**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

BETAFEN 100MG/5mL SYRUP

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5mL contains Ibuprofen 100mg

For Excipients see section 6.1

*Quantitative composition of special excipients* in Betafen Syrup (per 5mL)

Sodium Propyl Parabenzoate (Antimicrobial Preservative) …… 2.30mg

## 3. PHARMACEUTICAL FORM

Syrup

An orange syrupy liquid with a pleasant odour and taste of orange flavor

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Betafen Syrup is indicated for symptomatic relief of fever, pain and inflammation associated with colds and flu and other common childhood complaints. Also, mild to moderate pain including teething, dental pain, headache and minor muscular pains.

### 4.2 Posology and Method of Administration

***Posology***

| Dosage | | |
|---|---|---|
| Age (yr.) | No. of 5ml spoonful | Frequency per day |
| 0.5 upto1 | 1x1/2 | Up to 3 |
| 1 -2 | 1x1/2 | 3-4 |
| 3-7 | 1x1 | 3-4 |
| 8-12 | 1x2 | 3-4 |

It is important to shake the bottle for at least 10 seconds before use.

***Method of Administration***

For Oral Administration

### 4.3 Contraindications

- In common with other potent, non-steroidal anti-inflammatory agents, Ibuprofen should given to patients with active or severe peptic ulceration.
- Use of Ibuprofen during pregnancy should,
- if possible, be avoided. Ibuprofen should be prescribed with caution for those with asthma especially for patients who have developed bronchospasm with other non-steroidal agents.

### 4.4 Special Warnings and Special Precautions for Use

***Warnings***

- Do not exceed the stated dosage

***Precautions***

- Should be given with care to patients with impaired kidney or liver function
- Although Betafen Syrup is very effective in managing fever associated with malaria and other infections, it is not a cure and should be used in combination with suitable anti-infectives.

### 4.5 Interaction with Other FPPs and Other Forms of Interaction

- Should be given with care to patients with impaired kidney or liver function
- Although Betafen Syrup is very effective in managing fever associated with malaria and other infections, it is not a cure and should be used in combination with suitable anti-infectives.

### 4.6 Pregnancy and Lactation

***Use during Pregnancy***

Epidemiological studies in human pregnancy have shown no effects due to Ibuprofen used in the recommended dosage. However, Ibuprofen should be avoided in pregnancy unless considered essential by the physician.

***Use during Lactation***

Ibuprofen is safe in moderate doses during breastfeeding as only minimal quantities of the drug get into breast milk.

### 4.7 Effects on Ability to Drive and Use Machines

It does not have any known any effect on the ability to drive and use machines.

### 4.8 Undesirable Effects

- Adverse effects of Ibuprofen are rare but hypersensitivity including skin rash may occur.
- There have been reports of blood dyscrasias including thrombocytopenia, neutropenia, pancytopenia, leukopenia and agranulocytosis but these were not necessarily causality related to Ibuprofen.
- Very rare cases of serious skin reactions have been reported.

### 4.9 Overdose

Liver damage is possible in adults who have taken 10g or more of Ibuprofen. Ingestion of 5g or more of Ibuprofen may lead to liver damage if the patient has risk factors (see below).

***Risk Factors:***

If the patient:-

- Is on long term treatment with carbamazepine, phenobarbital, phenytoin, primidone, rifampicin,St John's Wort or other drugs than induce liver enzymes.
- Regularly consumes ethanol in excess of recommended amounts.
- Is likely to be glutathione depleted e.g. eating disorders, cystic fibrosis, HIV, starvation, cachexia.

***Symptoms and Signs***

Symptoms of Ibuprofen over dosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain.

Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur.

In severe poisoning, hepatic failure may progress to encephalopathy, hemorrhage, hypoglycemia, cerebral edema, and death.

Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, hematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

***Treatment***

Immediate treatment is essential in the management of Ibuprofen overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention.

Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma Ibuprofen concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetyl cysteine may be used up to 24 hours after ingestion of Ibuprofen; however, the maximum protective effect is obtained up to 8 hours postingestion.

