

Nasal and Otic Preparations

مستحضرات
بالأذن ear

1

1

Injection Independent Routes:

- **Injection independent** since a ^{Syringe} needle or catheter is not required to administered formulations via these routes.
- Pharmaceutical dosage forms and drug delivery systems applied topically to the eye, nose, or ear can include solutions, suspensions, gels, ointments, and (drug-impregnated inserts.)

Cannula
على يد المريض
(مقدي)

← للعين (مستحضر داخلها)



2

2

Various routes of administration

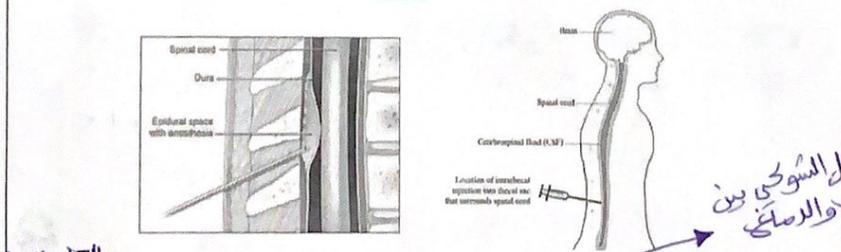
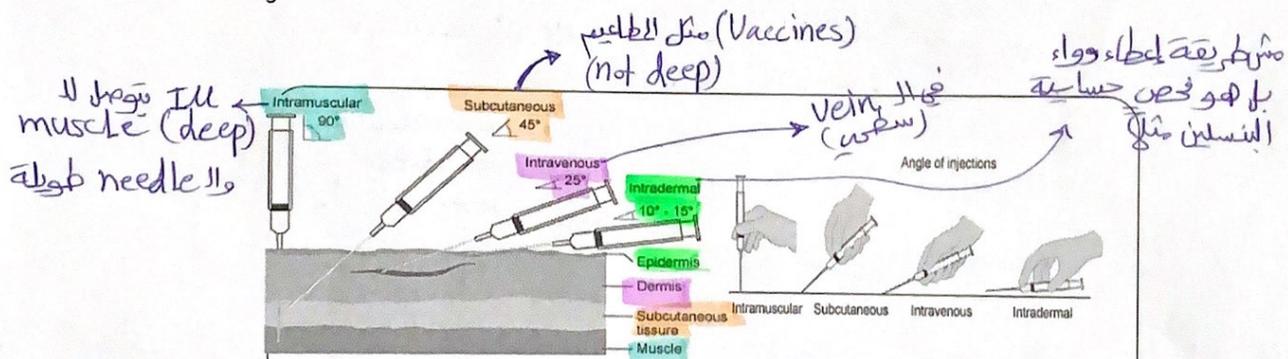
1. Injection **dependent** routes of administration:

- Intravenous **IV**
- Intramuscular **IM**
- Intradermal
- Subcutaneous
- Epidural
- Intrathecal

2. Injection **independent** routes of administration:

- Intranasal (target organ is Lung)
- **Inhalation**
- Ophthalmics
- Otic

3



Intrathecal administration is delivered directly into the **CSF** and into the superficial spinal cord; **epidural** administration diffuses through the **dura** into the CSF, and thus has a **slower** onset of action.

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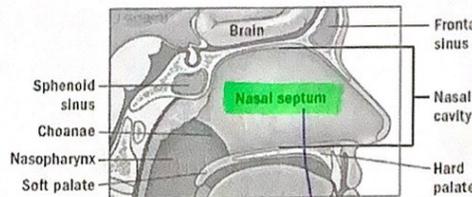
احتقان / التهاب / حساسية / سيلان

1. Intranasal

- Intranasal administration has typically been used to administer drugs to the upper respiratory tract.
- The absorption of some drugs give blood concentrations that are very similar to concentrations seen when the drug is intravenously administered.
- Because of this favorable absorption, intranasal administration has been investigated as a possible route of systemic administration for drugs such as insulin, glucagon, progesterone, propranolol, and narcotic analgesics (to mention a few).

إذا أعطينا الدواء
Nasal mucosa
يكون التأثير مشابه
لإعطائه بآلية أخرى
Pathway (مسار)
من الأنف للدماغ
(في حالات الزهايمر
والشقيقة)

خيار أو
مؤثر عقلي



الهدف منه هو الوصول مكان
ثاني غير الأنف

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Vascularization

عالية جداً بحيث لا تشبه
أنفك بغير نزع سدادة (تروية دموية عالية)

1. Intranasal

- **Dosage form:** Solutions, suspensions, and gels.
- The liquids are typically sterile, isotonic, buffered, and preserved so as to not interfere with the nasal cilia.
- The buffered products are generally at pH between 4 and 8
- Osmotic pressures ranging from 200 to 600 mOsmol/L are acceptable for intranasal administration.

