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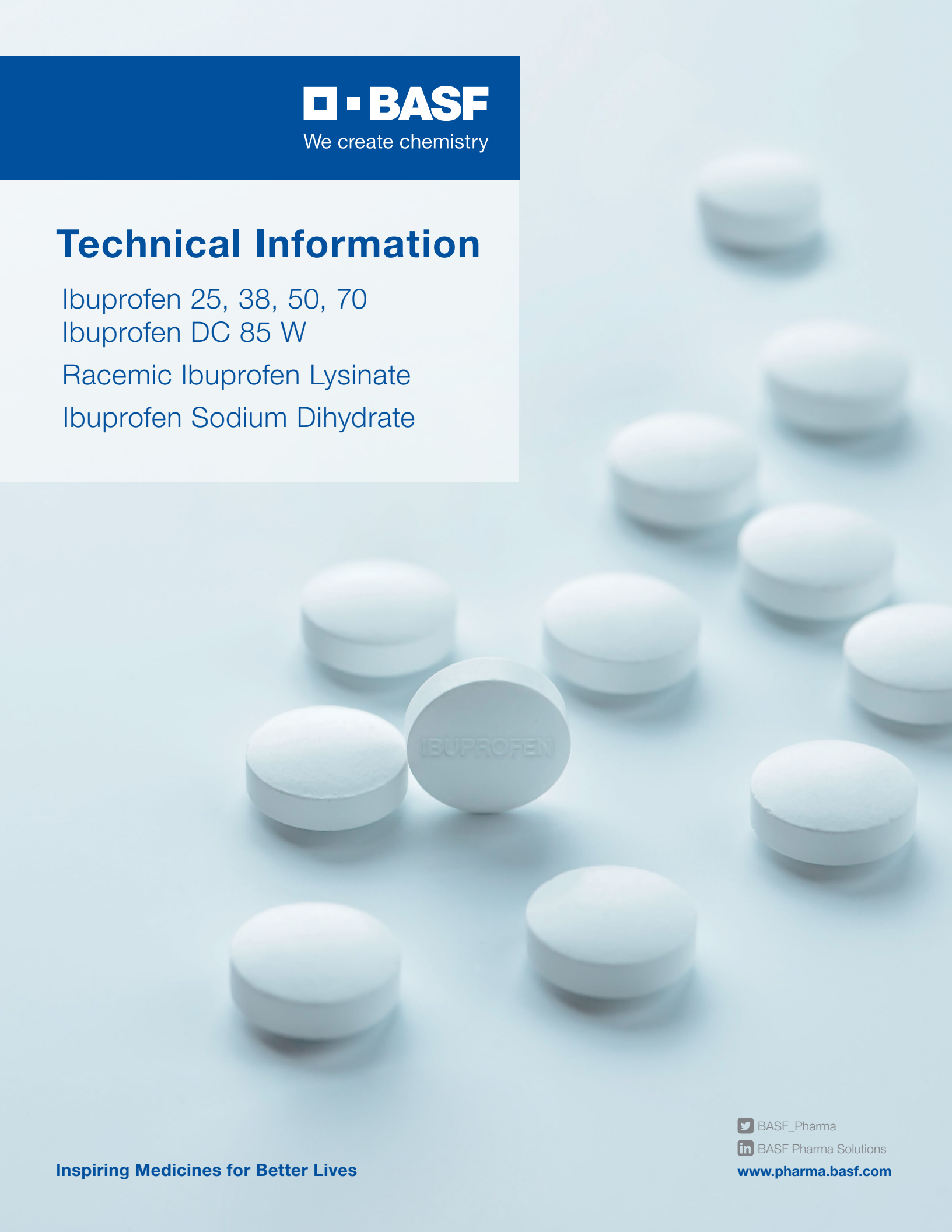
Technical Information

Ibuprofen 25, 38, 50, 70
Ibuprofen DC 85 W

Racemic Ibuprofen Lysinate

Ibuprofen Sodium Dihydrate



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POWDER GRADES, A
DIRECT COMPRESSI-
BLE GRADE, AND TWO
FAST-ACTING GRADES.

Introduction

Medical indication

Ibuprofen is a chiral propionic acid derivative belonging to the class of non-steroidal anti-inflammatory drugs (NSAIDs).

Due to its analgesic, antipyretic and anti-inflammatory actions, it is used in the treatment of inflammatory conditions such as rheumatoid arthritis, osteoarthritis, mild to moderate pain, dysmenorrhea, headache, and fever.[1]

The common active ingredient dosage in tablets is 200, 400, 600 and 800 mg. The OTC dosage forms are mainly the 200 and 400 mg forms (except for the United States and some other countries, where the 200 mg form is the only OTC form). Other common dosage forms are capsules, syrups, suspensions, suppositories, and topical dosage forms like creams and gels.

Pharmacokinetics

Orally administered ibuprofen is absorbed rapidly in the GI tract.[2] After a single oral dose on an empty stomach, peak plasma levels are reached within 45 to 90 minutes and the apparent plasma volume of distribution is reported to be between 0.1 to 0.2 l/kg.[3–5]

Ibuprofen has an extensive protein binding capacity (>98%)[6–7] and is excreted via the kidneys. The biological half-life is between 2 and 4 hours.[2] After 24 h, 100% of the active substance is excreted in the urine.[8]

Pharmacology

The mode of action of ibuprofen, while not completely understood, is believed to involve the reversible inhibition of the enzyme cyclooxygenase (COX) which is responsible for the biosynthesis of prostaglandins (PGs) from arachidonic acid in the cellular membrane.[9]

Prostaglandins are distributed in the various tissues and have, among other properties, a powerful effect on the smooth muscles. In case of an inflammatory stimulus or blood flow disturbances, PGs are synthesized in increased amounts and sensitize the tissues to the action of other agents such as histamine and kinins. As a result, symptoms such as pain and inflammation appear. Fever occurs by the influence of the PGs on the heat regulation center in the hypothalamus. There they raise the normal body temperature of 37 °C.[10]

References

1 U.S. Food & Drug Administration "Ibuprofen Drug Facts Label" Revised 6 April 2016.

2 Davies, N. M., "Clinical Pharmacokinetics of Ibuprofen," Clinical Pharmacokinetics, 34:101-154, 1998.

3 Gillespie, W. R. et al., "Relative Bioavailability of Commercially Available Ibuprofen Oral Dosage Forms in Humans," Journal of Pharmaceutical Sciences, 71:1034-1038, 1982.

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5 Jamali, F. and D. R. Brocks, "Clinical Pharmacokinetics of Ketoprofen and Its Enantiomers," Clinical Pharmacokinetics, 19:197-217, 1990.

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7 Whitlam, J. B. and K. F. Brown, "Ultrafiltration in Serum Protein Binding Determinations," Journal of Pharmaceutical Sciences, 70:146-50, 1981.

8 Rudy, A. C. et al., "Stereoselective Metabolism of Ibuprofen in Humans: Administration of R-, S- and Racemic Ibuprofen," Journal of Pharmacology and Experimental Therapeutics, 259:1133-1139, 1991.

9 Neupert, W. et al., "Effects of Ibuprofen Enantiomers and Its Coenzyme a Thioester on Human Prostaglandin Endoperoxide Synthases," British Journal of Pharmacology, 122:487-92, 1997.

10 Ricciotti, E. and G. A. FitzGerald, "Prostaglandins and Inflammation," Arteriosclerosis Thrombosis, and Vascular Biology, 31(5): 986-1000, 2011.

Ibuprofen

Chemical information

Ibuprofen

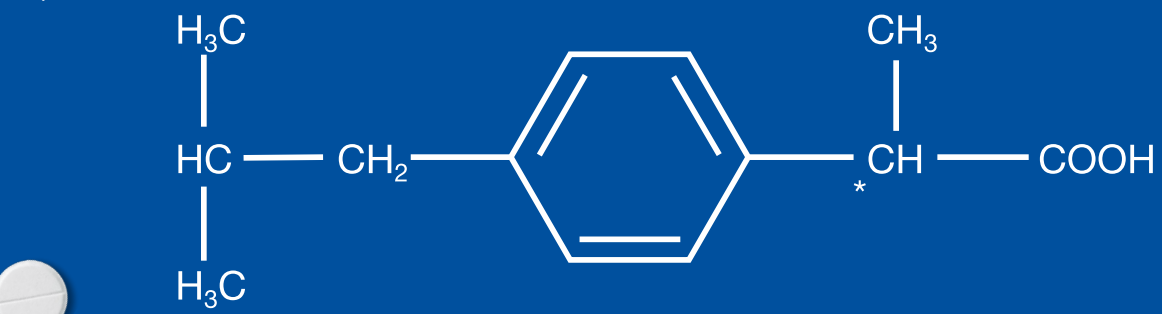
Chemical name	(2RS)-2[4-(2-Methylpropyl)phenyl]propanoic acid
CAS number	15687-27-1
EINECS number	239-784-6
Molecular formula	$C_{13}H_{18}O_2$
Molecular weight	206.28 g/mol
Product grades	BASF offers 4 grades based on different particle size distributions (see particle characterization). Furthermore, a direct compressible grade is offered: Ibuprofen DC 85 W, the composition of which can be found in chemical and physical properties section below.
Synonyms	(±)-2-[4-(2-methylpropyl)phenyl]propanoic acid; (±)-Benzeneacetic acid, alpha-methyl-4-(2-methylpropyl); (±)-p-Isobutylhydratropic acid; (±)-2-p-Isobutylphenylpropionic acid
Regulatory status	Ibuprofen meets the current Ph. Eur., USP, JP and IP monographs. DMFs and CEP are available upon request.

Ibuprofen is the racemate of (+)-Ibuprofen and (-)-Ibuprofen (optical rotation = 0°). According to the literature, the pharmacologically active form is (+)-Ibuprofen.*

Approximately 30 to 70% of the (-)-Ibuprofen is converted to the active form (+)-Ibuprofen in the body. This process proceeds solely from the (-)- form to the (+)- form.

Structural formula:

Ibuprofen



*Ibuprofen: a critical bibliographic review, K. D. Rainsford, Taylor & Francis Ltd., London, UK, 1999, page 104

Chemical and physical properties

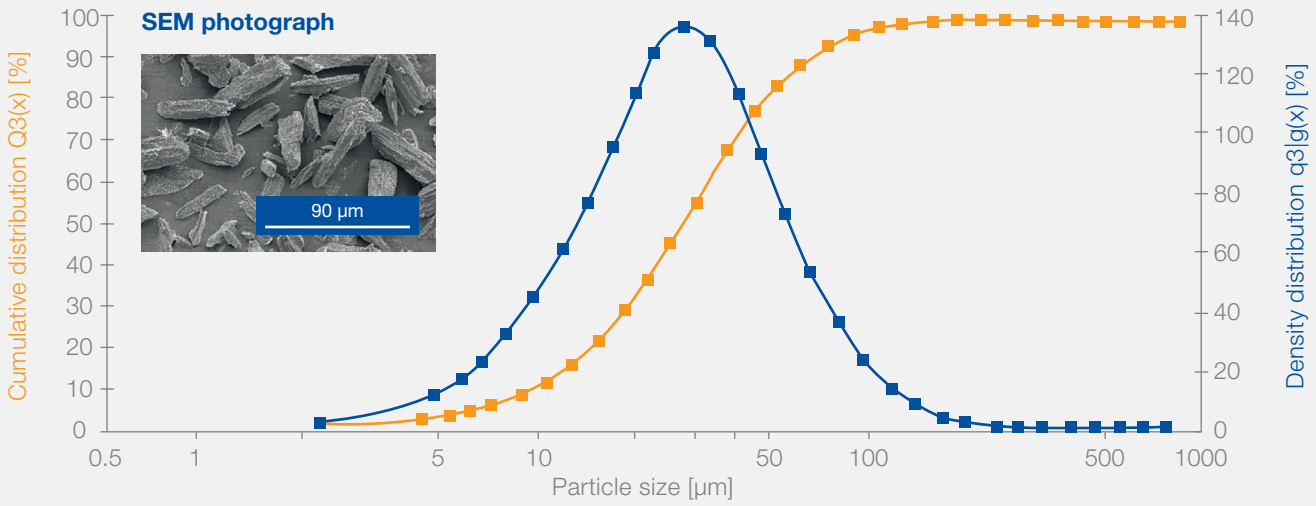
Ibuprofen grades 25, 38, 50, 70

Appearance	Crystalline powder
Color	White
Odor	Characteristic
Melting range	75–78 °C
Solubility in phosphate buffer pH 7.2 (37 °C)	5.2 mg/ml
Partition coefficient n-octanol/water	3.3

The chemical parameters of all pure ibuprofen powder grades are identical.
The only difference is the particle size distribution (*see particle characteristics*).

