

**IRISH MEDICINES BOARD ACTS 1995 AND 2006**

**MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007**

**(S.I. No.540 of 2007)**

**PA0616/002/001**

Case No: 2000544

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

**Hofels Pure Foods Limited**

**Hedon Road, Marfleet, Hull HU9 5NJ, England**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

**Hofels Garlic and Parsley 0.15mg Coated tablets**

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **22/03/2009**.

Signed on behalf of the Irish Medicines Board this

\_\_\_\_\_

A person authorised in that behalf by the said Board.

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Hofels Garlic and Parsley 0.15mg coated tablets.

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Garlic Oil 0.15 mg.  
For a full list of excipients, see section 6.1.

#### 3 PHARMACEUTICAL FORM

Coated tablet  
Round, white, sugar-coated, biconvex tablets.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

In the symptomatic treatment of the common cold and influenza.

##### 4.2 Posology and method of administration

Adults and Elderly:	3 tablets daily, 1 before each meal or 3 before retiring
Children 7 - 12 years:	2 tablets daily, 1 before a meal or 2 before retiring
	Not recommended for children under 7 years

##### 4.3 Contraindications

There are no contraindications for this product.

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

If symptoms persist consult the doctor.

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

None known.

##### 4.6 Pregnancy and lactation

No precautions noted.

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

None.

#### **4.8 Undesirable effects**

Rarely stomach/intestinal pains.

#### **4.9 Overdose**

Not applicable.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Garlic possesses expectorant, diaphoretic, disinfectant and diuretic properties

#### **5.2 Pharmacokinetic properties**

None stated

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

There are no preclinical safety data of relevance which are additional to those already included in other sections of the SPC

### **6 PHARMACEUTICAL PARTICULARS**

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

Apiol  
Calcium phosphate  
Lactose (Monohydrate)  
Pregelatinised Maize Starch  
Dextrin  
Maize Starch  
Magnesium Stearate

Sugar-coating  
Pharmaceutical glaze  
Kaolin (heavy)  
Sucrose  
Calcium Carbonate  
Talc  
Acacia  
Gelatin  
Titanium Dioxide (E171)

#### **6.2 Incompatibilities**

Not applicable

#### **6.3 Shelf Life**

2 years.

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

Store below 25°C.

#### **6.5 Nature and contents of container**

Blister packs consisting of PVC coated with PVDC heat sealed onto aluminium foil and packed into cardboard cartons.  
Pack sizes: 30, 45, 60 and 180 tablets.

Not all pack sizes may be marketed.

#### **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

### **7 MARKETING AUTHORISATION HOLDER**

Hofels Pure Foods Limited  
Hedon Road  
Marfleet  
Hull  
HU9 5NJ  
United Kingdom

### **8 MARKETING AUTHORISATION NUMBER**

PA 616/2/1

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

Date of 1st authorization: 22<sup>nd</sup> March 1994

Date of next renewal: 22<sup>nd</sup> March 2009

### **10 DATE OF REVISION OF THE TEXT**

February 2010