الطريق

to prevent pain
of the tissues

تصديقاً (PH) 7.4

لما يدخل مستحضر الأنف مريض
لازماً تكون (thick) عسناً
ما يؤثر على حركة الـ (cilia) وطريقها تنظيف الأنف

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* قاعدة: إذا تحضير الدواء suspensions وكان من oral
 drops (eye, nasal) أو paritral
 prolong release solution تأخير أطول مدة ال solution

1. Intranasal (Sprays, drops, Inhaler)

- Generally solutions and suspensions are administered as drops.
- Solutions can also be administered as a fine mist from a nasal spray bottle.
- Nasal sprays are preferred to drops because (drops are more likely to drain into the back of the mouth and throat and be swallowed).
- If the drug is sufficiently volatile, it can be administered as a nasal inhaler.
- The inhaler is a cylindrical tube with a cap that contains fibrous material impregnated with a volatile drug. The patient removes the cap, and the inhaler tip is placed just inside the nostril.
- As the patient inhales, air is pulled through the tube and the vaporized drug is pulled into the nasal cavity.

قطرات الأنف تعمل للتزول
 لأسفل الفم وتُشعر بطعمها
 وتجنب هذه المشكلة
 Suspension أو زئبق
 Viscosity أو لزوجة
 enhancer
 عشان يصير thick
 أو انجاز Nasal
 Sprays

* عند إعطاء الدواء عن طريق الأنف لازم بالبراية المريض يعمل تفرغ (exhale) bottle
 عشان تفضل مكان ثم إغلاق فتحة الأنف وبعد inhale من ال bottle

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1. Intranasal

- If drops or sprays are used, the quantity of drug administered in each drop or each spray should be calibrated.
- **To calibrate a dropper:**
 - drop the formulation into a small graduated cylinder (5 ml or 10 ml) using the dropper the patient will use
 - count the number of drops required to dispense 3 ml of solution
 - divide the number of drops by 3; this will give the number of drops per ml
 - calculate the number of drops needed to dispense the volume of formulation in one dose

الفكرة: يقسم 1ml من
 السخيرة cylinders

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ويكون بظلم في dropper
 ويظهرهم وبعد القطرات عشان أسوف ال 1ml
 كم قطرة في بظلم ثم نقسم 1ml
 على عدد القطرات عشان
 نعرف كل قطرة كم حجمها بالمل

number of drops per ml

* قاعدة (1ml → 20 drops)

سبب الاحتقان : تضيق الأوعية
(Vasoconstriction)
ويمكن نزيف

منزلة الاحتقان

NASAL DECONGESTANT SOLUTIONS

- Most preparations intended for intranasal use contain **adrenergic** agents and are employed for their **decongestant activity on the nasal mucosa**

Most nasal decongestant solutions:

- are **aqueous**,
- rendered **isotonic** to nasal fluids (approximately equivalent to **0.9% sodium chloride**),
- buffered to maintain drug stability** while approximating the normal pH range of the nasal fluids (**pH 5.5 to 6.5**),
- stabilized and **preserved** as required.



Nasal drops +
فترة أطول من eyes drops
(تستعمل لفترة أطول) بشرط عدم تلوثها
وما حذا يستعملها غير patient

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NASAL DECONGESTANT SOLUTIONS

- they are best used for **short periods (no longer than 3 to 5 days)**, and the patient should be advised **not to exceed the recommended dosage and frequency of use**
- Rebound congestion**
- Most solutions for nasal use are packaged in **dropper bottles or in plastic spray bottles**, usually containing **15 to 30 mL** of medication
- The patient should be advised to discard the solution if it becomes **discolored and/or contains precipitated matter**

multiple use
للاستعمال المتكرر
(drops) مثل الـ

تضيق اللوز

راسب



ياخذ استراحة لهم
يوم بعدين لارجع ياخذهم
والسبب انه الاستمرار
في استعمالهم يجعل
Rebound Congestion
وهو احتقان ناتج من
طول استعمالهم
(احتقان آخر غير
الاحتقان الأولي)

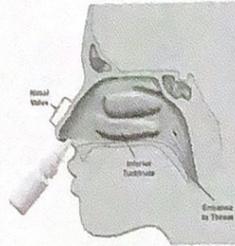
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PROPER ADMINISTRATION AND USE OF NASAL DROPS AND SPRAYS

- To minimize the possibility of contamination, the pharmacist should point out to the patient that the nasal product should be used by one person only and kept out of the reach of children.

