Product Information

Product	Container type	Concentration (mg/ml)	Volume (ml)	Units per box
Ibuprofen B. Braun 400 mg Solution for Infusion	Ecoflac® plus	4	100	10
Ibuprofen B. Braun 600 mg Solution for Infusion	Ecoflac® plus	6	100	10

Ibuprofen B. Braun 400 mg Solution for Infusion/ Ibuprofen B. Braun 600 mg Solution for Infusion

COMPOSITION

Ibuprofen B. Braun 400 mg Solution for Infusion
Each ml of solution contains 4 mg of Ibuprofen.
Each 100 ml bottle contains 400 mg of Ibuprofen.

Excipient with known effect:
Each ml of solution contains 9.10 mg of sodium chloride (3.58 mg of sodium).
Each 100 ml bottle contains 910 mg of sodium chloride (358 mg of sodium).

Ibuprofen B. Braun 600 mg Solution for Infusion
Each ml of solution contains 6 mg of Ibuprofen.
Each 100 ml bottle contains 600 mg of Ibuprofen.

Excipient with known effect:
Each ml of solution contains 9.15 mg of sodium chloride (3.60 mg of sodium).
Each 100 ml bottle contains 915 mg of sodium chloride (360 mg of sodium).

Excipients
L-Arginine, Sodium chloride, Hydrochloric acid (for pH adjustment), Sodium hydroxide (for pH adjustment), Water for injections

THERAPEUTIC INDICATIONS
- Ibuprofen B. Braun 400 mg is indicated in adults for the short-term symptomatic treatment of acute moderate pain, and for the short-term symptomatic treatment of fever,
- Ibuprofen B. Braun 600 mg is indicated in adults for the short-term symptomatic treatment of acute moderate pain,

when administration by intravenous route is clinically justified, when other routes of administration are not possible.

CONTRAINDICATIONS
- Hypersensitivity to the active substance, to other NSAIDs or to any of the excipients
- A history of bronchospasm, asthma, rhinitis, angioedema or urticaria associated with taking acetylsalicylic acid (ASA) or other non-steroidal anti-inflammatory drugs (NSAIDs);
- Conditions involving an increased tendency or active bleeding such as thrombocytopenia;
- Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding);
- History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy;
- Cerebrovascular or other active bleeding;
- Severe hepatic or renal insufficiency;
- Severe heart failure (NYHA Class IV);
- Severe dehydration (caused by vomiting, diarrhoea or insufficient fluid intake);
- Pregnancy, in the last trimester.

UNDESIRABLE EFFECTS
Very common (≥ 1/10):
Fatigue or sleeplessness, headache, dizziness, pyrosis, abdominal pain, nausea, vomiting, flatulence, diarrhoea, constipation and slight gastro-intestinal blood losses that may cause anaemia in exceptional cases.

Common (≥ 1/100 to < 1/10):
Vertigo, gastrointestinal ulcers, potentially with bleeding and perforation. Ulcerative stomatitis, exacerbation of colitis and Crohn´s disease, skin eruption, pain and burning sensation in the administration site

Uncommon (≥ 1/1000 to < 1/100):
Hypersensitivity reactions with skin rashes and itching, as well as asthma attacks (possibly with drop in blood pressure), anxiety, restlessness, insomnia, agitation, irritability or tiredness, visual disturbances, tinnitus, gastritis, urticaria, pruritus, purpura (including allergic purpura), skin rash, 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 (>1/10 000, <1/1000):
Psychotic reactions, nervousness, irritability, confusion or disorientation and depression, reversible toxic amblyopia, hearing disorders, esophageal stenosis, exacerbation of diverticular disease, unspecific haemorrhagic colitis, jaundice, hepatic dysfunction, hepatic damage, particularly in long-term therapy, acute hepatitis, bullous 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-tissue complications in varicella infection (see also "Infections and infestations"), stiff neck, renal tissue damage (papillary necrosis), particularly in long-term therapy, increased serum uric acid concentration in the blood.

Very rare (<1/10000):
Exacerbation 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, disturbances to blood formation (anaemia, agranulocytosis, leucopenia, thrombocytopenia, and pancytopenia,). First symptoms are: fever, sore throat, superficial mouth wounds, influenza-like complaints, severe lassitude, nosebleeds and skin bleeding, 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), aseptic meningitis (stiff neck, headache, nausea, vomiting, fever or confusion). Patients with autoimmune disorders (SLE, mixed connective-tissue disease) appear to be predisposed. Palpitations, heart failure, myocardial infarction, arterial hypertension, asthma, bronchospasm, dyspnoea and wheezing, oesophagitis, pancreatitis, formation of intestinal, diaphragm-like strictures.

WARNINGS
Keep out of the sight and reach of children.
For single use in one patient only.

