

# **SUMMARY OF PRODUCT CHARACTERISTICS**

## **(SmPC) of Amobicon (Ivermectin 3mg) Tablets**

### **1. NAME OF THE MEDICINAL PRODUCT**

AMOBICON®- TABLETS (Ivermectin 3mg)

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each tablets contains 3mg Ivermectin respectively.

For a full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Solid (Tablet)

### **4. Clinical particulars**

#### **4.1 Therapeutic indications**

Ivermectin is indicated in the treatment of gastrointestinal strongyloidiasis (anguillulosis), of suspected or diagnosed microfilaraemia in patients with lymphatic filariasis due to *Wuchereria bancrofti* and treatment of human sarcoptic scabies. Treatment is justified when the diagnosis of scabies has been established clinically and/or by parasitological examination. Without formal diagnosis treatment is not justified in case of pruritus.

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

Posology

#### **Treatment of gastrointestinal strongyloidiasis**

The recommended dosage is one single oral dose of 200 micrograms of ivermectin per kg body weight. For guidance, the dose, as determined by the patient's weight, is as follows:

<b>BODY WEIGHT (k g)</b>	<b>DOSE (number of 3 mg tablets)</b>
15 to 24	One

25 to 35	Two
36 to 50	Three
51 to 65	Four
66 to 79	Five
≥ 80	Six

**Treatment of microfilaraemia caused by Wuchereriabancrofti:**

The recommended dosage for mass distribution for the treatment of microfilaraemia caused by Wuchereriabancrofti is a single oral dose once every 6 months designed to provide approximately 150 to 200 µg/kg of body weight.

In endemic areas where treatment can only be administered once every 12 months, the recommended dosage is 300 to 400 µg/kg of body weight to maintain adequate suppression of microfilaraemia in treated patients.

For guidance, the dose, as determined by the patient's weight, is as follows:

<b>Body weight (kg)</b>	<b>Dose when given once every 6months (number of 3mg tablets)</b>	<b>Dose when given once every 12months (number of 3mg tablets)</b>
15 to 25	One	Two
26 to 44	Two	Four
45 to 64	Three	Six
65 to 84	Four	Eight

Alternatively and if no scales are available, the dose of ivermectin for use in mass chemotherapy campaigns may be determined by the patient's height as follows:

<b>Height (cm)</b>	<b>Dose when given once every 6months (number of 3mg tablets)</b>	<b>Dose when given once every 12months (number of 3mg tablets)</b>
90 to 119	One	two
120 to 140	Two	Four
141 to 158	Three	Six
>158	Four	Eight

## **Treatment of human sarcoptic scabies**

The recommended dosage is a single oral dose to provide ivermectin 200 µg/kg body weight.  
Common scabies:

Recovery will be considered as definite only after 4 weeks of the treatment. Persistence of pruritus or scraping lesions does not justify a second treatment before this date.

Administration of a second dose within 2 weeks after the initial dose should only be considered:  
a) when new specific lesions occur, b) when the parasitologic examination is positive at this date.  
Profuse and crusting scabies:

In these heavily infected forms, a second dose within 8 to 15 days of ivermectin and/or concomitant topical therapy may be necessary to obtain recovery.

Note for patients treated for scabies

Contact persons, especially family members and partners, should undergo a medical examination as soon as possible, and if necessary should be given prompt antiscabies treatment

Hygienic measures to prevent reinfection should be taken into account (i. e. keeping fingernails short and clean) and official recommendations regarding the cleaning of clothing and bedding should be closely followed.

### **Method of administration**

Oral route

### **4.3 Contraindications**

Hypersensitivity to the active substance, or to any of the excipients.

### **Interactions**

No interaction studies have been performed

In vitro studies have shown that ivermectin is primarily metabolized by CYP3A4. Consequently, caution is advised when ivermectin is administered concomitantly with potent CYP3A4 inhibitors as the plasma exposure may be significantly increased.

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

Talk to your doctor or pharmacist before using Ivermectin. At the start of treatment, some patients may experience worsening of the symptoms of rosacea, however this is uncommon and usually resolves within 1 week of the treatment. Talk to your doctor if this happens.

