DGH Drugfield **PHARMACEUTICALS LIMITED**

# SUMMARY OF PRODUCT CHARACTERISTICS

# Amobicon (Ivermectin 12mg) Tablets

## 1. NAME OF THE MEDICINALPRODUCT

Amobicon® Tablets (Ivermectin12mg)

## 2. QUALITATIVE AND QUANTITATIVECOMPOSITION

Each tablets contains 12mg 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 Wuchereriabancrofti 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:

| BODY WEIGHT (k g) | DOSE (number of 3 mg tablets) |
|---|---|
| 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:

| Body weight (kg) | Dose when given once every 6months (number of 3mg tablets) | Dose when given once every 12months (number of 3mg tablets) |
|---|---|---|
| 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:

| **Height (cm)** | **Dose when given once every 6months (number of 3mg tablets)** | **Dose when given once every 12months (number of 3mg tablets)** |
|---|---|---|
| 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

## 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 foruse

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 breast-feeding.

## 4.7 Effects on ability to drive and usemachines

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. PHARMACOLOGICALPROPERTIES

## 5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Anthelmintics, ATC code: P02CF01.

Ivermectin is derived from avermectins isolated from fermentation broths of Streptomyces avermitilis. It has high affinity with glutamate-gated chloride channels present in invertebrate nerve and muscle cells. Its binding to these channels promotes an increase in membrane permeability to chloride ions, leading to hyperpolarization of the neural or muscle cell. This results in neuromuscular paralysis and may lead to the death of certain parasites.

**Pharmacodynamics**

Ivermectin interacts with other ligand-gated chloride channels such as the one involving the GABAneurotransmitter (gamma-aminobutyric acid). Mammals do not have glutamate-gated chloride channels. Avermectins have only low affinity for other ligand-gated chloride channels. They do not readily cross the blood/brain barrier.

### 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**
Hepatic (CYP3A4, CYP2D6, CYP2E1)

**Excretion**
Half-life: 18 hr
Excretion: Feces; urine (<1%)

### 5.3 Preclinical safety data

Not applicable

## 6. PHARMACEUTICALPARTICULARS

### 6.1 List of excipients

Microcrystalline Cellulose
Pregelatinised Cellulose
Citric Acid Anhydrous
ButylatedHydroxy Anisole
Magnesium Stearate

### 6.2 Incompatibilities

None have been reported or are known

### 6.3 Shelf life

36 Months

### 6.4 Special precautions for storage

Store below 30°C in tight container protected from light and moisture.

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

Ivermectin® Tablet is available as 12mg of 10 x 10 tablets.

### 6.6 Special precautions for disposal and other handling

No special requirements.

## 7. APPLICANT/MANUFACTURER

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