# WAXSOL®

**SCHEDULING STATUS:** S0

**PROPRIETARY NAME AND DOSAGE FORM:**
**WAXSOL® Ear Drops**

**COMPOSITION:**
Each 10 ml contains:
Docusate Sodium 0,05 g
Esters of p-hydroxybenzoic acid 0,6 % m/v as preservative

**Excipients:** Glycerol and purified water.

**PHARMACOLOGICAL CLASSIFICATION:** A 16.2 Ear, nose and throat preparations. Aural preparations.

**PHARMACOLOGICAL ACTION:** Docusate, because of its low surface tension and water miscibility, rapidly penetrates the dry matrix of the ceruminous mass, reducing the solid material to a semi-solid debris which may be readily irrigated or ejected by normal physiological processes.

**INDICATIONS:** For removal of ear wax.

**CONTRAINDICATIONS:** The preparation must not be used in the presence of infection or tympanic perforation.

**WARNINGS AND SPECIAL PRECAUTIONS:** Skin sensitivity may occur. Such reactions usually resolve on withdrawal of treatment

**INTERACTIONS:** None known.

**PREGNANCY AND LACTATION**
**WAXSOL®** should not be used in pregnancy and lactation.

**DOSAGE AND DIRECTIONS FOR USE:** For aural use only. Tilt the head and fill the ear canal (usually 10 drops) with **WAXSOL®** on two consecutive nights. Plug the ear with cottonwool, leaving in the ear overnight. After two nights, if the wax is still blocking the ear, consult your doctor or nurse to have your ear syringed.
If the problem persists patients should consult their doctor.

**SIDE EFFECTS:**

| System Organ Class | Frequency | Adverse Reaction |
|---|---|---|
| Immune system disorders | Not known | Hypersensitivity/allergic reactions |
| Skin and subcutaneous tissue disorders | Not known | Allergic skin reactions and contact dermatitis |
| General disorders and administration site conditions | Less frequent | Application site reactions including transient stinging or irritation |
| | Not known | Injuries or inflammation in the auditory canal may result in painful symptoms |

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:** Skin sensitivity may result from accidental overdosage. Excess **WAXSOL®** may seep from the ear and treatment or any resulting adverse events, such as skin irritation should be symptomatic.

**IDENTIFICATION:** A clear liquid.

**PRESENTATION:** Amber dropper bottles of 10 ml.

**STORAGE INSTRUCTIONS:** Store at or below 25°C.
**KEEP OUT OF REACH OF CHILDREN**

**REGISTRATION NUMBER:** V/16.2/289

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**
**Mylan (Pty) Ltd**
4 Brewery Street, Isando, Johannesburg, South Africa, 1600

**DATE OF PUBLICATION OF THIS PACKAGE INSERT:** 22 November 2012

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# WAXSOL®

**SKEDULERINGSTATUS:** S0
**EIENDOMSNAAM EN DOSEERVORM: WAXSOL® Oordruppels**

**SAMESTELLING:**

Elke 10 ml bevat:
Natriumdokusaat 0,05 g
Esters van p-hidroksibensoësuur 0,6 % m/v as preserveermiddel

**Eksipiënte:** Gliserol en gesuiwerde water.

**FARMAKOLOGIESE KLASSIFIKASIE:** A16.2 Oor-, neus- en keelpreparate. Gehoorpreparate.

**FARMAKOLOGIESE WERKING:** Dokusaat deurdring die droë matriks van die serumenmassa vinnig a.g.v. sy lae oppervlakspanning en wateroplosbaarheid en reduseer die vaste stof na 'n semi-vaste oorblyfsel wat maklik deur normale fisiologiese prosesse bevogtig of uitgeskei kan word.

**INDIKASIES:** Vir die verwydering van oorwas.

**KONTRA-INDIKASIES:** Hierdie preparaat moet nie in die teenwoordigheid van infeksie of timpaniese perforasie gebruik word nie.

**WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:** Velsensitiwiteit mag voorkom.

Sulke reaksies klaar gewoonlik op met die onttrekking van die behandeling.

**INTERAKSIES:** Geen bekend.

**SWANGERSKAP EN BORSVOEDING: WAXSOL®** behoort nie in swangeskap en borsvoeding gebruik te word nie

**DOSIS EN GEBRUIKSAANWYSINGS:** Vir gebruik in die oor alleenlik. Kantel die kop en vul die gehoorkanaal met **WAXSOL®** (gewoonlik 10 druppels) vir twee opeenvolgende aande. Plaas watte in die oor en laat dit daarin vir die duur van die nag. Indien die oorwas na die twee nagte nog steeds die oor blokkeer, raadpleeg u dokter of verpleegster om u oor te laat uitspuit. Indien die probleem voortduur behoort die pasiënt sy dokter te raadpleeg.

**NEWE-EFFEKTE:**

| Sistemiese Orgaan Klas | Frekwensie | Ongunstige Reaksie |
|---|---|---|
| Immuunsisteem aandoeninge | Nie bekend | Hipersensitiwiteit/allergiese reaksies |
| Vel en subkutane weefsel aandoeninge | Nie bekend | Allergiese velreaksies en kontakdermatitis |
| Algemene aandoeninge en toestande by die aanwendingsplek | Minder gereeld | Reaksies by die aanwendingsplek insluitend verbygaande brand en irritasie |
| | Nie bekend | Beserings of inflammasie in die gehoorkanaal mag lei tot pynlike simptome |

**BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:** Velsensitiwiteit mag volg na toevallige oordosering. Oormatige **WAXSOL®** mag uit die oor syfer en die behandeling van enige gevolglike ongunstige reaksies soos velirritasie, behoort simptomaties te wees.

**IDENTIFIKASIE:** 'n Helder vloeistof.

**AANBIEDING:** Amberkleurige drupbottels van 10 ml.

**BERGINGSAANWYSINGS:** Bewaar teen of benede 25°C.

**HOU BUITE DIE BEREIK VAN KINDERS**

**REGISTRASIENOMMER:** V/16.2/289

**NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:**
**Mylan (Edms) Bpk.**
4 Brewery Straat, Isando, Johannesburg, Suid Afrika, 1600

**DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:** 22 November 2012

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