

	Title: Multi-center, open-label, non-randomized, single-arm clinical study to assess the safety and performance of Earol® in adult patients with ear wax	
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Safety & performance sub- categories	Precis results	Clinically demonstrated safety/performance benefit	Clinically demonstrated product benefit
Safety	0% of patients reported any SAE (Serious Adverse Event)	The device is safe to use at home and during the de-waxing procedure	There is significant clinical benefit and very low clinical risk to both the patient and the clinician during the Earol® dosing process and during and after the clinical de-waxing procedure. Earol® is a simple to use, safe and effective medical device which is fit for purpose for use (for its intended purpose) in both the home and clinical settings.
	0.93% (one subject) of patients presented a 'possible' device-related AE (Adverse Event) that being clogging of one ear. The patient continued in the study		
	0% of patients reported any pain during the study		
Ease of dosing and wax removal	94.33% of clinicians stated that 'the following of instructions' was an easy/very easy process'	Design of the device and instructions for use are fit for purpose and easy to follow	The technique of massaging the tragus and movement of the jaw after dosing with Earol® oil significantly facilitates the coating of the contents of the ear canal and ensures that there is limited leakage of the oil from the auditory canal.
	92.45% of clinicians stated that the dewaxing procedure (after product application) was considered 'easy' (19.81%) or a 'very easy' (72.64%) and 89.6 % stated that it had 'aided the de-waxing procedure' either 'quite a lot' (17.9%) or 'very much' (71.7%) when compared to a normal procedure where Earol® wasn't used	Earol® is highly effectively at preparing the ear canals (skin & wax) for the de-waxing procedure and significantly enhances the ease of removal of the wax when compared to not using Earol®	
Effect of Earol® (oil, dosing and massaging) on the wax deposits	83.02% of clinicians stated that the oil had coated the wax deposits and the auditory canal skin either 'quite a lot' (20.76%) or 'very much' (62.26%)	The oil and the massaging process (tragus and jaw manipulation) have allowed the oil to significantly soften, loosen and break-up the ear wax deposits and coat the auditory canal and wax deposits.	
	86.79% of clinicians stated that the oil had softened the wax deposits either 'quite a lot' (16.98%) or 'very much' (69.81%)		
	83.02% of clinicians stated that the oil had broken-up the wax deposits either 'quite a lot' (16.98%) or 'very much' (66.04%)		
	83.02% of clinicians stated that the oil had loosened the wax deposits and the auditory canal skin either 'quite a lot' (18.87%) or 'very much' (64.15%)		
Effect of Earol® (oil, dosing and	83.96% of clinicians stated that the oil had moisturised the ear canal either 'quite a lot' (20.75%) or 'very much' (63.21%)	The oil and the massaging techniques (tragus and jaw manipulation) have allowed the oil to significantly	

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massaging) on the auditory canal skin surfaces	81.13% of clinicians stated that the oil had soothed the ear canal either 'quite a lot' (18.87%) or 'very much' (62.26%)	moisturise, lubricate and soothe the auditory canal skin surfaces	Earol® oil is highly effective at softening, loosening and breaking-up the wax deposits and lubricating and moisturising the skin covering the ear canal and tympanic membrane which facilitates the de-waxing procedure by allowing the clinician to easily and safely separate the ear wax deposits from the delicate skin and remove the wax deposits from the ear canal in a pain free and effective manner. Further Earol oil has been shown to significantly reduces the ear wax occlusion prior to the clinical de-waxing procedure.
	89.63% of clinicians stated that the oil had lubricated the ear canal either 'quite a lot' (18.87%) or 'very much' (70.76%)		
Wax reduction pre-dewaxing procedure	Day 0: 81.02% of tympanic membranes analysed had >76% wax occlusion.	The data demonstrate that Earol® is capable of significantly reducing the ear wax blockage without any requirement for the de-waxing procedure. Validates the dosing frequency (morning & evening) for 6 days prior to the de-waxing procedure.	
	Day 6: 13.90% reduction in wax occlusion & 15.4% reduction where the protocol was followed exactly.		
Wax reduction post-dewaxing procedure (after 6 days dosing)	Day 0: 81.02% of tympanic membranes analysed had >76% wax occlusion.	The data demonstrate that Earol® is capable of preparing the ear canals for the de-waxing procedure such that more than 90% of the wax can be removed. Validates the dosing frequency (morning & evening) for 6 days prior to the de-waxing procedure.	
	Day 6: 90.91% reduction in wax occlusion & 98.40% reduction where the protocol was followed exactly.		
Ear itchiness, dryness & other ear canal symptoms	80.00% of patients with baseline itchiness reported relief/disappearance of symptoms after dosing for 6 days. (Pre-dewaxing procedure)	The data demonstrate that dosing with Earol® significantly reduces itchy ears and dryness of the ears irrespective of the de-waxing procedure. It is further demonstrated that Earol® significantly improves ear health as 60% of 'other symptoms' were also relieved/disappeared after dosing with Earol®.	
	71.43% of patients with baseline dryness reported relief/disappearance of symptoms after dosing for 6 days. (Pre-dewaxing procedure)		
	60.00% of patients with other baseline symptoms reported relief/disappearance of symptoms after dosing for 6 days. (Pre-dewaxing procedure)		
Overall ease of use & following patient information	97.85% of patients reported that Earol® was easy to use, with 100% stating that placing the actuator into the ear was easy.	Earol® is an over-the-counter healthcare product which is used by the patient in the home environment without medical supervision. The data demonstrates that Earol® is extremely intuitive to use and that the	
	98.92% of patients reported that the instructions for use were easy to follow		

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instructions (IFU)	Only 6.45% of patients experienced leakage of the oil out of the ear canal after dosing.	patient information leaflet (instructions for use) is very easy to follow. The fact that only a very small percentage of patients reported leakage from the ear after dosing further validates that the ears can be dosed effectively with the patient being in the upright position without the oil leaking from the ears and creating mess. It further validates that a cotton wool swab/stopper is not required after dosing the ears.	Earol® is highly effective at reducing itching and ear irritation and improving ear hygiene.
Device Deficiency	0.96% device deficiency (i.e. one device). The deficiency was due to patient miss-use	This demonstrates that the device is robust and fit for purpose both in the home and clinical setting.	