Particle characterization

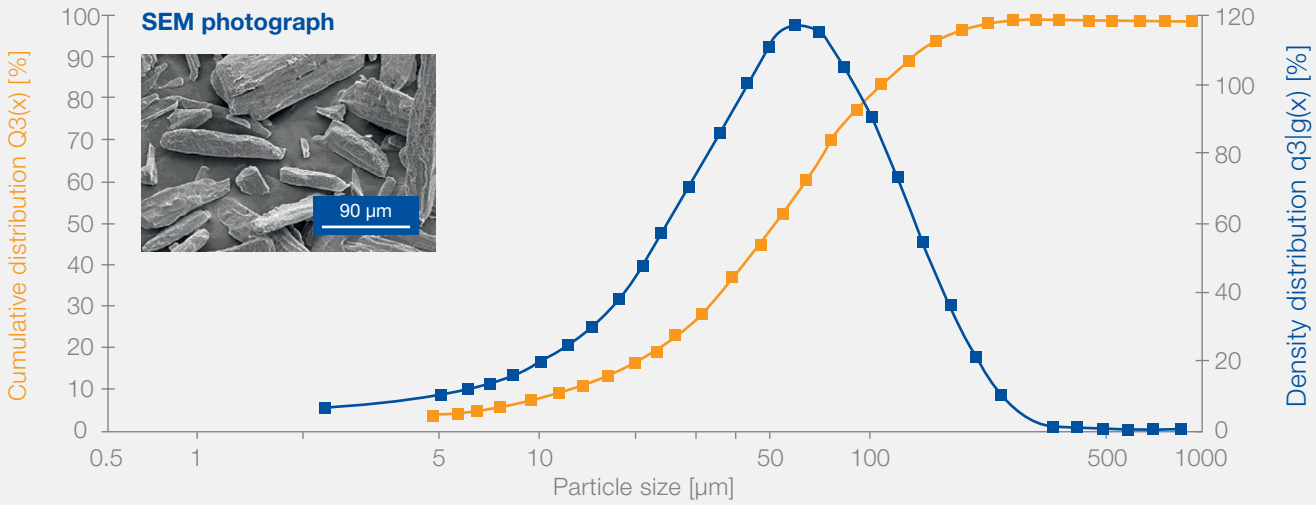
Ibuprofen 25 Particle Size Distribution



An example of the particle size distribution, as determined by laser diffraction using a dry powder morphology, is given in the diagram above. **The median particle size for Ibuprofen 25 is between 20 µm and 33 µm.**

Bulk density	Approximately 0.30 g/ml.
Tapped density	Approximately 0.48 g/ml.

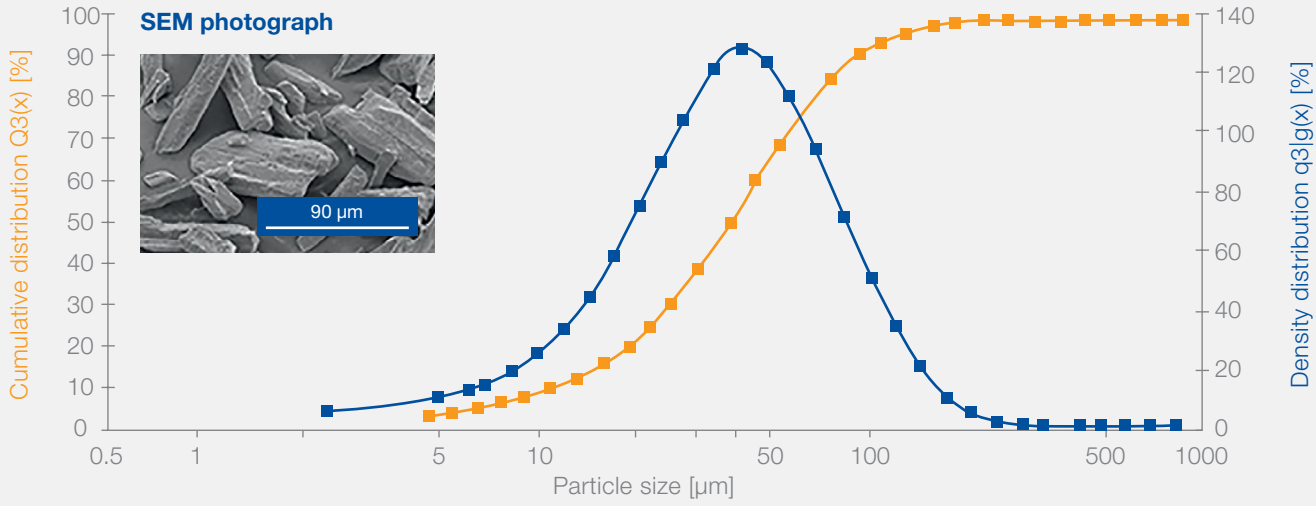
Ibuprofen 50 Particle Size Distribution



An example of the particle size distribution, as determined by laser diffraction using a dry powder morphology, is given in the diagram above. **The median particle size for Ibuprofen 50 is between 45 µm and 60 µm.**

Bulk density	Approximately 0.34 g/ml.
Tapped density	Approximately 0.60 g/ml.

