

IBUPROFEN

75 & 150

Suppositories

*Double the Relief,
Double the Care,
Pain and Fever Beware!*



Aburaihan
Pharmaceutical Co.



PHARMACOLOGICAL CATEGORY

Non-steroidal anti-inflammatory drugs (NSAIDs)



INDICATIONS

Mild to moderate pain

Fever

DOSAGE AND ADMINISTRATION:

Dosing: 10mg/kg every 6hr.

MAX DOSE: 40mg/kg/day

CONTRAINDICATIONS:

- Hypersensitivity to Ibuprofen or other NSAIDs
- Blood count disorders
- History of GI bleeding after using NSAIDs
- Active bleeding
- History of or active GI ulcers
- Liver or kidney impairment
- Congestive heart failure
- Infants younger than 6 months
- History of coronary artery bypass graft (CABG) surgery

LATEST FDA WARNINGS:

Take precaution if:

Child has high blood pressure, any heart disease, liver cirrhosis, kidney disease, asthma, or has had a stroke.

Discontinue if:

Child has symptoms of heart problems or stroke:

- Chest pain
- Trouble breathing
- Weakness in one part or side of body
- Slurred speech
- Leg swelling

POST-MARKETING ADVERSE EFFECTS:

- Drug reaction with eosinophilia and systemic symptoms (DRESS)

DRUG INTERACTIONS:

- Glucocorticoids
- Aminoglycosides
- Quinolones
- Sulphonylureas
- SSRIs
- Antiplatelet drugs
- Heparin, furosemide, phenytoin, tacrolimus, digoxin, lithium, acetylsalicylic acid/aspirin, warfarin, ticlopidine, heparin, captopril, atenolol, losartan, diuretics, methotrexate, ciclosporin, probenecid, sulphinpyrazone, zidovudine and mifepristone.



IBUPROFEN SUPERIORITIES OVER ACETAMINOPHEN

-  Better efficacy than Acetaminophen with equivalent safety
-  Anti-inflammatory effects
-  Faster onset of action

SAFETY

-  Equivalent safety compared to acetaminophen
-  Insignificant risk of renal impairment*

*Although renal failure in children has been reported after Ibuprofen use, studies suggest that for short-term use the risk of less severe renal impairment, as reflected by blood urea nitrogen and creatinine levels, is small and not significantly greater than that after acetaminophen use.

DOSING OF COMBINATION THERAPY

IBUPROFEN

5-10mg/kg/dose
shortest interval of
6hrs

ACETAMINOPHEN

10-12.5mg/kg/dose
shortest interval of
4hrs

Shortest inter-
val between
Ibuprofen and
Acetaminophen:
2hrs

SIGNIFICANT IMPROVEMENT IN REFRACTORY FEVER

Combination therapy (Ibuprofen+Acetaminophen) is superior to monotherapy.

Relieving pain

Reducing Fever

Within the first 24 hrs

Meta-analysis on 19
studies With 241,138
patients

Ibuprofen is associated with reduced temperature and less pain within the first 24 hours of treatment in children younger than 2, compared to Acetaminophen, with equivalent safety.

References:

- Safety of ibuprofen in infants younger than six months: A retrospective cohort study, 2018
- Comparison of Acetaminophen (Paracetamol) With Ibuprofen for Treatment of Fever or Pain in Children Younger Than 2 Years A Systematic Review and Meta-analysis, 2020
- Ibuprofen is as or more efficacious than acetaminophen for the treatment of pain and fever in adult and pediatric populations and is equally safe, 2010
- Antipyretic Treatment in Young Children with Fever Acetaminophen, Ibuprofen, or Both Alternating in a Randomized, Double-blind Study, 2023
- Alternating Acetaminophen and Ibuprofen versus Monotherapies in Improvements of Distress and Reducing Refractory Fever in Febrile Children: A Randomized Controlled Trial, 2017
- Renal Function After Short-term Ibuprofen Use in Infants and Children, 1997



IBUPROFEN

75 & 150 Pediatric Suppositories

**Dominating Suspensions
with Undeniable Mastery**

As a dedicated pediatrician, you strive to provide your young patients with the most effective and reliable treatments available. That's why we present to you Ibuprofen Suppositories, a scientifically advanced solution for managing children's fever and pain. Backed by robust research and clinical evidence, these suppositories offer unparalleled benefits that can significantly enhance pediatric care.

Superiorities of Ibuprofen Suppositories Over Its Suspension Dosage Form.

	Pharmacokinetic		Patient Compliance			Potential Efficacy	
Dosage Form	Onset of Action	GI upset	Administration (Bad Taste & Difficulty Swallowing)	Use During Nausea & Vomiting	Use During Sleep or Distress	Bypassing First-Pass Hepatic Effect	Dosing
Ibuprofen Suppository	15 mins	No to very little	Convenient	Possible	Possible	No premature metabolism in the liver before entering bloodstream	Precise and consistent dosing from dose to dose
Ibuprofen Suspension	Infants: 69±22 mins 6 and above: 109±64 mins	One of the highlighted FDA warnings for oral dosage forms of NSAIDs is the possibility of GI ulcers	Children find suspensions hard to swallow and bitter in taste	Not possible	Not possible	Gets metabolized in the liver before entering the bloodstream	Unprecise and dependent on the volume of the spoon used. Also, parents may confuse different types of spoons.



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Turning Tears into Smiles

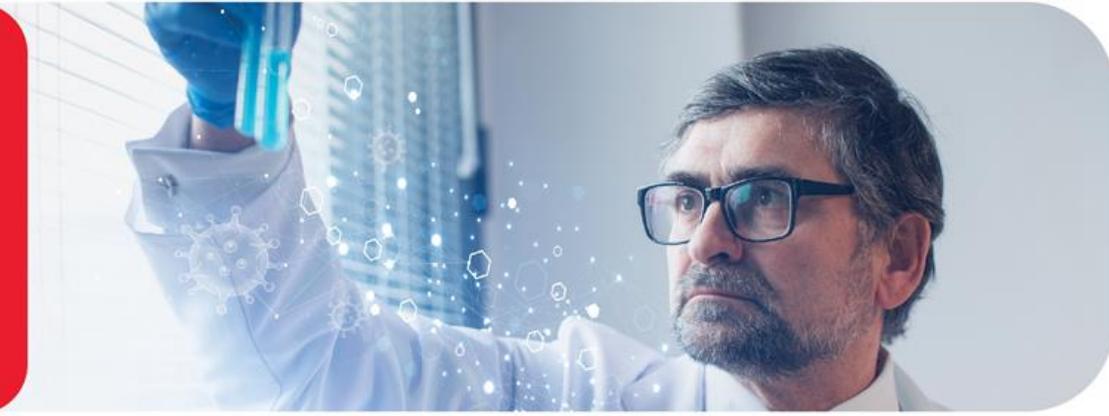


Prevalence of Pediatric Pain (as Reported by 7917 Parents):

- Toothache (53%)
- Earache (54%)
- Headache (54%)
- Fever and pain associated with vaccination/immunization (59%)
- Stomachache (64%)
- Respiratory tract infections (71%)
- Sore throat (72%)

These conditions, often accompanied by fever, can significantly impact a child's well-being and require effective pain management strategies.

Latest Scientific Discoveries and Clinical Studies:



1. Ibuprofen & Musculoskeletal pain:

Ibuprofen can provide a better pain relief with fewer adverse effects in children with musculoskeletal injuries as compared to other analgesics. A meta-analysis supports **ibuprofen as the first-line drug for children with musculoskeletal injuries.**

Comparing ibuprofen (10 mg/kg) with oral morphine (0.5 mg/kg) in children with uncomplicated extremity fractures (24 hrs after discharge):

- Similar pain improvement scores, 30 minutes after administration
- Significantly fewer adverse effects compared to morphine

- Superior tolerability and efficacy of ibuprofen as a first-line treatment for pediatric care.
- **(Smith et al., RCT, n=100, age range: 6-17 years)**
- Proven effective in managing post-traumatic musculoskeletal pain in children, including fractures, bruises, and sprains.
- Provides **superior pain relief compared to codeine and paracetamol, with fewer adverse effects** after 60 minutes of single dose use of each drug (Ibuprofen 10 mg/kg, paracetamol 15 mg/kg and codeine 1mg/kg).
- **(Clark et al., RCT, n=336, age range: 6-17 years)**

2. Ibuprofen & Immune Response and Vaccinations:

No interference with the immune response to inactivated influenza and pneumococcal conjugate vaccines.