① استعمال فردی فقط

②



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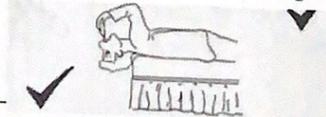
How to Use Intranasal Drops

- Blow your nose gently to clear the nostrils. *exhale*
- Wash your hands with soap and warm water.
- Lie down on a bed with your head tilted back and the neck supported (allow the head to hang over the edge of the bed or place a small pillow under your shoulders).

Tilt your head back so that it is hanging lower than your shoulders. Note: If putting drops into the nose of a child, lie the child on his or her back over your lap. The head should be tilted back.

- Draw up a small amount of medication into the medicine dropper.
- Breathe through your mouth.

6. Place the tip of the medicine dropper just inside your nostril (about 1/3 inch). Avoid touching the dropper against the nostril or anything else.

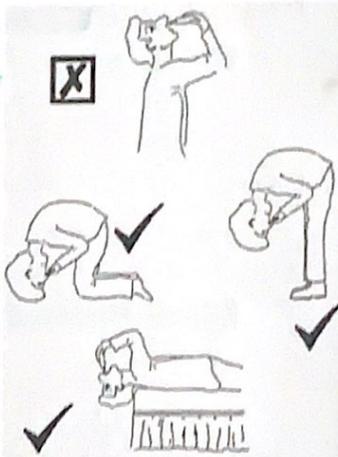


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How to Use Intranasal Drops

1. Place the directed number of drops into your nostril.
للمقحة الأخرى تكرر الخطوات السابقة
2. Repeat steps 3 - 7 for the other nostril if directed to do so.
3. Remain lying down for about 5 minutes, so the medication has a chance to spread throughout your nasal passages.
4. Replace the medicine dropper to its container and tightly close the bottle.
5. Wash your hands



Cap the (إغلاق) Container

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How to Use Intranasal Sprays or Pumps

- Blow your nose gently to clear the nostrils.
- Wash your hands with soap and warm water.
- Hold your head in an upright position, *وربعية قائمة*
- Close one nostril with one finger.
- With the mouth closed, insert the tip of the spray or pump into the open nostril.
- Sniff in through the nostril while quickly and firmly squeezing the spray container or activating the pump.
- Hold your breath for a few seconds and then breathe out through your mouth. Repeat this procedure for the other nostril only if directed to do so.
- Rinse the spray or pump tip with hot water and replace the cap tightly on the container.
- Wash your hands.



Inhale from Spray

نشأنا يتطير

اغسل البتخ

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<https://www.youtube.com/watch?v=r4rWN8T89yU>

دتم مارفاق ضد يوعلى
التيمر لتوضيح العناية

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How to Use Intranasal Sprays or Pumps

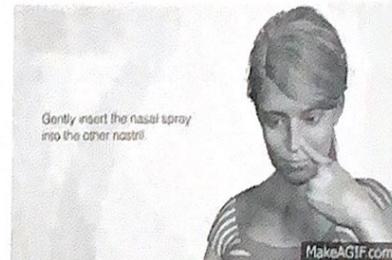
لو كان suspension بهل
Shake ويزا ما فيه
لا داعي للقلق

- The patient should be told **not to shake the plastic squeeze bottle** but be sure to remove the plastic cap **Note**



أول ما ترفع اسحب
(sniff)

- Remove the bottle tip from the nose while maintaining pressure on the bottle sides so as **not to aspirate** any nasal material into the bottle.