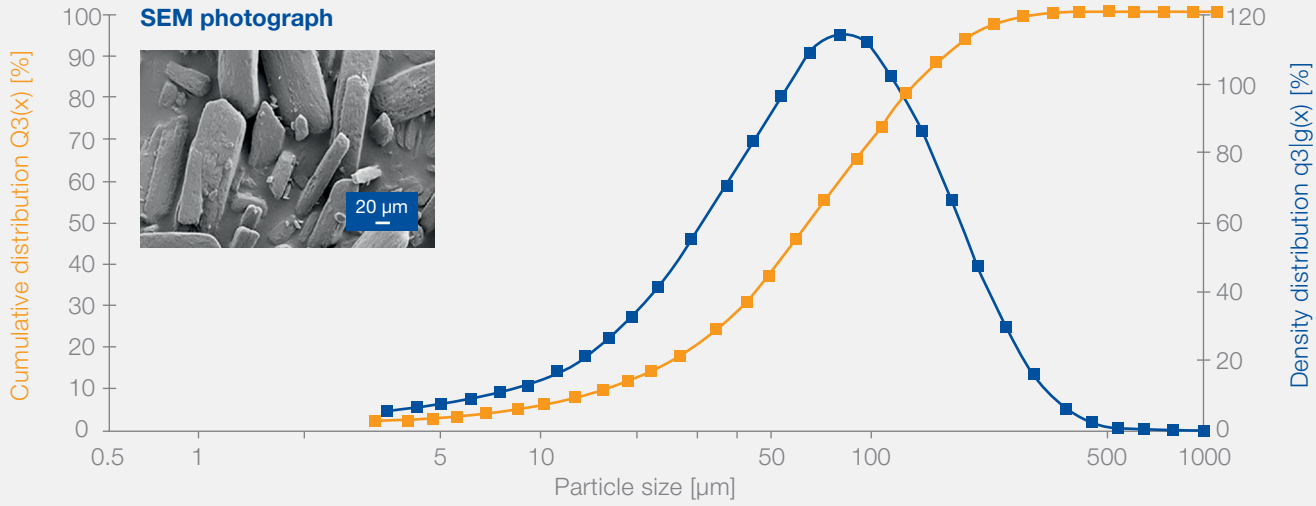
Ibuprofen 38 Particle Size Distribution



An example of the particle size distribution, as determined by laser diffraction using a dry powder morphology, is given in the diagram above. **The median particle size for Ibuprofen 38 is between 33 µm and 45 µm.**

Bulk density	Approximately 0.33 g/ml.
Tapped density	Approximately 0.60 g/ml.

Ibuprofen 70 Particle Size Distribution



An example of the particle size distribution, as determined by laser diffraction using a dry powder morphology, is given in the diagram above. **The median particle size for Ibuprofen 70 is between 60 µm and 85 µm.**

Bulk density	Approximately 0.38 g/ml.
Tapped density	Approximately 0.68 g/ml.

Ibuprofen DC 85 W

Appearance	Granules, free flowing, homogeneous material
Color	White
Assay	82–88%

The ibuprofen used to manufacture Ibuprofen DC 85 W meets the current Ph. Eur., USP, JP and IP monographs. A Technical Package and a US-DMF are available upon request.

Particle Size Distribution

Sieve analysis	Min. 15% retained on 0.850 mm sieve Min. 45% retained on 0.640 mm sieve
Bulk density	Approximately 0.55 g/ml.
Tapped density	Approximately 0.64 g/ml.
Angle of repose	33°

SEM photograph

Typical composition

Ibuprofen 50	84.66–85.34%
Microcrystalline Cellulose	6.59–6.67%
Colloidal Silicon Dioxide	5.34–5.52%
Croscarmellose Sodium	2.86–3.02%

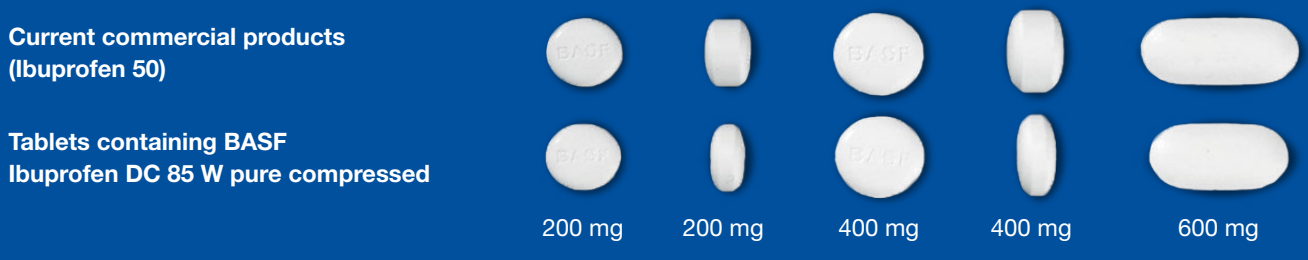
Recommendation for direct compression

Today the manufacturing of ibuprofen tablets is often done by direct compression. Using this method, the expensive and time-consuming wet granulation method can be avoided. But in general, ibuprofen has the disadvantage of sticking on the tablet tools so that the process must be interrupted often.

Therefore, direct compression formulations with a high content of ibuprofen per tablet are often avoided. Mostly tablets with an ibuprofen content of maximum 60% are compressed.

BASF offers a formulated ibuprofen product ideal for direct compression: Ibuprofen DC 85 W. The direct compression (DC) grade ensures that tablet sticking is minimized and allows for excellent tablet engraving.

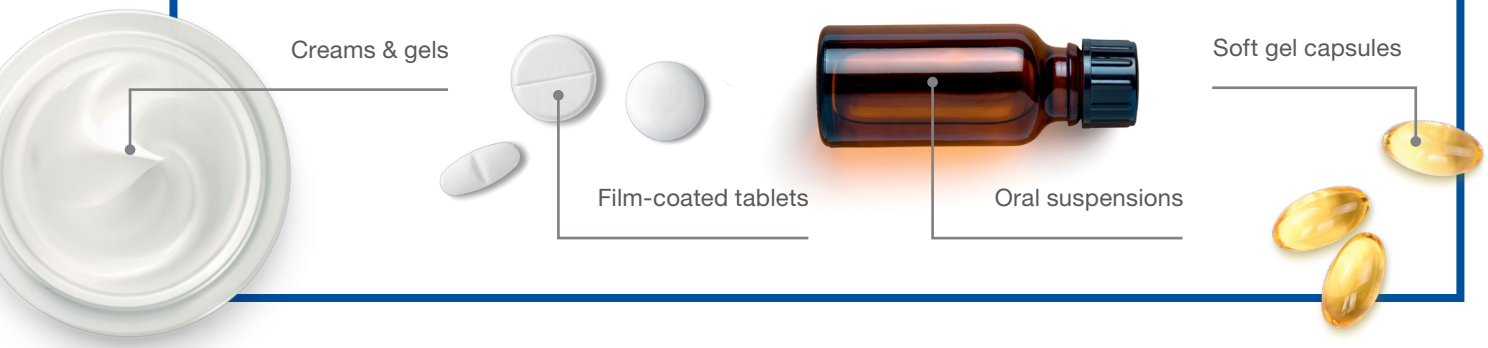
Furthermore, Ibuprofen DC 85 W has a lower angle of repose compared to standard grades, resulting in improved flowability.



General information on processing of Ibuprofen

Ibuprofen is used mainly in three (3) different dosage forms:

- **Oral film-coated tablets** showing rapid disintegration and fast release of the active substance. The common strengths are 200, 400, 600 and 800 mg. There are also slow release formulations containing 800 mg of Ibuprofen.
- **Oral suspensions** which are used mainly for patients who have difficulties swallowing tablets and for pediatric patients.
- **Creams and gels** for topical application, generally used for treating rheumatic disorders or sports injuries.



Tablets

Recommended grade(s)	Ibuprofen 50, Ibuprofen 70, Ibuprofen DC 85 W (for direct compression)
Formulation guidance	High concentrations of magnesium stearate as a lubricant are not recommended. For direct compression, the ready-to-use Ibuprofen DC 85 W reduces sticking. For a film coating, Kollicoat® IR has a reduced viscosity in aqueous solutions compared to HPMC suspensions, which leads to higher solids content and a faster coating process.

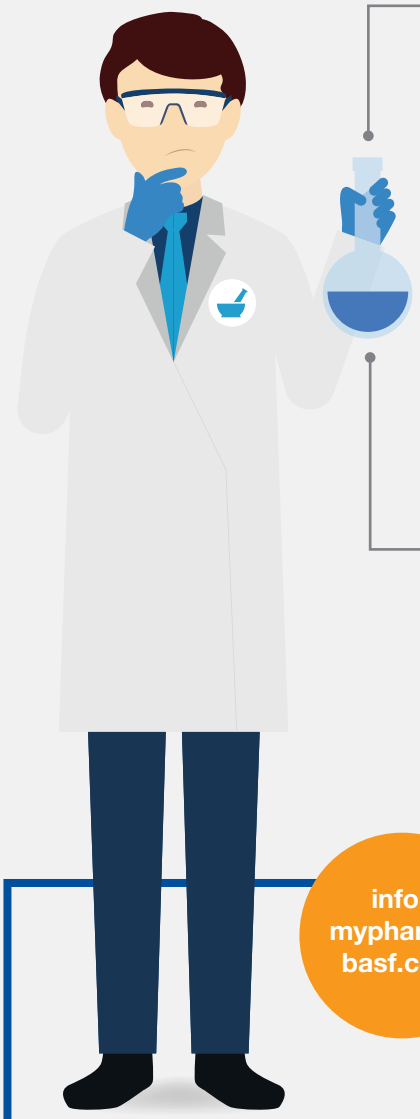
Suspensions

Recommended grade(s)	Ibuprofen 25, Ibuprofen 38
Formulation guidance	To stabilize against sedimentation, fine particles should be used. The pH of the suspension should be in the acid range so that ibuprofen is undissolved, which will reduce bitter taste if any.

Creams & Gels

Recommended grade(s)	Ibuprofen 25, Ibuprofen 38, Ibuprofen 50, Ibuprofen 70
Formulation guidance	Ibuprofen is dissolved in the lipophilic phase of creams, thus there is no impact of particle size. Propylene glycol or low molecular weight polyethylene glycols are recommended as the oily component.

ZoomLab™ – Your Virtual Formulation Assistant



Access example formulations and build your own

ZoomLab™ Formulation Wizard identifies suitable excipients and calculates potential formulations depending on the selected dosage form, defined target profile, and properties of the active ingredient. Example formulations include creams, tablets, and more!

Evaluate bioequivalence of your final formulation

A WHO biowaiver monograph is available for ibuprofen. The **ZoomLab™** dissolution module can be used to calculate difference and similarity factors (f1, f2) required for showing bioequivalence.

Estimate the processability and tabletability of the API and powder blend

ZoomLab™ provides values for parameters relating to particle size, powder density, flowability, and tabletability. The parameters are scaled from 0 to 10, a risk analysis is run, and an interpretation of results/formulation advice is provided.

