SCHEDULING STATUS: **S2**

PROPRIETARY NAME: **ADCO-OTISED EAR DROPS**

(AND DOSAGE FORM) **(EAR DROPS)**

COMPOSITION:

Each 1 ml contains:

Phenazone	0,05 g
Benzocaine	0,01 g
Glycerine	1,185 g
Preservative:	
Chlorbutol	1 % m/v

PHARMACOLOGICAL CLASSIFICATION:

A 16.2 Aural preparations, ear drops

PHARMACOLOGICAL ACTION:

ADCO-OTISED EAR DROPS has analgesic, local anaesthetic and demulcent properties.

INDICATIONS:

Ear infections with intact eardrum.

CONTRAINDICATIONS:

Perforation of the eardrum.

Known hypersensitivity to any of the ingredients.

DOSAGE AND DIRECTIONS FOR USE:

3 to 4 Drops in ear every 4 hours.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Allergic reactions.

Methaemoglobinaemia has been reported in infants following the topical application of benzocaine and it should not be used in infants. Benzocaine may be slowly absorbed through mucous membranes and damaged skin and should, therefore, be used with caution in patients with low plasmacholinesterase concentrations or in those receiving anticholinesterases.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Allergic reactions.

Treatment: Withdrawal of the medicine.

Further treatment is symptomatic and supportive.

IDENTIFICATION:

Clear, colourless to pale yellow, viscous liquid.

PRESENTATION:

Applicator bottle containing 15 ml.

STORAGE INSTRUCTIONS:

Store in airtight containers below 30 °C and protect from light.

KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER:

H 1418 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Private Bag X69

Bryanston, 2021

www.adcock.com

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

17 February 1975

SKEDULERINGSTATUS: **S2**

EIENDOMSNAAM: **ADCO-OTISED EAR DROPS**

(EN DOSEERVORM): **(OORDRUPPELS)**

SAMESTELLING:

Elke 1 ml bevat:

Fenasoon	0,05 g
Bensokaïen	0,01 g
Gliserien	1,185 g
Preserveermiddel:	
Chloorbutol	1 % m/v

FARMAKOLOGIESE KLASSIFIKASIE:

A 16.2 Oorpreparate, oordruppels

FARMAKOLOGIESE WERKING:

ADCO-OTISED EAR DROPS het pynstillende, oppervlakverdowende en versagtende werkinge.

INDIKASIES:

Oorinfeksies met 'n onbeskadigde oordrom.

KONTRA-INDIKASIES:

Geperforeerde oordrom. Bekende hipersensitiwiteit teenoor enige van die bestanddele.

DOSIS EN GEBRUIKSAANWYSINGS:

3 tot 4 Druppels in oor elke 4 uur.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Allergiese reaksies.

Methemoglobinemie is aangemeld by kleuters na die plaaslike aanwending van bensokaïen en dit moet nie by kleuters gebruik word nie. Bensokaïen kan stadig geabsorbeer word deur slymvliese en beskadigde vel en moet versigtig gebruik word by pasiënte met lae plasmacholienesterase-konsentrasies of by diè wat anticholienesterase ontvang.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN BEHANDELING DAARVAN:

Allergiese reaksies.

Behandeling: Onttrekking van die medisyne.

Verdere behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

Helder, kleurlose tot liggeel, klewerige vloeistof.

AANBIEDING:

Toedieningsbottel met 15 ml.

BERGINGSAANWYSINGS:

Bêre in lugdigte houers onder 30 °C en beskerm teen lig.

HOU BUITE BEREIK VAN KINDERS.

VERWYSINGSNOMMER:

H 1418 (Wet 101/1965)

NAAM EN BESIGHEIDSADRES VAN DIE APPLIKANT :

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Privaatsak X69

Bryanston, 2021

www.adcock.com

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:

17 Februarie 1975

Facsimile of Label:

S2

COVANCAINE EAR DROPS

COMPOSITION:		**SAMESTELLING:**
Contains per ml :		Bevat per ml:
Phenazone	0,05 g	Fenasoon
Benzocaine	0,01 g	Bensokaïen
Glycerine	1,185 g	Gliserien
Preservative:		Preserveermiddel:
Chlorbutol	1 % m/v	Chloorbutol

Store in airtight containers below 30 °C and protect from light.

KEEP OUT OF REACH OF CHILDREN.

Bêre in lugdigte houers onder 30 °C en beskerm teen lig.

HOU BUITE BEREIK VAN KINDERS.

DOSAGE AND DIRECTIONS FOR USE:

3 to 4 drops in each ear every 4 hours.

DOSIS EN GEBRUIKSAANWYSINGS:

3 tot 4 druppels in oor elke 4 uur.

Applicant:

Adcock Ingram Limited

www.adcock.co.za

Ref. No.: H 1474 (Act 101/1965)

Batch No:

Expiry Date: