

**Product Name: HABIFEN-600 TABLETS**

Module 1: Administrative Information & Prescribing Information.

**SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)  
TEMPLATE**

**1. NAME OF THE MEDICINAL PRODUCT**

**HABIFEN-600 TABLETS**

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each film coated tablet contains:

Ibuprofen BP 600 mg

Excipients Q.S.

Erythrosine & Titanium Dioxide (In house)

For a full list of excipients, see Section 6.1.

<b>Sr. No.</b>	<b>Ingredients</b>	<b>Specification</b>	<b>Label claim/Tab (in mg)</b>	<b>Per dosage unit (mg)</b>	<b>Reason for Inclusion</b>
1	Ibuprofen	BP	600	600	Medicament
2	Starch	BP	--	196	Diluent / lubricant
3	Talc	BP	--	5	Lubricant
4	Methyl Paraben	BP	--	0.15	Preservative
5	Propyl Paraben	BP	--	0.15	Preservative
6	Dicalcium Phosphate	BP	--	200	Diluent
7	Magnesium Stearate	BP	--	8	Lubricant
8	Sodium Starch Glycolate	BP	--	5	Lubricant
9	Colloidal Silicon Dioxide	BP	--	2	Lubricant
10	Stearic Acid	BP	--	0.1	Binder
11	Ultracoat AQ pink	IHS	--	30	Coating Material

BP = British Pharmacopeia

IH = In House.

**Product Name: HABIFEN-600 TABLETS**

Module 1: Administrative Information & Prescribing Information.

### **3. PHARMACEUTICAL form**

Tablet

**Description:** Pink coloured, capsule shaped, film coated tablet having a break line on one side of each tablet.

### **4. Clinical particulars**

#### **4.1 Therapeutic indications**

Ibuprofen is a Nonsteroidal Anti-inflammatory Drug used in painful and inflammatory conditions. Ibuprofen is used in the management of mild to moderate pain and inflammation in conditions such as dysmenorrhea, migraine, postoperative pain, dental pain, musculoskeletal and joint disorders such as ankylosing spondylitis, osteoarthritis and rheumatoid arthritis including juvenile rheumatoid arthritis, peri-articular disorders such as bursitis and tenosynovitis, and soft tissue disorders such as sprains and strains.

#### **4.2 Posology and method of administration**

Posology: 1 Tablet 2 to 3 times a day or as directed by the physician.

**Method of administration:** Oral

#### **4.3 Contraindications**

HABIFEN – 600 is contraindicated in patients with known hypersensitivity to Ibuprofen. HABIFEN – 600 should not be given to patients who have experienced asthma, urticarial or allergic type reactions after taking aspirin or other NSAIDs. Severe rarely fatal, anaphylactic like reactions to NSAIDs have been reported in such patients. HABIFEN – 600 are contraindicated for the treatment of peri – operative pain in the setting of coronary artery bypass graft (CABG) surgery.

<b>Product Name: HABIFEN-600 TABLETS</b>
Module 1: Administrative Information & Prescribing Information.

#### **4.4 Special warnings and precautions for use.**

HABIFEN – 600 should be given with care to the elderly, to patients with asthma or bronchospasm, bleeding disorders, cardiovascular disease, a history of peptic ulceration, and in liver or renal failure.

Care is required in those who are also receiving coumarin anticoagulants.

Patients who are sensitive to aspirin or other NSAIDs should generally not be given Ibuprofen.

Ibuprofen should be discontinued in patients who experience blurred or diminished vision or changes in colour vision. Patients with collagen disease may be at increased risk of developing aseptic meningitis.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

HABIFEN – 600 may interact with aspirin, naproxen, celecoxib, diclofenac, indomethacin, meloxicam, and other heart or blood pressure medicine such as benazepril, enalapril, Lisinopril, quinapril, ramipril, lithium, diuretics (water pills) such as furosemide, methotrexate, steroids (prednisone and others) or a blood thinner such as warfarin

#### **4.6 Pregnancy and lactation**

Use in pregnancy and lactation is not recommended. Regular use of Non – steroidal Anti – inflammatory drugs during the third trimester of pregnancy, may result in premature closure of the foetal ductus arteriosus in uterus and possibly in persistent pulmonary hypertension of the newborn.