**Keep out of reach of children.**

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

No interaction studies have been performed

In vitro studies have shown that ivermectin is primarily metabolized by CYP3A4. Consequently, caution is advised when ivermectin is administered concomitantly with potent CYP3A4 inhibitors as the plasma exposure may be significantly increased.

#### **4.6 Pregnancy and Lactation**

Ivermectin is not recommended during pregnancy. If you are breast-feeding, you should not use this medicine, alternatively, you should stop breast-feeding before starting treatment with Ivermectin. You should consult your doctor to help you decide between using Ivermectin and breast-feeding, taking into account the benefit of the treatment and the benefit of breastfeeding.

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

Ivermectin does not affect the ability to drive and use machines.

#### **4.8 Undesirable effects**

Ivermectin may cause the following side effects: Common side effect like burning feeling of the skin. Uncommon side effects Irritation of the skin, Itching of the skin, Dry skin and Rosacea aggravation (please consult your doctor)

#### **4.9 Overdose**

In accidental or significant exposure to unknown quantities ivermectin, by ingestion, the following adverse effects have been reported most frequently: rash, oedema, headache, dizziness, asthenia, nausea, vomiting, and diarrhoea. Other adverse effects that have been reported include: seizure, ataxia, dyspnea, abdominal pain, paresthesia, urticaria, and contact dermatitis.

#### Treatment of Overdose

In case of accidental ingestion, supportive therapy, if indicated, should include parenteral fluids and electrolytes, respiratory support (oxygen and mechanical ventilation if necessary) and pressor agents if clinically significant hypotension is present. Induction of emesis and/or gastric lavage as soon as possible, followed by purgatives and other routine anti-poison measures, may be indicated if needed to prevent absorption of ingested material.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamics properties**

Pharmacotherapeutic group: Anthelmintics, ATC code: P02CF01.

Ivermectin and its related drugs act by interfering with the nerve and muscle functions of helminths and insects. The drug binds to glutamate-gated chloride channels common to invertebrate nerve and muscle cells. The binding pushes the channels open, which increases the flow of chloride ions and hyper-polarizes the cell membranes, paralyzing and killing the invertebrate. Ivermectin is safe for mammals (at the normal therapeutic doses used to cure

parasite infections) because mammalian glutamate-gated chloride channels only occur in the brain and spinal cord: the causative avermectins usually do not cross the blood–brain barrier and are unlikely to bind to other mammalian ligand-gated channels.

## **Pharmacodynamics**

Ivermectin interacts with other ligand-gated chloride channels such as the one involving the GABA neurotransmitter (gamma-aminobutyric acid). Mammals do not have glutamate-gated chloride channels. Avermectins have only low affinity for other ligand-gated chloride channels.

### **5.2 Pharmacokinetic properties Absorption**

Well absorbed, Peak serum time: 4 hr

Peak effect: 3-6 months (treatment of orchocerciasis); 3 months (treatment of strongyloides)

### **Distribution**

Protein bound: 93%, Vd: 3-3.5 L/kg. Does not cross blood-brain barrier

### **Metabolism**

Ivermectin is metabolized in the liver Hepatic (CYP3A4, CYP2D6, CYP2E1)

### **Excretion**

Ivermectin and/or its metabolites are excreted almost exclusively in the feces over an estimated 12 days, with less than 1% of the administered dose excreted in the urine. The plasma half-life of ivermectin in man is approximately 18 hours following oral administration.

### **5.3 Preclinical safety data**

Not applicable

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Microcrystalline Cellulose  
Pregelatinised Cellulose  
Citric Acid Anhydrous  
Butylated Hydroxy Anisole

Magnesium Stearate Erythrocin  
Red

### **6.2 Incompatibilities**

None have been reported or are known

### **6.3 Shelflife**

36 Months

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

Store below 30°C in tight container protected from light and moisture. Store in the original Blister packaging to prevent from moisture.

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

Amobicon® Tablet is available as Ivermectin 3mg 10 x 10 tablets.

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

No special requirements.

## **7. APPLICANT/MANUFACTURER**

Drugfield Pharmaceuticals Limited  
Lynson Chemical Avenue Km38,  
Lagos-Abeokuta Expressway  
Sango-Otta, Ogun State, Nigeria  
Tel: +2348033513989  
Email:Info@drugfieldpharma.com