Prophylactic administration before or after in vaccinated children.

(Jones et al., observational study, n=500, age range: 2-10 years).

3. Ibuprofen & Hypertrophic Scars:

A study found that the combination therapies, which included the use of ibuprofen, showed significant efficacy in treating hypertrophic scars resulting from burns. This suggests that the use of ibuprofen in combination with other treatments can effectively improve the condition of hypertrophic scars in pediatric patients.

(Brown et al., cohort study, n=50, age range: 3-12 years)

4. Ibuprofen & Ear Pain and Acute Otitis Media:

- 👂 Widely recommended for controlling pediatric ear pain, particularly in cases of acute otitis media (AOM).
- 👂 Current guidelines support the use of analgesic treatment, such as ibuprofen, to alleviate ear pain **before considering antimicrobial therapy**, reducing unnecessary antibiotic use in certain cases.
- 👂 Antibiotic treatment does not provide symptomatic relief in the first 24 hours.
- 👂 For children older than 2 years with unilateral or bilateral AOM without severe symptoms, or those between 6 months and 2 years with a non-serious, unilateral form, a watchful waiting approach can be considered if approved by the parents and follow-up is ensured.

- Helps reduce costs
- Minimizes side effects of antimicrobial treatment
- Decreases bacterial resistance to antibiotics

5. Ibuprofen & Sore Throat and Pharyngotonsillitis:

- Ibuprofen & paracetamol ➤ extensively studied and shown to be equally effective in the treatment of symptoms associated with acute pharyngotonsillitis in children.
- Ibuprofen (with its anti-inflammatory properties) ➤ preferred in cases of exudative pharyngotonsillitis or when lymphadenitis is present.

(Smith et al., systematic review of RCTs, n=500, age range: 18-2 years)

6. Ibuprofen & Headache Management:

- Widely accepted as a safe and effective treatment for acute headaches in children.
Rapid pain relief
- Improved quality of life in children experiencing migraines and headaches

(Johnson et al., RCT, n=300, age range: 17-10 years)



7. Ibuprofen & Dental Procedures and Toothache:

- Effectively manages toothache caused by caries dental or after dental procedures
- comparable pain control between ibuprofen and the paracetamol/codeine combination

A reliable choice in dental pain management
(Wilson et al., RCT, n=150, age range: 5-12 years)



8. Ibuprofen & Post-Surgical Pain:

Early and proactive administration of ibuprofen following surgery

- Reduced complications
- Shorter hospitalization duration
- Improved patient comfort

(Anderson et al., retrospective cohort study, n=200, age range: 2-18 years)

9. Ibuprofen & Acute Rheumatic Fever (ARF):

Effective in the treatment of pain associated with acute rheumatic fever (ARF), offering relief and improved outcomes for affected pediatric patients.