وبعد ما تفعل holding
وبنفس ال tip من الأنف
وبنفسها ومنوعا
تنفس في العبوة

ما تدخل أي شيء
من طرف الأناف
للعبوة

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How to Use Intranasal Sprays or Pumps

نظف

- Wipe the tip with alcohol or some other appropriate agent, release the pressure on the sides, and repeat the application as necessary
- Sprays** should always be administered with the patient **upright** *وضعية الوقوف*. Spraying medicine into the nostrils should not be performed with the head over the edge of a bed (the preferred procedure for administration of nasal drops) because it could result in **systemic absorption** of the drug rather than a **local** effect.

mist لو انبقت
ووصلت الجسم
ممكن تسبب أعراض
جانسية ورجعة.

drops → Lie position
Sprays → upright position



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للتوضيح وليست
القطر

Rifampin 1% Nasal Drops		
Rx (for 100 g):	Ingredient	
	Rifampin	1 g
	Hydroxypropyl methylcellulose K4M	1.25 g
	Polysorbate 80	300 mg
	Ascorbic acid	100 mg
	Sodium sulfite	400 mg
	Purified water	qs 100 g

Nitrofurazone 0.02% Nasal Solution/Spray

Rx (for 100 mL):	Ingredient	
	Nitrofurazone	20 mg
	Phenylephrine HCl	250 mg
	Polyethylene glycol 300	10 mL
	Sodium chloride	800 mg
	Bacteriostatic water	qs 100 mL

Ephedrine Nasal Drop B.P.C.		
Rx		
	Ephedrine	0.5 g
	Chlorobutal	0.5 g
	Sodium Chloride	0.5 g
	Water	upto 1000 ml

Prepare nasal drop, send 30 ml

• **Direction:**
Place 2-3 drop in each nostril as directed.

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- Inhalations will be discussed in Aerosols chapter

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Otic Formulations

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Uses of Otic Formulations

• Dosage forms include :

• Solutions, suspensions, gels, and ointments

Uses:

A. Bacterial growth in external auditory canal:

B. Ear Wax Impaction in External Auditory Canal:

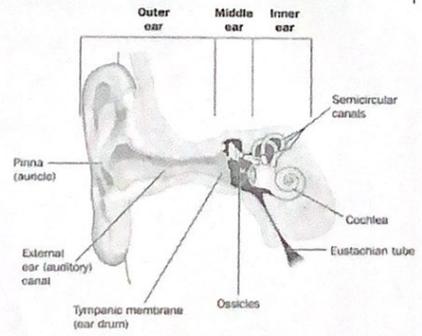
C. Irrigation solution:

D. Swimmer's Ear (otitis externa):

E. Skin Disorders of the Ear:

slow release but longer effect
 معقول يبقى أطول
 Solution
 من أنظف
 Semisolid

quick release
 رطبى أسرع معقول
 وسقوله يروح بسرعة
 (Infection)
 ما رطبى فيسبب مشكلة
 بال مع
 كغسول
 بسبب تجمع الماء بالأذن
 خارجية ما لها علاقة
 بالأذن نفسها



20

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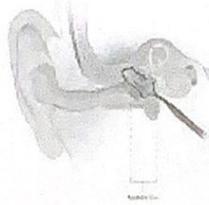
* إذا المرض كانت مستقلة في
 Otic Formulation في external ear
 تارة لو مستقلة في الأذن الوسطى مثلا
 (تعدت ال Canal) لأن ياخذ ال
 Formulation.
 ما يربط أيسر external

A. Bacterial growth in external auditory canal:

- Otic solutions and suspensions are used to treat infections in the external auditory canal
- The solvents are **glycerin, propylene glycol, vegetable oils, mineral oils, or low molecular weight (polyethylene glycols) PEG (Liquid)**
- The above solvents adhere to the canal better than water and alcohol
- **Suspensions provide longer drug effect**

highly viscous
 highly adhesive
 يتصقوا على الأذن بطول التأثير
 تأخير ال Susp أو طول Solution

MIDDLE EAR INFECTION VS OUTER EAR INFECTION



antibiotic

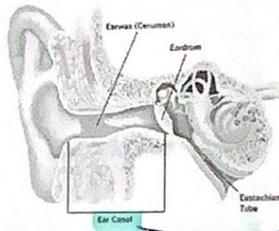
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B. Ear Wax Impaction in External Auditory Canal:

- The **cerumen** remaining in the ear will become **dry** and difficult to remove from the canal
- Formulation containing **carbamide peroxide, glycerin, hydrogen peroxide, and olive oil**
- **Carbamide peroxide and hydrogen peroxide:**
 1. cause a mechanical "bubbling" action that softens and breaks up the dried cerumen and
 2. have **anti-infective action**
- **Glycerin** is **hygroscopic** and **absorbs moisture** → help soften the cerumen
- **Olive oil** serves as a **softening agent** and **increase viscosity** of the formulation to **stay longer in the ear**

تفتتو المادة لطع صغيرة
 الرطوبة ناتجة عن الأسموليات
 بمصر الرطوبة



تجمع ال ear wax بال Canal
 ويسبب حكة ويؤثر على السمع
 ورج يسهل medica for bacterial growth