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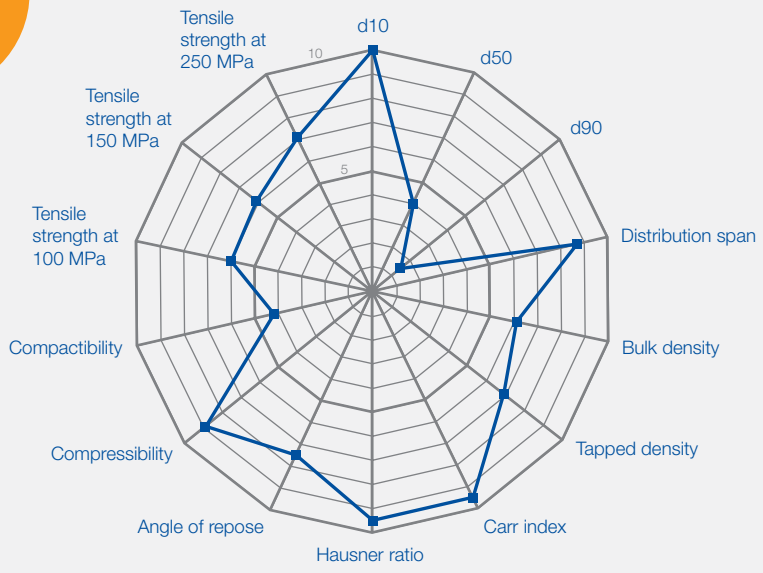
Example: Ibuprofen DC 85 W

- ☑ **Direct compression** is possible
- ☑ **Dry granulation** (roller compaction) is possible
- ☑ **Wet granulation** (fluid-bed or high-shear granulation) is possible



Example formulations

Production of granules for 200, 400, 600 and 800 mg forms

The following ingredients are placed in a high shear mixer and granulated with water:

Ibuprofen 50	60.1% w/w
Lactose	18% w/w
Corn starch	9% w/w
Kollicoat® IR*	3.6% w/w

Amount of water: approximately 0.2 kg water per 1 kg ibuprofen. Wet sieving (4 mm) and drying in a fluid bed granulator at 60 °C (inlet air) for approximately 30 minutes and sieved dry (1 mm). The batch is mixed with the following additives to form granules suitable for tableting.

Extra granular material

Avicel® PH 102	3.6% w/w
AcDiSol	4.8% w/w
Magnesium stearate	0.6% w/w
Aerosil® 200	0.3% w/w

Coating formulations for Ibuprofen tablets

Composition	Fraction with reference to the atomised suspension [%]	Fraction with reference to the dry film [%]
Polymer		
Kollicoat® IR	16.0	64
Pigments		
Talc	6.0	24
Sicovit® Red 30	3.0	12
Total	**25**	**100**

(*HPMC 6 cp can also be used)

Large scale processing

Materials and methods

Component	Quantity
Ibuprofen 70	78.0%
Avicel® PH-105 (microcrystalline cellulose)	10.4%
Aerosil® 200 (fumed silica)	1.0%
DiCaFos® A12 (dicalcium phosphate anhydrous)	3.6%
AcDiSol® SD-711 (croscarmellose sodium)	4.0%
Kolliwax® S Fine (stearic acid)	1.0%

1. **Sieving I (Ibuprofen 70, DiCaFos® A12)**
2. **Blending I (Ibuprofen 70, DiCaFos® A12)**
3. **Sieving II (Avicel® PH-105, Aerosil® 200, AcDiSol® SD-711)**
4. **Blending II (all components without lubricant)**
5. **Sieving III (Kolliwax® S Fine)**
6. **Blending III (all components)**

Handling & Safety

Please refer to the individual material safety data sheet (MSDS) for instructions on safe and proper handling and disposal. Material safety data sheets are sent with every consignment. In addition they are available on **MyProduct-World** or from your local BASF sales representative.

Product specification

The current version of the product specification is available on **RegXcellence®** or from your local BASF sales representative.

Regulatory & Quality

Please refer to the individual document quality & regulatory product information (QRPI) which is available on **RegXcellence®** and from your local sales representative. **The QRPI covers all relevant information including retest dates and storage conditions.**

Publications

Publications including scientific posters are available on:

http://pharmaceutical.basf.com/en.html

PRD and article numbers

PRD-No.*	Product name	Article numbers	Packaging
30076127	**Ibuprofen 25**	50909135 56929776	50 kg Fiber drum 0.5 kg Plastic bottle
30076128	**Ibuprofen 38**	54888322 50909188 56929829	51.5 kg Fiber drum 50 kg Fiber drum 0.5 kg Plastic bottle
30076166	**Ibuprofen 50**	50742398 50914488 56929882	62.8 kg Fiber drum 50 kg Fiber drum 0.5 kg Plastic bottle
30487271	**Ibuprofen 70**	54017960 54165459	50 kg Fiber drum 0.5 kg Plastic bottle
30526498	**Ibuprofen DC 85 W**	50192890 50192933	50 kg Fiber drum 2 kg Metal pail

* BASF's commercial product number.

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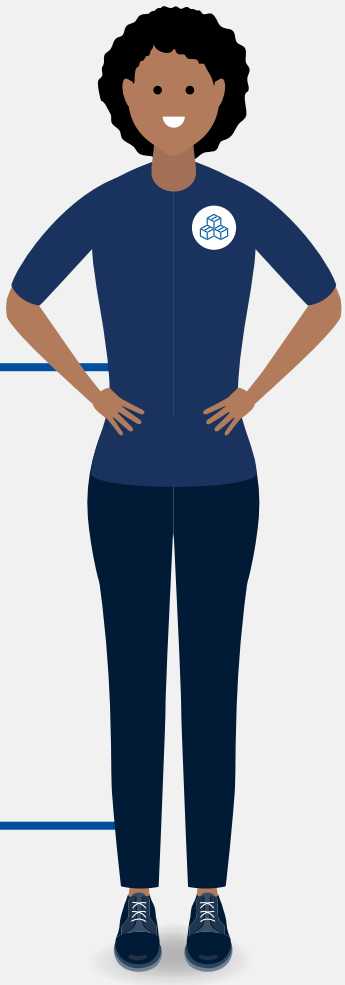

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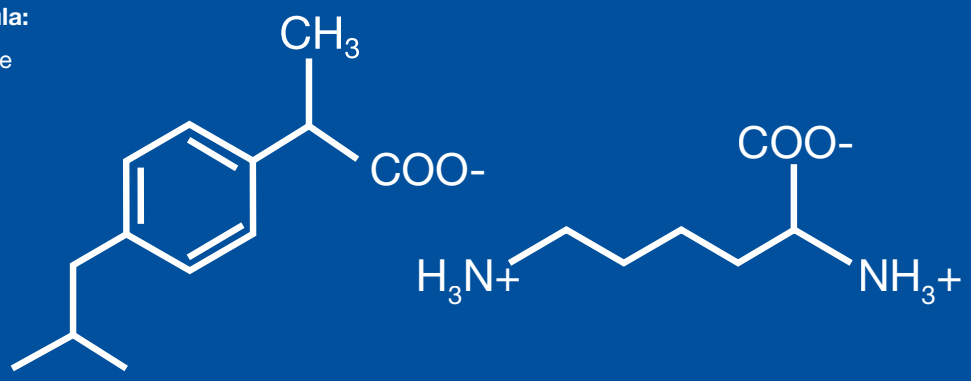
Racemic Ibuprofen Lysinate (RIBL)