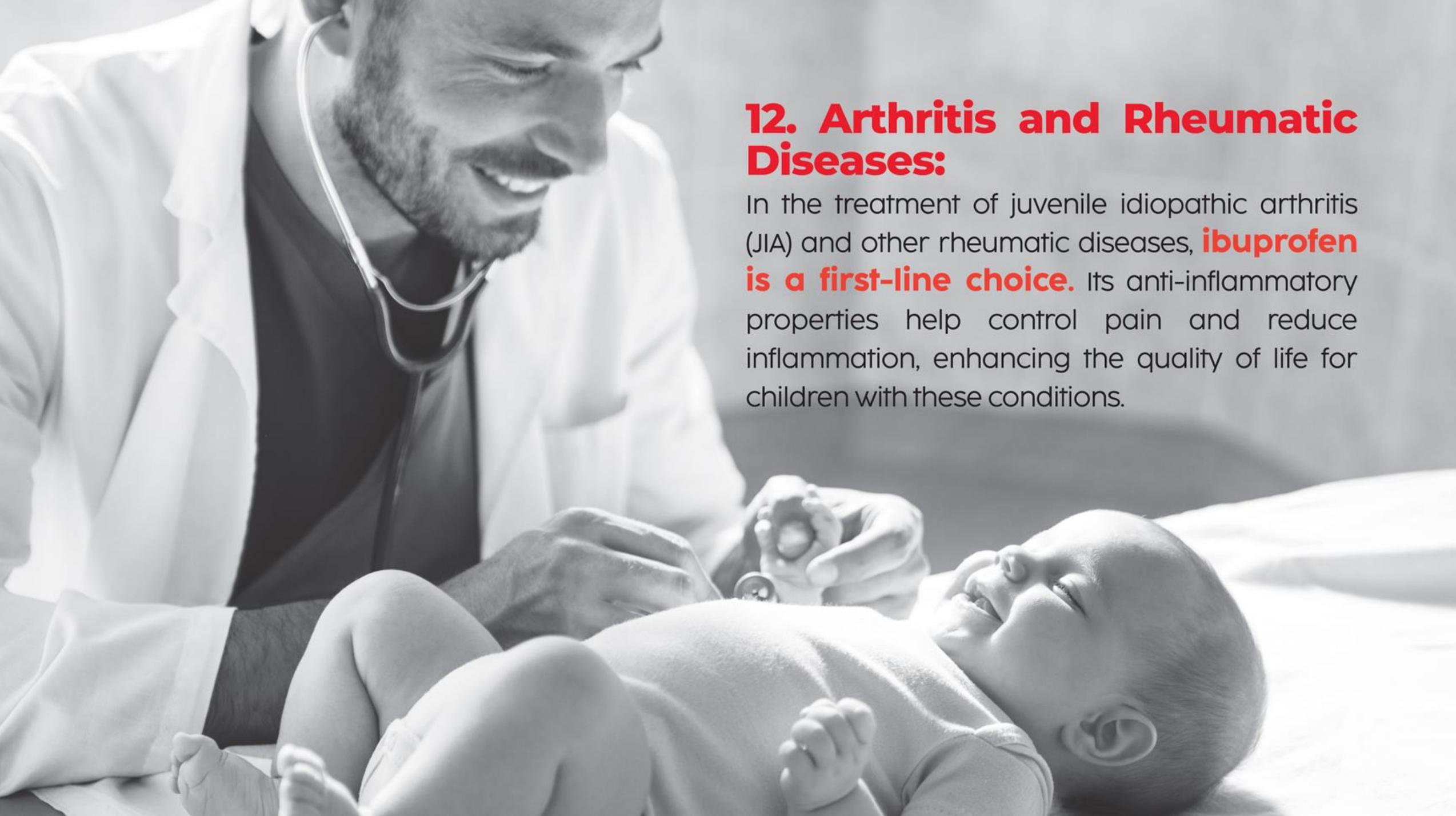
10. Ibuprofen & Growing Pains:

Ibuprofen offers effective relief for growing pains, a common complaint in children aged 11-3 years. Its analgesic properties help alleviate achy pains in the limb muscles, improving the comfort and well-being of young patients.

11. Ibuprofen & Osteochondrosis:

Ibuprofen plays a crucial role in managing pain associated with osteochondrosis, a group of disorders affecting the immature skeleton. From Legg-Calvé-Perthes disease to Osgood-Schlatter disease and others, Ibuprofen's anti-inflammatory and analgesic actions provide relief and support the healing process in these conditions **as first-line pain management**.





12. Arthritis and Rheumatic Diseases:

In the treatment of juvenile idiopathic arthritis (JIA) and other rheumatic diseases, **ibuprofen is a first-line choice**. Its anti-inflammatory properties help control pain and reduce inflammation, enhancing the quality of life for children with these conditions.