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عسولة الأذن
إذا السمع ماطلع تطرقه
الأذن فإع Irrigation

C. Irrigation solution:

- An ear irrigation solution that **contain water and alcohol** is used following the treatment with Carbamide peroxide formulation
- Flow out of the canal easily
- The ear is **flushed** with the solution (with a soft rubber ear syringe)
- **Water** should leave the canal out because it will **support bacterial growth**
- May contain **surfactants** to **remove the dirt** (enhance the spreading of the solution)
- May contain **weak boric acid (0.5-1%)** or aluminum acetate solutions **to lower the pH in the canal**



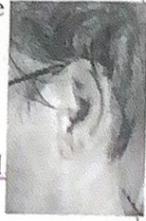
بخط الطبيب كمية
محلوله كبيرة داخل
الأذن ورج سجع
الموساخ التي تنزل
في طبوع

السباحين يصابون فتحة طويلة بالماء فممكن
تدخس المي جوا وتعمل
التهاب بكثري

تدل على التهاب → this

D. Swimmer's Ear (otitis externa):

- Water becomes **lodged** between **cerumen impaction** and the tympanic membrane
- (Trapped water) can encourage **bacterial growth** leading to **inflammation and infection** of the external auditory canal
- Formulations include: **isopropyl alcohol, glycerin, boric acid, hydrocortisone, ethyl alcohol, and acetic acid**
- Also **aminoglycoside antibiotics** can be added (if) **infection is present**
- The **alcohol** in the formulation **help to reduce the surface tension** of water which aids in its removal from the canal
- **Glycerin** in the formulation **absorbs water**
- **Acetic acid** reduces pH in the canal to minimize bacterial growth



المياه الصورة

الكورتيزون يخفف الكحة
بسبب inflammation

soften

and boric acid

بال Immunity (المناعة)

به كورتيزون مثل:

(Seborrhea & psoriasis)

Immunity disease.

يشبهه ال dermatological (بمشافون الخارج) بدون ما تدخل لجوا الأذن

E. Skin Disorders of the Ear:

- The outer ear is a skin-covered structure and is susceptible to the same dermatological conditions as other body part

Skin condition	Major ingredients	Function
Contact dermatitis	2.5% aluminum acetate solution	Antipruritic, anti-inflammatory, and antibacterial
Seborrhea or psoriasis	Topical corticosteroids (gels or ointments)	Anti-itching Otic ointments typically use petrolatum as the base.
Boils (localized infection of the hair follicles with pus)	- Topical antibiotics - Antipyrine (analgesic) in propylene glycol or anhydrous glycerin	Topical analgesics (antipyrine) with hygroscopic vehicle reduce swelling and retard bacterial growth by drawing moisture from the swollen tissue into the vehicle

موض جلدی تساع ← Contact dermatitis
له هو رد فعل ضايع وليس التهاب كثير

← Seborrhea or psoriasis (تقشیر وحب Sebum)

← Boils (تقشیر وحب Sebum)

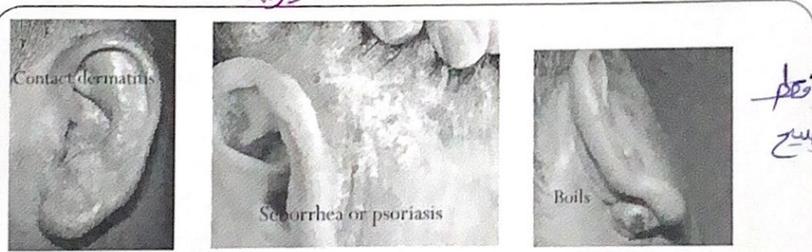
مانع الحكة

فازلین مانع للحكة

في حالة ال ointment

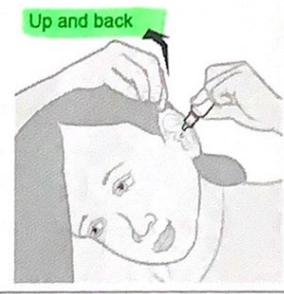
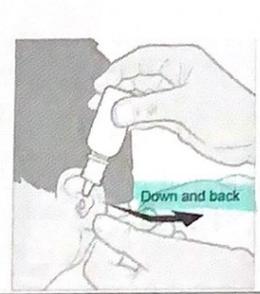
25 Sebum (تقشیر)

emollient + hygroscopic ← ليصنع الرطوبة



الصور تظهر للتوضيح

How to use Otic Drops



for children (تحت ولولاً)

for adult (لفوق ولولاً)

