

IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0616/001/002

Case No: 2042327

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 One-A-Day Garlic Pearles 2mg soft capsules

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 **15/03/2010**.

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 One-A-Day Garlic Pearles 2mg soft capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains Garlic oil 2.0 mg.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, soft

Size 5 oval, colourless, soft gelatin capsule containing a transparent pale yellow liquid, printed with Hofels in white ink.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the symptomatic treatment of the common cold and influenza

4.2 Posology and method of administration

Recommended Dosage

Adults:	1 capsule daily
Elderly:	1 capsule daily
Children 7 and over	1 capsule daily

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, discomfort and allergic reactions.

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

Soya Bean Oil, refined

Capsule shell

Gelatin

Glycerol (E422)

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 packed into cardboard cartons.
Pack sizes of 30, 45, 60 or 180 capsules.

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 616/1/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of 1st Authorization: 22nd March 1994

Date of next renewal 22nd March 2009.

10 DATE OF REVISION OF THE TEXT

February 2010