connective-tissue disease) appear to be predisposed.
Eye disorder
Uncommon: Visual disturbances,
Rare: Reversible toxic amblyopia
Ear and labyrinth disorders
Common: Vertigo
Uncommon: Tinnitus,
Rare : Hearing disorders
Cardiac disorders *Very rare* : Palpitations, heart failure, myocardial infarction
Vascular disorders *Very rare* : Arterial hypertension
Respiratory, thoracic and mediastinal disorders *Very rare* : Asthma, bronchospasm, dyspnoea and wheezing
Gastrointestinal disorders
Very common: Pyrosis, abdominal pain, nausea, vomiting, flatulence, diarrhoea, constipation and slight gastro-intestinal blood losses that may cause anaemia in exceptional cases,
Common: Gastrointestinal ulcers, potentially with bleeding and perforation. Ulcerative stomatitis, exacerbation of colitis and Crohn's disease.
Uncommon: Gastritis, Rare : Esophageal stenosis, exacerbation of diverticular disease, unspecified haemorrhagic colitis. If gastrointestinal bleeding occurs could cause anaemia and haematemesis
Very rare: Oesophagitis, pancreatitis, formation of intestinal, diaphragm-like strictures
Hepatobiliary disorders *Rare:* Jaundice, hepatic dysfunction, hepatic damage, particularly in long-term therapy, acute hepatitis
Not known: Hepatic insufficiency
Skin and subcutaneous tissue disorders
Common: Skin eruption,
Uncommon: Urticaria, pruritus, purpura (including allergic purpura), skin rash,
very rare: Bullous or vesicular reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis (Lyell´s syndrome), erythema multiforme, alopecia. Photosensitivity reactions and allergic vasculitis.
In exceptional cases, severe skin infections and soft tissues complications in varicella infection (see also 'Infections and infestations')
Not known: Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome)
Acute generalised exanthematous pustulosis (AGEP), photosensitivity reactions
Musculoskeletal and connective tissue disorders *Rare:* Stiff neck
Renal and urinary disorders *Uncommon:* Reduced urinary excretion and formation of oedemas, particularly in patients with arterial hypertension or renal insufficiency, nephrotic syndrome, interstitial nephritis that may be accompanied by acute renal insufficiency.
Rare: Renal tissue damage (papillary necrosis), particularly in long-term therapy, increased serum uric acid concentration in the blood
General disorders and administration site conditions *Common* : Pain and burning sensation in the administration site
Not known: Site of injection reactions such as swelling, haematoma or bleeding.
Reporting of side effects or suspected adverse reaction: If you experience any side effects, talk to your doctor or pharmacist or report to indiadrugsafety@akums.in. You can also report side effects directly via the National Pharmacovigilance Program of India by calling on 18003133363. By reporting side effects, you can help provide more information on the safety of this product.
OVERDOSE
Plasmatic half-life in an overdose is 1.5-3 hours.
Symptoms
Most patients who have ingested important quantities of NSAIDs will develop nausea, vomiting, epigastric pain or rarely diarrhoea. Other possible effects are: tinnitus, headache, dizziness, hypotension and gastrointestinal bleeding. In more severe intoxications, toxicity is observed in the central nervous system, exhibit as drowsiness, agitation (occasionally) and disorientation and coma. Sometimes patients develop convulsions. In a severe intoxication it can be developed metabolic acidosis and an increase in the prothrombin time/INR probably due to an interference with the action of circulating coagulation factors. Acute renal and hepatic impairment can be produced. In asthmatic patient's exacerbation of asthma is possible.
In serious poisoning metabolic acidosis may occur.
Therapeutic measures
There is no specific antidote available and patients should be initiate symptomatic treatment. The therapeutic possibilities for treatment of intoxication are dictated by the extent, level and clinical symptoms according to the common intensive care practices
PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids; Propionic acid derivatives.
Mechanism of action
Ibuprofen is a non-steroidal anti-inflammatory drug that, in conventional animal-experiment inflammation models, has proven to be effective, probably through prostaglandin synthesis inhibition. In humans, ibuprofen has an antipyretic effect, reduces inflammatory-related pain and swelling. Furthermore, ibuprofen reversibly inhibits ADP- and collagen-induced platelet aggregation.
Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose acetylsalicylic acid on platelet aggregation when they are dosed concomitantly. Some pharmacodynamic studies showed that when a single dose of 400 mg ibuprofen were taken within 8 hours before or within 30 minutes after immediate release acetylsalycilic acid dosing (81 mg), the effect of the acetylsalicylic acid on the thromboxane formation or in the platelet aggregation was reduced.
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.
Pharmacokinetics properties
Absorption
Ibuprofen is administered by intravenous route, so that, no absorption process occurs and the bioavailability of ibuprofen is total.
Distribution
The estimated distribution volume is 0.11 to 0.21 L/kg.
Ibuprofen is extensively bound to plasmatic proteins, mainly albumin.
Biotransformation
Ibuprofen is metabolized in the liver into two inactive metabolites, and those together with the unchanged ibuprofen are excreted by the kidneys either as such or as conjugates.
Elimination
The excretion through the kidneys is fast and complete. The elimination half-life is approximately 2 hours.
Linearity/non-linearity
Ibuprofen shows a linearity in the AUC of the plasmatic concentration-time after a single administration of ibuprofen (in a range of 200-800 mg).
Pharmacokinetic / pharmacodinamic relationship
A correlation between plasmatic levels of ibuprofen, its pharmacodynamic properties and its overall safety profile exists. Ibuprofen pharmacokinetic is stereoselective after an intravenous or oral administration.
The mechanism of action and the pharmacology of intravenous ibuprofen do not differ from the mechanism of oral ibuprofen.
INCOMPATIBILITIES
None stated.
STORAGE AND HANDLING INSTRUCTIONS
Store below 30°C. Protect from light. Do not refrigerate or freeze.
Keep medicine out of reach of children.
SHELF LIFE
As per carton
PRESENTATION
Brufocan IV is available in a 100 ml LDPE bottle.

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