How to use Otic Drops

First: The patient should be aware of the purpose of the formulation:

- If it is to remove impacted cerumen the drops are to be instilled and then removed with an irrigation solution
- If the drops for infection or inflammation they are instilled and left in the ear

Second: the patient should understand the length of time to use the formulations:

- antibiotic ear drops: continue using the drops for 3 days beyond the time the ear symptoms disappear
- Product for swimmer's ear may need 7-10 days to demonstrate relief

بمحتاجون
علاج أطول

إذا كانت المسكلة التهاب لاذع بعد القطرة يسكن زانه قطنة وتركها تلتد ساعة تقريباً.

إذا كانت المسكلة wax أو استعمال القطرة ثم استعمال نكاشة الأذن لإزالة الشمع وإذا ما حسن بحسن ومهار في خزينة الأذن يراجع الطبيب.

في قطرات المضاد الحيوي قطعاً وفيه صبر بعد اصفاء الأعراض لمدة 3 أيام

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How to use Ear Drops

1. Wash your hands
2. Warm the dropper bottle in your hands
3. If a suspension, shake well
4. Draw up a small amount of medication into the dropper
5. Lie on your side so the affected ear points toward the ceiling
6. Position the tip of the dropper just inside the canal. Avoid touching the dropper against the ear

خصوصاً في الشتاء

استلق على جانبك

توضيح نقطة 4: هذه الخطوة تعني أن قطرة الأذن قد بدأت كانت سائلة (علبة ومعهما قطارة) لكن لم يعد موجود هذا الشكل، drop tainer هو الـ شئ غنياً.

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How to use Ear Drops

7. For adults, hold the ear lobe up and back; for children, hold the ear lobe down and back
8. Squeeze the directed numbers of drops into the ear canal and allow the drops to run into the ear
9. Remain lying 3-5 minutes, gently massage the area around ear to aid in spreading of drops in the canal
10. Place a clean cotton pledget just inside ear to prevent leakage when in (upright position)
11. Replace cap



وضع قطرة زيتية في الأذن
لتخفيف الالتهاب والوقوع
أما إذا ما به يتحرك
لإداعي القطن بس
لازم يظل على وضعيته
ثلاث ساعة.

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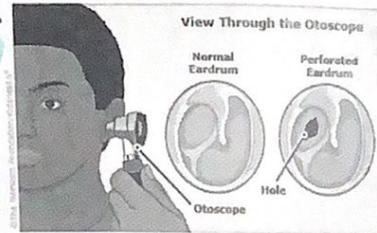
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Tips

- Do not use ear drops if your eardrum has been damaged
- Avoid using very hot or very cold eardrops.
- The medication should be at room temperature or slightly warmer.
- Warm the drops by holding the bottle in your hands for a few minutes

tympanic membrane

طبلة الأذن



لتبين أن طبلة الأذن
فيها مشكلة وتلف
المرض بحسن التصرف
هو بقوة ويبلغ

دفي القطرة باليدك
(تدليك)

30

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Packaging

- Solutions and suspensions packaged in small (5-15 ml) dropper bottles or droptainers
- Otic ointments can be packaged in an ophthalmic tube
- Many otic formulations are self preserving because of the high concentration of glycerin, propylene glycol, or alcohol
- If the above agents are not present a preservative should be added



Drop tainer

أما في حالة كان Solution (water) لازم المريض يغسل أذنه ولا يمس الأذن نهائياً

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النوع من الزيت

تستخدم في علاج الأذن

Swimmer ear: علاج

R, 10 ml Sodium Bicarbonate Ear Drops BR

مادة (antipruritic) ← Sodium bicarbonate
 Preservative hygroscopic ← Glycerol
 Water

Master formula	For 10ml
5 g	500 mg
30 ml	3 ml
to 100ml	to 10ml

antipiotic ear drops

antipiotic
 vehicles

The formula for a ciprofloxacin otic drop is given in the literature as follows¹⁰:

Ciprofloxacin	1 g
Propylene glycol	50 mL
Glycerin, ad	100 mL

How many grams of ciprofloxacin would be required to prepare two hundred 15-mL bottles of the ear drop?

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* في الـ 1 أنا بحاجة لـ preservative لأن الـ water ← vehicle
 * في الـ 2 أنا بحاجة لـ preservative لأن الـ Glycerin ← vehicle