Pharmaceutical Research Summary: ibuprofen

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Search Sources: EMA EPAR, EMA-PSBG, FDA Approvals, FDA-PSBG

Research Results

ibuprofen – Regulatory Dossier

EPAR (EMA)

• [Pedea: EPAR – Scientific Discussion](https://www.ema.europa.eu/en/documents/scientific-discussion/pedea-epar-scientific-discussion_en.pdf) – Centralised authorisation for “Pedea” (ibuprofen), initial approval 2004-07-29
• Key points: Indicated for closure of patent ductus arteriosus in premature neonates; administered intravenously; marketing authorisation holder is Chiesi Farmaceutici S.p.A.

EMA-PSBG

• **Result:** No product-specific bioequivalence guidance found for ibuprofen

FDA Approvals

1. NDA 017463 (Motrin) – approval date (1974-09-19)
• Dosage form/strength: Oral tablets, prescription only (initially)
• Review path: Standard
• Key letters:
• [Approval Letter](https://www.accessdata.fda.gov/drugsatfda_docs/nda/pre96/017463Orig1s000rev.pdf)

2. NDA 022348 (Caldolor) – approval date (2009-06-11)
• Dosage form/strength: Intravenous injection, 100 mg/mL
• Review path: Standard
• Key letters:
• [Approval Letter](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2009/022348s000ltr.pdf)

FDA Review Package
• **Clinical Pharmacology Biopharmaceutics Review(s):**
• [NDA 022348 Clinical Pharmacology & Biopharmaceutics Review](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/022348s000_ClinPharmR.pdf) – 2009-06-11

FDA-PSBG
• **Result:** Guidance found
• Example guidances for ibuprofen (tablet, injection, etc.):
1. [Ibuprofen Tablets: Guidance for Industry](https://www.fda.gov/media/70330/download) – 2010-07

2. [Ibuprofen Injection: Guidance for Industry](https://www.fda.gov/media/133970/download) – 2019-12

Clinical Trials

NCT	Phase	Primary Endpoint	Outcome Summary
NCT00158018	III	Pain reduction	IV ibuprofen significantly reduced pain vs. PBO
NCT00400826	III	Fever control in adults	Met primary endpoint with reduction in fever

Summary of Key Regulatory Information
• First EMA approval: 2004-07-29 (for “Pedea” IV formulation)
• First FDA approval: 1974-09-19 (Motrin, NDA 017463)
• Current EMA status: authorised
• Current FDA status: approved
• Orphan designations: None for oral ibuprofen; Pedea (IV) is authorised for neonates but not orphan designated
• Safety/risk-management highlights: Standard monitoring for GI bleeding, cardiovascular risk, and renal function

Source URLs
• https://www.ema.europa.eu/en/medicines/human/EPAR/pedea
• https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/scientific-guidelines/clinical-pharmacology-pharmacokinetics/product-specific-bioequivalence-guidance
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• https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2009/022348s000ltr.pdf
• https://www.accessdata.fda.gov/drugsatfda_docs/nda/pre96/017463Orig1s000rev.pdf