

# **SUMMARY OF PRODUCT CHARACTERISTICS**

## **(SmPC)**

## 1. NAME OF THE MEDICINAL PRODUCT

Detonic Syrup

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains

Ferrous Gluconate (equivalent to elemental Iron 14mg)	120.00mg
Vitamin B <sub>1</sub> (Thiamine HCl)	2.00 mg
Vitamin B <sub>2</sub> (Riboflavin-5-Phosphate)	1.00 mg
Vitamin B <sub>6</sub> (Pyridoxine HCl)	2.00 mg
Vitamin B <sub>12</sub> (Cyanocobalamin)	5.00 mcg
Folic acid	0.30 mg

## 3. PHARMACEUTICAL FORM

A dark brown syrup with a pleasant sweet taste

## 4. Clinical particulars

### 4.1 Therapeutic indications

- Iron deficiency anaemia due to blood loss.
- Increased iron demand
  - *Pregnancy*
  - *In growing children*
  - *After surgical operation*
  - *Child birth*
  - *Accidents*
  - *Post operative period*
- Nutritional supplement for elderly and in malnutrition.
- For rapid recuperation during convalescence.

### 4.2 Posology and method of administration

Adult and Children above 12 years: (10ml) twice daily

Children 6-12 years: (5ml) twice daily

Children below 6 years: Only on recommendation of a physician.

### 4.3 Contraindications

Iron preparations should not be given to patients receiving repeated blood transfusions or to patients with anaemia not produced by Iron deficiency. Iron decreases the absorption of other drugs like Levodopa, Methylidopa, Penicillamine, Tetracycline etc and such should be administered concurrently.

Preparations containing Thiamine Hydrochloride are usually incompatible with phenobarbitone sodium. If given together results in deterioration of thiamine. Folic acid should be given with care in patients who may have folate-dependent tumours.

### 4.4 Special warnings and precautions for use

No special warnings

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

The pyridoxine hydrochloride may reduce the effectiveness of levodopa

### 4.6 Pregnancy and Lactation

Considered safe in the recommended dose

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

None stated

### 4.8 Undesirable effects

None known

### 4.9 Overdose

Detonic syrup contains levels of vitamins which present little risk in overdose.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamics properties

Vitamin B Complex.

***Thiamine Hydrochloride (Vit B1):*** A water soluble vitamin. It is a co-enzyme for carbohydrate metabolism.

***Riboflavine Sodium Phosphate (Vit B2):*** A water soluble vitamin converted in the body to flavine mononucleotide and flavine adenine dinucleotide and then involved as co-enzymes in oxidative and reductive metabolic processes.

***Pyridoxine Hydrochloride (Vit B6):*** A water soluble vitamin. Involved in carbohydrate and fat metabolism, but also important in haemoglobin formation.

#### **Folic Acid**

Folic acid is absorbed mainly from the proximal part of the small intestine. Folate polyglutamates are considered to be deconjugated to monoglutamates during absorption.

Folic acid rapidly appears in the blood where it is extensively bound to plasma proteins. Some folic acid is distributed in body tissues, some is excreted as folate in the urine, and some is stored in the liver as folate.

## 5.2 Pharmacokinetic properties

### Absorption

the acid conditions of the gastric contents, ferrous gluconate is dissociated and ferrous ions are liberated. These ions are absorbed in the proximal portion of the duodenum.

The ferrous iron absorbed by the mucosal cells of the duodenum is oxidised to the ferric form, and this is bound to protein to form Ferritin.

### Distribution

Ferritin in the mucosal cells releases iron into the blood, where it is bound to transferrin and passed into the iron stores - liver, spleen, and bone marrow.

These stores are a reserve of iron for synthesis of haemoglobin, myoglobin, and iron containing enzymes.

### Elimination

Iron is lost from the body through loss of cells in urine, faeces, hair, skin, sputum, nails, and mucosal cells, and through blood loss.

Ferrous gluconate has the same pattern of absorption and excretion as dietary iron.

## 5.3 Preclinical safety data

None stated

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sodium Bicarbonate, Sodium citrate, Methyl paraben, Propyl paraben, Alcohol, sugar, Sorbitol solution, citric acid, Caramel colour, Bronopol, Xanthan gum, Vanilla essence, Allura red colour, Tutti frutti flavor, Sodium saccharin.

### 6.2 Incompatibilities

None known

### 6.3 Shelf life

36 months

### 6.4 Special precautions for storage

Store below 30°C

### 6.5 Nature and contents of container

200ml Amber Glass bottle and 1000ml amber plastic bottle with cap and measuring device

### 6.6 Special precautions for disposal

No special requirements

## **7. APPLICANT/MANUFACTURER**

Afrab-Chem Limited,  
22, Abimbola Street,  
Isolo Ind. Estate,  
Isolo, Lagos.  
Nigeria.