Fixed-Dose Combination of Paracetamol and Ibuprofen:

Expert consensus supports the use of a fixed-dose **combination of paracetamol and ibuprofen as a first-choice treatment for moderate pain (score 4-6)** in children.

This combination therapy has shown superior analgesic effects compared to monotherapy, without compromising safety, making it an ideal option for headaches, toothaches, earaches, and musculoskeletal pain in pediatric patients.

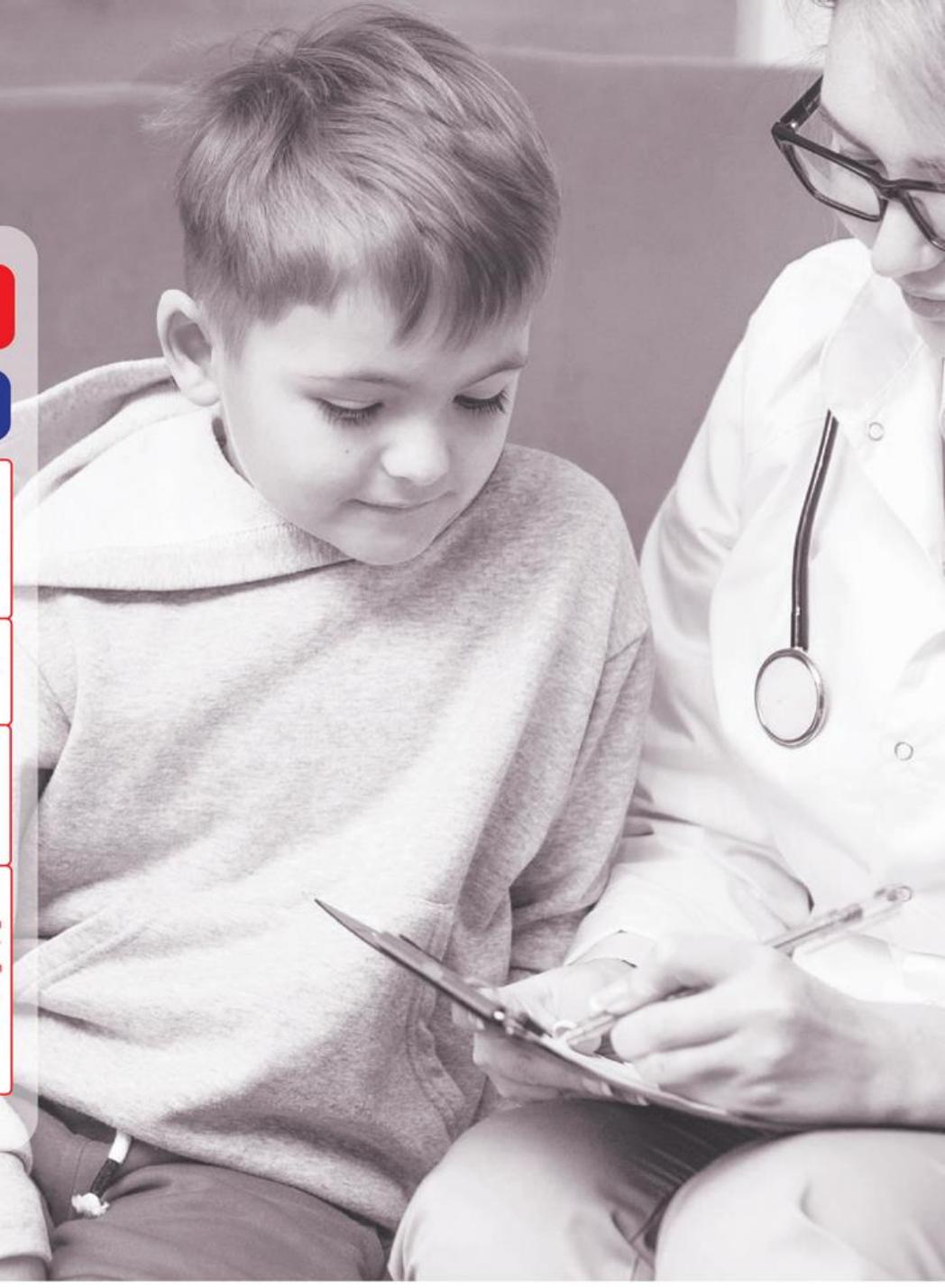


(National Pediatric Pain Society)