MARKETING AUTHORIZATION HOLDER
B. Braun Melsungen AG, 34209 Melsungen, Germany

Last revision: 23/04/2021

Prescription only

Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

B. Braun Melsungen AG | Hospital Care | 34209 Melsungen | Germany
Tel. +49 5661 71-0 | www.bbraun.com

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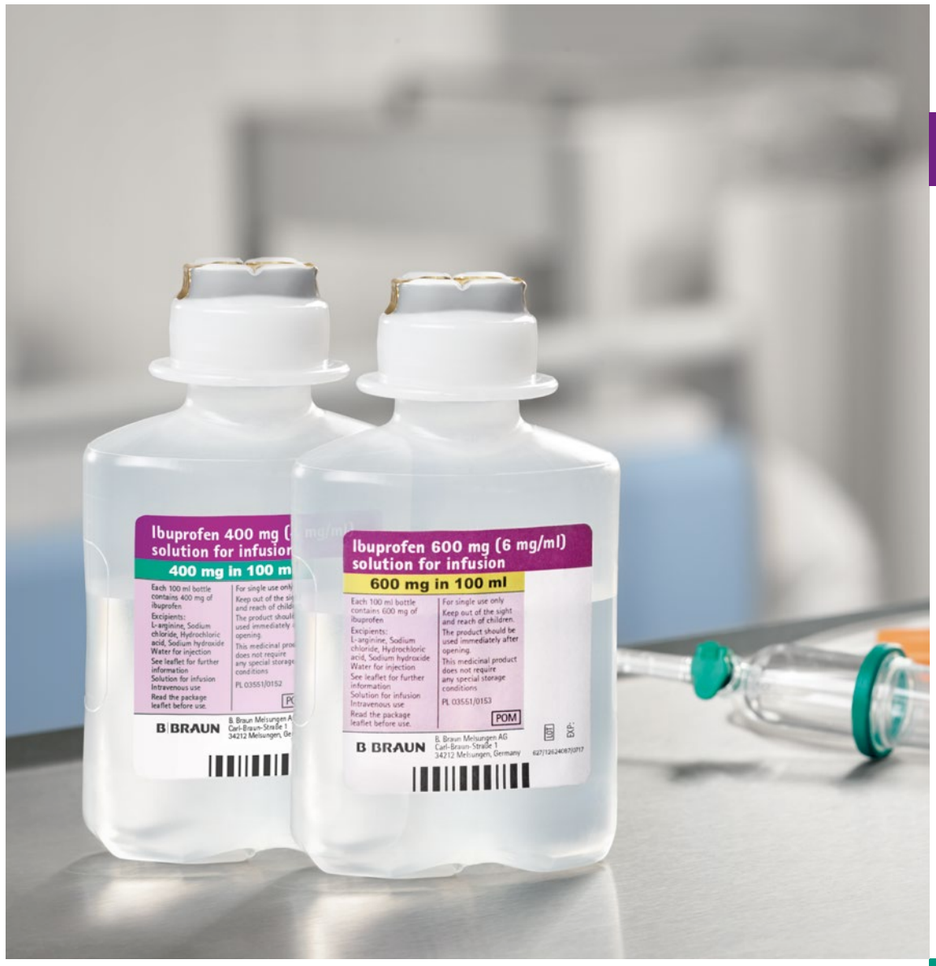
SHARING EXPERTISE



READY-TO-USE

PRESCRIPTION | PATIENT ACCESS | PREPARATION | APPLICATION | DISCHARGE MANAGEMENT

Ibuprofen B. Braun

Effective IV-treatment of pain

Ibuprofen B. Braun

Balanced treatment of acute moderate pain

Ibuprofen has **proved its efficacy and safety over more than 40 years of use**[1] and is **listed in the WHO List of Essential Medicines*** in different dosages and administration forms.[2]

The combination of analgesic, antipyretic, and anti-inflammatory properties is the key to its success.

Now Ibuprofen can be administered intravenously.

*WHO Model List lists efficacious, safe and cost-effective medicines for priority conditions.

Your benefits with Ibuprofen

- Over 40 years with successful experience with Ibuprofen[2]
- IV Ibuprofen is bioequivalent with the oral presentation[3]
- Triple action profile:
  - Analgesic
  - Antipyretic
  - Anti-inflammatory[4]
- IV administration is independent from patients' ability to swallow
  - Suitable at all stages of perioperative pain management

Available in:

4 mg/ml in 100 ml indicated in adults for:

- Short-term symptomatic treatment of **acute moderate pain**
- Short-term symptomatic treatment of **fever**

6 mg/ml in 100 ml indicated in adults for:

- Short-term symptomatic treatment of **acute moderate pain**

Ibuprofen-Arginine combination

Pain-relieving effect

Anti-pyretic effect

Anti-inflammatory action

Ibuprofen B. Braun

Ready-to-use in Ecoflac® plus

Your benefits with Ecoflac® plus

- 20 years of experience
- Still one of the most innovative infusion containers
- Ready-to-use – preventing for manipulation, accidents & dilution errors
- Time saving – no mixing necessary

1. Twin-cap, two separate and identical ports
2. Area of protection against punctures
3. Sturdy hanger cap

- Safe and ergonomic design
- Completely collapsible
- Suitable material

LITERATURE

1. Rainsford KD, Inflammopharmacology 2009; 17:275–342.
2. WHO Model List of Essential Medicines, 20th edition, March 2017, amended August 2017), www.who.int/medicines/publications/essentialmedicines/en/
3. EudraCT: 2012-003264-53 (data on file); EudraCT: 2013-004877-28 (data on file).
4. Ulufer Sivrikaya G (2012); Multimodal Analgesia for Postoperative Pain Management, Pain Management -Current Issues and Opinions, Dr. Gabor Racz (Ed.), ISBN: 978-953-307-813-7.