Chemical information

Ibuprofen Lysinate

Synonymous names	(±)-2-[4-(2-methylpropyl)phenyl]propanoic acid lysinate (±)-Benzeneacetic acid, alpha-methyl-4-(2-methylpropyl) lysinate (±)-p-Isobutylhydratropic acid lysinate (±)-2-p-Isobutylphenylpropionic acid lysinate
Empirical formula	$C_{19}H_{32}N_2O_4$
Molecular weight	352.48 g/mol

Structural formula:
Ibuprofen Lysinate



Product information

PRD-No.	Product name	Article no.	Packaging
30081848	Racemic Ibuprofen Lysinate	56477527	25 kg, 0.1 kg (sample)

Retest period: See separate documentation: “Q&R PI (not for regulatory purposes)” available at **RegXcellence®**: info-mypharma.basf.com (registered access).

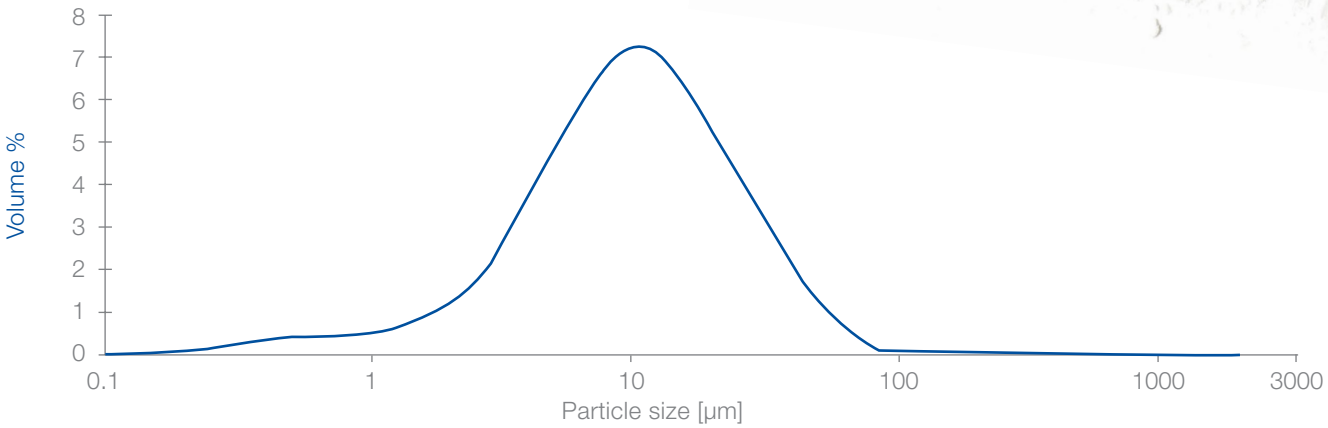
Chemical and physical properties

White to almost white, very fine crystalline powder with a high volume.

In the literature the solubility of Ibuprofen (acid) in distilled water is reported to be less than 0.1%. The solubility of Ibuprofen Lysinate is 1:5, or about 17%.*

Particle characterization

An example particle size distribution is shown below.
The median particle size for RIBL is approximately 10 µm.



Regulatory status

No monographs exist.
E-DMF is available upon request.

Specification

See separate documentation: “Standard Specification (not for regulatory purposes)” available via **RegXcellence®**: (registered access)

https://info-mypharma.basf.com/

*Ibuprofen, K. D. Rainsford, Taylor & Francis Ltd., London, UK, 1999

Medical indication

The term RIBL is the acronym for Racemic Ibuprofen Lysinate. Racemic signifies that the ibuprofen drug substance and the lysine anion are both racemic compounds. RIBL differs from the common ibuprofen acid, generally referred to as ibuprofen, in that it is more rapidly absorbed from the intestinal tract and reaches peak plasma levels and t_{max} more quickly.[1–2] After absorption, RIBL is available in the form of pure ibuprofen acid and is therefore to be handled like ibuprofen.

Ibuprofen is a chiral propionic acid derivative belonging to the class of non-steroidal anti-inflammatory drugs (NSAIDs). Due to its analgesic, antipyretic and anti-inflammatory effects, ibuprofen is used in the treatment of inflammatory conditions such as rheumatoid arthritis, osteoarthritis, mild to moderate pain, dysmenorrhea, headache, and fever.[3]

For RIBL the usual dosage ranges are tablets containing 340 mg and 680 mg. RIBL has not yet been approved in the USA.

Pharmacokinetics

RIBL is readily and quickly absorbed from the gastrointestinal tract.[1–2] The peak plasma level of the free acid is reached within 30 to 60 min (with the free acid ibuprofen, t_{max} was measured between 60 and 120 minutes, depending on the dosage form).[1, 6] After absorption, there is no difference between RIBL and the free acid.

Pharmacology

From a pharmacological point of view, there is no difference between RIBL and the free ibuprofen acid because it is the free acid and not the RIBL salt that is the active form.

The mode of action of ibuprofen, while not completely understood, is believed to involve reversible inhibition of the cyclooxygenase (COX) enzyme, which is responsible for the biosynthesis of prostaglandins (PGs) from arachidonic acid in the cellular membrane.[4]

Prostaglandins are distributed in the various tissues and have among other properties a powerful effect on the smooth muscles. In case of inflammatory stimuli or blood flow disorders, PGs are synthesized in increased amounts, making the tissues sensitive to the action of other agents such as histamine and kinins. As a result, symptoms like pain and inflammation occur. The incidence of fever is raised by the influence of the PGs on the heat regulation center in the hypothalamus. There they scale up the normal set point of 37 °C.[5]

References

1 Martin, W. et al., “Pharmacokinetics and Absolute Bioavailability of Ibuprofen After Oral Administration of Ibuprofen Lysine in Man,” Biopharmaceutics & Drug Disposition, 11(3): 265-278, 1990.