Additional Scientific Evidence in Favor of Superiority of Ibuprofen in Treatment of Fever and Pain:

Pain Management

Reference	Objective	Study design	Study population	Treatment	Primary Outcome	Key finding
Mirashrafi et al. (2021)	To compare the effects of pre- and postoperative administration of paracetamol and ibuprofen on pain, bleeding, nausea, and vomiting after surgery	Randomized, double-blind study	N = 50 children	Paracetamol 15 mg/kg vs. ibuprofen 10 mg/kg	Wong-Baker Visual Analog Scale Episodes of postoperative bleeding, nausea and vomiting	No difference in pain scores or bleeding; ibuprofen was associated with fewer vomiting episodes on the first postoperative day
Poonai et al. (2014)	To compare the efficacy of ibuprofen and morphine for the relief of fracture-related pain	Randomized, blinded, parallel-group superiority study	N = 134 children	Ibuprofen 10 mg/kg vs. morphine 0.5 mg/kg	Change in pain score on the Faces Pain Scale-Revised before and after the first dose	Both drugs had similar efficacy, but ibuprofen was more tolerable
Silver et al. (2008)	To compile a single data set of all randomized clinical trials evaluating the acute treatment of pediatric migraine	Meta-analysis	Pediatric patients with headache/migraine	Paracetamol, ibuprofen, sumatriptan, zolmitriptan, rizatriptan, dihydroergotamine	Headache/pain relief	Only ibuprofen and sumatriptan have shown statistically significant pain and headache relief in pediatric patients compared with placebo
Raslan and Zouzou (2021)	To compare the efficacy of preemptive paracetamol or ibuprofen with placebo in reducing pain during injection, extraction, and postoperatively	Randomized, placebo-controlled, triple-blinded clinical study	N = 60 children (6-8 years) undergoing primary tooth extraction	Paracetamol 320 mg vs. ibuprofen 200 mg vs. placebo	Pain level after injection, extraction, and postoperatively	Pretreatment with paracetamol and ibuprofen exhibited significant differences in pain scores vs. placebo, and ibuprofen pretreatment resulted in significantly lower pain scores vs. paracetamol immediately after injection, immediately after extraction, and at 3, 4 and 5 h after extraction (P < 0.05)



Fever Management:

