

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Golden Ear Drops  
Nowax Ear Drops  
Superdrug Ear Wax Remover Drops  
Wilko Ear Wax Removal Drops

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

Eucalyptol	7.50	v/v	BPC
Nutmeg Oil	0.40	v/v	BP
Terpineol	2.00	v/v	BP
Arachis Oil	90.10	v/v	BP

For excipients see 6.1

### **3 PHARMACEUTICAL FORM**

Ear drops, solution

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

For the loosening and removal of ear wax, and relief of any pain associated with the wax.

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

For aural use. Instil a few drops in the ear.

Warm the bottle to body temperature. With the head inclined to one side instil a few drops and insert a cotton wool plug.

Repeat at night and morning for a few days until wax is cleared.

If symptoms persist consult your doctor.

#### **4.3 Contraindications**

Hypersensitivity to any of the active ingredients.

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

For external use only.

Do not use if the ear is inflamed or infected.

If symptoms persist consult your doctor.

Keep out of the sight and reach of children.

This product contains arachis oil (peanut oil) and should not be taken/applied by patients known to be allergic to peanut. As there is a possible relationship between allergy to peanut and allergy to soya, patients with soya allergy should also avoid this product.

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

None

#### **4.6 Pregnancy and lactation**

Contains ingredients of adequate safety and therefore there are no limitations on its use during pregnancy and lactation.

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

None

#### **4.8 Undesirable effects**

None

##### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) by reporting side effects you can help provide more information on the safety of this medicine.

#### **4.9 Overdose**

None

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Eucalyptol:

Application to an intact skin results in an irritant and rubefacient action causing at first a sensation of warmth and smarting followed by mild local anesthesia. It also has mild anti-microbial action.

Nutmeg Oil:

Nutmeg oil is mildly rubefacient and appears to inhibit prostaglandin synthesis.

Terpineol:

It has disinfectant and solvent properties.

Arachis Oil:

Emollient and soothing to inflamed surfaces and softens wax.

## **5.2 Pharmacokinetic properties**

The active ingredients employed in the preparation have a local action in the outer ear, namely loosening and removal of the ear wax and relief of associated pain. Pharmacokinetic particulars of the actives are thus not applicable.

## **5.3 Preclinical safety data**

None

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

None

## **6.2 Incompatibilities**

None

## **6.3 Shelf life**

36 Months unopened.

## **6.4 Special precautions for storage**

Protect from heat. Do not store above 25°C.

**6.5 Nature and contents of container**

Amber glass bottle, 10ml, with a screw on plastic cap with a glass dropper.

**6.6 Special precautions for disposal**

None

**7 MARKETING AUTHORISATION HOLDER**

Bell, Sons & Co (Druggists) Ltd

Gifford House

Slaidburn Crescent

Southport

Merseyside

PR9 9AL

United Kingdom

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 03105/0074

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

11/09/1984 / 29/10/2001

**10 DATE OF REVISION OF THE TEXT**

24/03/2015