2 Hermann, T. W. et al., “Bioavailability of Racemic Ibuprofen and its Lysinate from Suppositories in Rabbits,” Journal of Pharmaceutical Sciences, 82(11):1102-1111, 1993.

3 U.S. Food & Drug Administration “Ibuprofen Drug Facts Label” Revised 6 April 2016.

4 Neupert, W. et al., “Effects of Ibuprofen Enantiomers and Its Coenzyme a Thioester on Human Prostaglandin Endoperoxide Synthases,” British Journal of Pharmacology, 122:487-92, 1997.

5 Ricciotti, E. and G. A. FitzGerald, “Prostaglandins and Inflammation,” Arteriosclerosis Thrombosis, and Vascular Biology, 31(5): 986-1000, 2011.

6 Davies, N. M., “Clinical Pharmacokinetics of Ibuprofen,” Clinical Pharmacokinetics, 34:101-154, 1998.

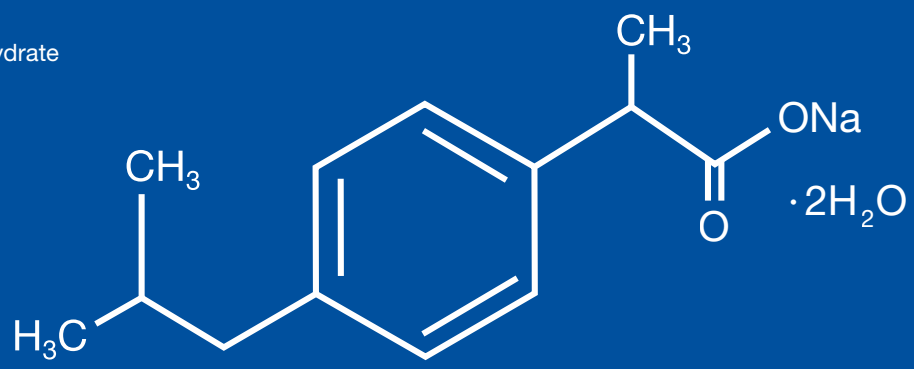
Ibuprofen Sodium Dihydrate

Chemical information

Ibuprofen Sodium Dihydrate

Chemical name	2-(4-isobutylphenyl)-propionate sodium dihydrate
CAS-No.	31121-93-4
Empirical formula	$C_{13}H_{17}O_2Na \times 2\ H_2O$
Molecular weight	228.26 + 36.03 g/mol
Appearance	White to almost-white powder

Structural formula:
Ibuprofen Sodium Dihydrate



Product information

PRD-No.	Product name	Article no.	Packaging
30260589	Ibuprofen Sodium Dihydrate	51224063	50 kg, 5 kg 0.5 kg (sample)

Retest period: See separate documentation: “Q&R PI (not for regulatory purposes)” available at **RegXcellence®**: info-mypharma.basf.com (registered access).

Storage

Ibuprofen Sodium Dihydrate should be stored in the original, tightly sealed container. It should be placed in a well-ventilated room at ambient temperature and protected from light.

The retest period of Ibuprofen Sodium Dihydrate is 60 months for material stored in the original, unopened container and according to our recommendations.

Regulatory status

Currently there are no monographs describing Ibuprofen Sodium Dihydrate in the major Pharmacopoeias (USP, Ph. Eur., and JP).

E-DMF and US-DMF are both available on **RegXcellence®**.

Specification

See separate documentation: “Standard Specification (not for regulatory purposes)” available via **RegXcellence®** (registered access)

https://info-mypharma.basf.com/

Pharmacokinetics

According to the literature, ibuprofen sodium dihydrate dissolves more quickly in vitro and is absorbed into blood plasma more quickly than conventional ibuprofen, whereas tolerability and safety profiles of the two APIs are comparable.[3]

In an investigation of the dissolution, plasma pharmacokinetics, and safety of ibuprofen sodium dihydrate versus conventional ibuprofen, the following results were reported:[3]

- Ibuprofen sodium dihydrate dissolved significantly more rapidly at pH 1.2, 3.5 and 7.2 compared to conventional ibuprofen.
- Ibuprofen sodium dihydrate reached the t_{max} significantly earlier than conventional ibuprofen.
- Ibuprofen sodium dihydrate showed significantly higher c_{max} compared to conventional ibuprofen.
- Ibuprofen sodium dihydrate was characterized by significantly higher mean plasma concentration (10 min post-dose) compared to conventional ibuprofen.

t_{max} is the necessary time until the maximum plasma concentration of a drug is reached; this is relevant for the drug onset. Generally, reaching the t_{max} early is of great advantage for analgesic treatment.

According to the literature, the first signs of pain relief occurred significantly earlier in ibuprofen sodium dihydrate treated patients, and pain intensity was reduced to half after 30 min for ibuprofen sodium dihydrate compared to 57 min for conventional ibuprofen. In summary, ibuprofen sodium dihydrate causes faster and more efficient pain relief during the first hour after oral intake compared to conventional ibuprofen.[4]

Pharmacology

The mode of action is believed to involve the reversible inhibition of the enzyme cyclooxygenase (CO)) which is responsible for the biosynthesis of prostaglandin (PGs) from arachidonic acid in the cellular membrane.[1]

Prostaglandins are distributed in the various tissues and have, among other properties, a powerful effect on the smooth muscles. In case of an inflammatory stimulus or blood flow disturbances, PGs are synthesized in increased amounts and sensitize the tissues to the action of other agents such as histamine and kinins. As a result, symptoms such as pain and inflammation appear. Fever occurs by the influence of the PGs on the heat regulation center in the hypothalamus. There they raise the normal body temperature of 37 °C.[2]

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