Reference	Objective	Study design	Study population	Treatment	Primary outcome	Key finding
Magni et al. (2011)	To compare the efficacy of ibuprofen and dipyron for childhood fever	Randomized, open-label, single-dose study	Randomized, open-label, single-dose study	Ibuprofen 10 mg/kg vs. dipyron 15 mg/kg	Reduction in temperature from baseline at 2,3,4,5,6,7 and 8 h after dosing	Ibuprofen had greater antipyretic efficacy than dipyron
Alaje et al. (2020)	To assess the effectiveness and safety of a single dose of ibuprofen vs. paracetamol for treating childhood fever	Randomized, controlled, single-dose study	N = 140 (6-59 months)	Paracetamol 15 mg/kg vs. ibuprofen 10 mg/kg	Reduction in tympanic temperature from baseline to 6 h post dosing	Paracetamol was less effective than ibuprofen
Tan et al. (2020)	To compare the antipyretic, analgesic, and safety profile of paracetamol with ibuprofen	Systematic review and meta-analysis	N = 241,138 children (< 2 years) from 19 studies	Paracetamol (≤ 10 vs. > 10 mg/kg) and ibuprofen (≤ 5 vs. > 5 mg/kg)	Fever (continuous variable) or pain within 4 h of treatment onset	Paracetamol had lower efficacy in reducing fever and pain vs. ibuprofen
Paul et al. (2010)	To compare the antipyretic effect of a single dose of ibuprofen, ibuprofen plus paracetamol, and ibuprofen followed 3 h later by paracetamol (alternating regimen)	Randomized, controlled, study	N = 60 (8 months-6 years)	Ibuprofen 10 mg/kg vs. ibuprofen 10 mg/kg plus paracetamol 15 mg/kg vs. ibuprofen 10 mg/kg followed by paracetamol 15 mg/kg (alternating regimen)	Temperature difference between treatment groups	Ibuprofen plus paracetamol had significantly greater antipyretic effect at hour 4 (P = 0.002), 5 (P < 0.001), and 6 (P < 0.001). Alternating regimen also had a significantly greater antipyretic effect than ibuprofen alone at hour 4 (P = 0.003), 5 (P < 0.001), and 6 (P < 0.001)
Hay et al. (2008)	To compare the antipyretic effect of multiple doses of paracetamol plus ibuprofen compared with either drug alone	Randomized, blinded, controlled study	N = 156 (6 months-6 years)	Paracetamol 15 mg/kg and ibuprofen 10 mg/kg	Number of minutes without fever ($< 37.2^{\circ}\text{C}$) in the first 4 h and proportion of children reported as being normal on the discomfort scale at 48 h	Paracetamol plus ibuprofen was significantly superior to paracetamol alone in the first 4 h (P < 0.001) but not to ibuprofen alone (P = 0.2)
Lesko and Mitchell (1999)	To assess the safety of paracetamol and ibuprofen	Practitioner-based, double-blind, clinical study	N = 27,065 (< 2 years of age)	Paracetamol (12 mg/kg) or ibuprofen in 1 of 2 doses (5 or 10 mg/kg)	Rates of hospitalization for specific diagnoses according to antipyretic assignment	Rate of serious adverse clinical events requiring hospitalization among febrile children treated with paracetamol and ibuprofen were low, with no significant difference between the two medications

Reference	Objective	Study design	Study population	Treatment	Primary outcome	Key finding
Yin et al. (2022)	To compile published research comparing ibuprofen and paracetamol in the treatment of infectious fever	Meta-analysis	Children with infectious fever (2-8 years)	Ibuprofen vs. paracetamol	Reduction in temperature and adverse events	A significant reduction in fever was noted with ibuprofen vs. paracetamol at 4 h ($P < 0.00001$); no significant differences were noted in adverse events for the two medications
Southey et al. (2009)	To compare the tolerability and safety between ibuprofen and paracetamol when used as antipyretic and analgesic agents	Systematic review and meta-analysis	Children (0-18 years)	Paracetamol vs. ibuprofen vs. placebo	Tolerability and safety, which included serious adverse events that were fatal, life threatening, or required hospitalization; serious adverse events that did not require hospitalization; adverse events that required discontinuation of medication; systemic reactions related to the use of ibuprofen or paracetamol	Comparable tolerability and safety profiles were noted for ibuprofen, paracetamol, and placebo, particularly in terms of gastrointestinal symptoms, asthma, and renal adverse effects
Sidler et al. (1990)	To compare the antipyretic efficacy and safety of ibuprofen and paracetamol	Double-blind, parallel-group, multicenter study	N = 89 (5 months-13 years)	Ibuprofen syrup at 7 mg/kg and 10 mg/kg vs. paracetamol 10 mg/kg	Reduction in temperature and incidence and severity of side effects	Reduction in temperature was significantly lower with ibuprofen 7 mg/kg ($P \leq 0.05$) and 10 mg/kg ($P \leq 0.01$) compared with paracetamol. Both medications were well tolerated

References:

1. Common Selfcare Indications of Pain Medications in Children, 2023
2. Efficacy and safety of ibuprofen in children with musculoskeletal injuries, 2021
3. The effectiveness and safety of ibuprofen and acetylsalicylic acid in acute rheumatic fever, 2022
4. Ibuprofen in the treatment of children's inflammatory pain: a clinical and pharmacological overview, 2019
5. Paracetamol and ibuprofen combination for the management of acute mild-to-moderate pain in children: expert consensus using the Nominal Group Technique (NGT), 2023

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