SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product :

1.1 Product Name : IBUNOVA 400

1.2 Strength : Provided in quality and quantitative composition

1.3 Pharmaceutical Dosage Form : Soft gelatin capsule

2. Quality and Quantitative Composition :

2.1 Qualitative Declaration

2.2 Quantitative Declaration

Name of ingredient	Specification	Label claim (mg/capsule)	Overages		Quantity (mg/capsule)	Function
			(mg/capsule)	(%)		
Active ingredients:						
Ibuprofen	USP Current Edition	400.00	-	-	400.0000	Active
				Total weight of active ingredients	**400.0000 mg**	
Inactive ingredients:						
Polyethylene Glycol 600	EP Current Edition	-	-	-	433.0940	Solvent
Potassium Hydroxide	EP Current Edition	-	-	-	50.9640	pH adjustant
Purified Water	EP Current Edition	-	-	-	45.9420	Solvent
				Total weight of inactive ingredients	**530.0000 mg**	
				Total fill weight	**930.0000 mg**	
Capsule shell:						
Gelatin	In-house specification	-	-	-	262.2625	Capsule shell
Sorbitol 70% Solution	EP Current Edition	-	-	-	118.0181	Plasticizer
Purified Water	EP Current Edition	-	-	-	19.7700	Solvent
FD & C Green No.3	In-house specification	-	-	-	0.0656	Colorant
				Total shell weight	**400.1162 mg**	
				Total capsule weight	**1330.1162 mg**	

3. Pharmaceutical Form :

Clear, colourless to greenish blue, oily liquid filled in 20 minim, oblong, green, transparent soft gelatin shell capsule

4. Clinical Particulars :

4.1 Therapeutic indications:

Temporarily relieves of minor aches and pains associated with the common cold, headache, toothache, muscular aches, backache, minor pain of arthritis, pain of menstrual cramps (dysmenorrhea). Temporarily reduces fever.

4.2 Posology and method of administration:

Adults and Adolescents weighing more than 40 kg (12 years and over): Initial dose take one capsule (400 mg ibuprofen) with water then if necessary one capsule (400 mg ibuprofen) every 4 to 6 hours. Do not exceed 3 capsules (1200 mg ibuprofen) in 24 hours.

Do not give ibuprofen 400 mg softgel capsules to adolescents weighing under 40 kg or children under 12 years of age.

4.3 Contraindications:

Contraindicated in person with known hypersensitivity to Aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs). Ibuprofen may cause a severe allergic reaction which may include Hives, Facial swelling, Asthma (wheezing), Shock, Skin reddening, Rash.

4.4 Special warning and precautions for use:

- Should not be administered with other nonsteroidal anti-inflammatory drugs (NSAIDs) and Aspirin due to potentiate adverse gastrointestinal effects.
- Should not be taken with alcoholic drink.
- Use with caution in person with peptic ulcer disease.
- Stop taking ibuprofen and consult physician if fever persists more than 3 days and/or pain persist more than 10 days.

4.5 Undesirable effects:

The most frequent adverse effects of ibuprofen involve the irritation of gastrointestinal tract.

4.6 Overdose and special antidotes:

The following signs and symptoms have occurred in individuals following an overdose of oral Ibuprofen; abdominal pain, nausea, vomiting, drowsiness, and dizziness. Emesis can be induced, by the use of an emetic or gastric lavage.

4.7 Pregnancy and Lactation:

Not recommended in lactating women and during pregnancy (especially during the last trimester) or during labor and delivery.

4.8 Drug Interactions:

Ibuprofen is associated with several suspected or probable interactions that can affect the action of other drugs. Ibuprofen may increase the blood levels of lithium (Eskalith) by reducing the excretion of lithium by the kidneys. Increased levels of lithium may lead to lithium toxicity. Ibuprofen may reduce the blood pressure-lowering effects of drugs that are given to reduce blood pressure. This may occur because prostaglandins play a role in the regulation of blood pressure. When ibuprofen is used in combination with aminoglycosides [for example, gentamicin] the blood levels of the aminoglycosides may increase, presumably because the elimination of aminoglycosides from the body is reduced. This may lead to aminoglycoside-related side effects. Individuals taking oral blood thinners or anticoagulants [for example, warfarin] should avoid ibuprofen because ibuprofen also thins the blood, and excessive blood thinning may lead to bleeding.

5. Pharmacological Properties:

5.1 Pharmacodynamic Properties/ Pharmacokinetic Properties

Pharmacodynamic Properties:

Not applicable.

Pharmacokinetic Properties:

Ibuprofen is absorbed from gastro-intestinal tract and pack plasma concentrations occurs about 1 or 2 hours after ingestion. Ibuprofen is extensively bound to plasma proteins and has a half-life about 2 hours. It is rapidly excreted in the urine mainly as metabolites and their conjugates. About 1% is excreted in urine as unchanged Ibuprofen and about 14% as conjugated ibuprofen.

5.2 Preclinical Safety Data:

Not applicable.

6. Pharmaceutical Particulars :

6.1 List of excipients:

Inactive: Polyethylene Glycol 600, Potassium Hydroxide, Purified Water, Gelatin, Sorbitol 70% Solution, FD & C Green No.3

6.2 Incompatibilities:

Not applicable.

6.3 Shelf life:

Two years from manufacture date.

6.4 Special precautions for storage:

Store below 30°C.

6.5 Nature and contents of container :

Aluminium foil:	Printed aluminium foil
Outer carton:	Printed cardboard carton
Insert:	Wood free paper

7. Marketing Authorization Holder :

MEGA LIFESCIENCES Public Company Limited

384 Moo 4, Soi 6, Bangpoo Industrial Estate, Pattana 3 Road,

Phraeksa, Mueang, Samutprakarn 10280, Thailand

Tel: +66-2-401-8686

Fax: +66-2-324-0451

Email: info@megawecare.com

Website: www.megawecare.com

8. Marketing Authorization Numbers: -

9. Date of first authorization / renewal of the authorization: -

10. Date of revision of the text: -