#### **4.7 Effects on ability to drive and use machines**

Not known.

#### **4.8 Undesirable effects**

Common adverse include nausea, dyspepsia, gastrointestinal ulceration / bleeding, raised liver enzymes, diarrhea, constipation, epistaxis, headache, dizziness, priapism, rash, salt and fluid retention and hypertension. A study from 210 has shown regular use of NSAIDs was associated with an increase in hearing loss. In frequent adverse effects include esophageal ulceration, heart failure, hyperkalaemia and renal impairment, confusion and bronchospasm. Ibuprofen can exacerbate asthma, sometimes fatally.

**Product Name: HABIFEN-600 TABLETS**

Module 1: Administrative Information & Prescribing Information.

#### **4.9 Overdose**

Most symptoms are an excess of the pharmacological action of ibuprofen and include abdominal pain, nausea, vomiting, drowsiness, dizziness, headache, tinnitus and nystagmus.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group:

Ibuprofen:

ATC code: M01AE51

Non Steroidal Anti-inflammatory products

#### **5.2 Pharmacokinetic properties**

Ibuprofen is rapidly absorbed from the gastrointestinal tract and peak – plasma concentrations occur about 1 – 2 hours after ingestion. It is rapidly metabolized and is excreted in the urine mainly as metabolites and their conjugates.

#### **5.3 Preclinical safety data**

Not Applicable.

**Product Name: HABIFEN-600 TABLETS**

Module 1: Administrative Information & Prescribing Information.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients:**

The excipients used in the formulation of HABIFEN-600 Tablets are mentioned as follows:

- ❖ Starch
- ❖ Talc
- ❖ Methyl Paraben
- ❖ Propyl Paraben
- ❖ Dicalcium Phosphate
- ❖ Magnesium Stearate
- ❖ Sodium Starch Glycolate
- ❖ Colloidal Silicon Dioxide
- ❖ Stearic Acid
- ❖ Ultracoat AQ Pink

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

36 Months from Date of Manufacturing.

### **6.4 Special precautions for storage**

Do not store above 30<sup>0</sup> C. Protect from Light.

### **6.5 Nature and contents of container <and special equipment for use, administration or implantation>**

An Alu Pvc blister of 10 tablets is packed in carton along with pack insert.

<b>Product Name: HABIFEN-600 TABLETS</b>
--

Module 1: Administrative Information & Prescribing Information.
---

#### **6.6 Special precautions for disposal <and other handling>**

Any unused medicinal products and waste materials should be disposed of in accordance with local requirements.

Product Name: **HABIFEN-600 TABLETS**

Module 1: Administrative Information & Prescribing Information.

**7. <APPLICANT/SUPPLIER>**

**Applicant:**

**Name** : Habmay Pharmacy Ltd.  
**Address** : P.O.Box No. AS81, Asawasi - Kumasi, Ghana.  
**Telephone Number** : 03220-38998.  
**E-mail** : habmay1010@yahoo.com  
**Web** : www.habmaypharmacy.com

**Supplier:**

**Name** : MERCURY HEALTHCARE PVT LTD  
**Address** : 12-B, Gr. Floor, Girichhaya, Loyalka Estate,  
Chowpatty Band Stand, Mumbai, 400 002.  
**Telephone Number** : ++91-22-66172224/5  
**E-mail** : info@mercuryhealthcare.net  
**Web** : www.mercuryhealthcare.net

**8. FDA APPLICATION NUMBER**

FDA/DRID/DER/FHR/17/0495

**9. DATE OF <REGISTRATION> / <RENEWAL OF REGISTRATION>**

**Date of Registration** : 04/05/2017.

**10. DATE OF REVISION OF THE TEXT**

24.07.2020.