The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetyl cysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with the NPIS or a liver unit.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic Properties

***Pharmacotherapeutic Group***: Antipyretic and Analgesic

***ATC code:***M01AE01

***Mechanism of Action***

Experimental data suggest that Ibuprofen may competitively inhibit the effect of low dose acetylsalicylic acid (aspirin) on platelet aggregation when they are dosed concomitantly. Some Pharmacodynamic studies show that when single doses of Ibuprofen 400 mg were taken within 8 h before or within 30 min after immediate release acetylsalicylic acid dosing (81 mg), a decreased effect of acetylsalicylic acid on the formation of thromboxane or platelet aggregation occurred.

Although there are uncertainties regarding extrapolation of these data to the clinical situation, the possibility that regular, long-term use of Ibuprofen may reduce the cardio protective effect of low dose acetylsalicylic acid cannot be excluded.

***Pharmacodynamic Effects***

Ibuprofen is a propionic acid derivative NSAID that has demonstrated its efficacy by inhibition of prostaglandin synthesis.

Ibuprofen is an inhibitor of the enzyme cyclo-oxygenase which results in the inhibition of the synthesis of prostaglandins that are associated with development of pain and the elevation of body temperature within the hypothalamus. The drug does not influence body temperature when it is elevated by such factors as

exercise or ambient temperature

### 5.2 Pharmacokinetic Properties

***Absorption***

Ibuprofen is rapidly absorbed following administration and is. Peak plasma concentrations occur about 1 to 2 hours after ingestion with food or in 45 minutes if taken on an empty stomach.

These times may vary with different dosage forms.

***Distribution***

Ibuprofen is rapidly distributed throughout the whole body.

In limited studies, Ibuprofen appears in the breast milk in very low concentrations.

***Metabolism***

Ibuprofen is metabolised to two inactive metabolites and these are rapidly excreted in urine.

***Elimination***

The excretion of Ibuprofen is rapid and complete via the kidneys.

The half-life of ibuprofen is about 2 hours.

Once Ibuprofen is metabolized to two inactive metabolites, about 1% is excreted in urine as unchanged Ibuprofen and about 14% as conjugated Ibuprofen.

### 5.3 Preclinical Safety Data

Preclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction.

Preclinical effects were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

Adverse reactions not observed in clinical studies and seen in animals at exposure levels similar to clinical exposure levels and with possible relevance to clinical use:-

- Mutagenicity - No data is available on the mutagenic potential of Ibuprofen
- Carcinogenicity - No data is available on the carcinogenic potential of Ibuprofen.
- Developmental Toxicity - No data is available on the developmental toxic potential of Ibuprofen

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of Excipients

- Avicel RC 591
- Keltrol Gum
- Citric Acid
- Sunset Yellow Colour
- Orange Flavour Liquid
- Glycerine
- Sodium Propyl Parabenzoate
- Sodium Benzoate
- Tween 80
- Rectified Spirit

- Sugar Syrup
- Purified Water

**6.2 Incompatibilities**

None known

In the absence of compatibility studies, this pharmaceutical product must not be mixed with other pharmaceutical products.

**6.3 Shelf life**

36 Months

**6.4 Special Precautions for Storage**

Store in a cool dry place below $30^0$C away from direct light

Keep all medicine out of reach of children

**6.5 Nature and Contents of Container**

***Nature of Container***

Amber coloured glass bottles

***Pack Size***

60ml and 100ml

**6.6 Special Precautions for Disposal and Other Handling**

No special requirement

## 7 MARKETING AUTHORISATION HOLDER

Name: **Beta Healthcare International Limited**

Address: **Plot No. LR 209/6554 Mogadishu Road, Industrial Area, Nairobi, Kenya**

**P.O. Box 42569-00100, Nairobi, Kenya**

Tel: **+254 20 2652042/89**

E-mail: **info@ke.betashelys.com**

## 8 NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

05230/07350/NMR/2019

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 6-August-2020

## 10 DATE OF REVISION OF THE TEXT

July 2023