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## Routes & Formulations

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### Factors Influencing the Route of Administration

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- Drugs are contained in dosing units called **formulations** or **dosage forms**.
  - A **route of administration** is a way of getting a drug onto or into the body.
  - It's classified into two categories:
    - ENTERAL
    - PARENTERAL
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## Chapter Outline

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- Parenteral Formulations
    - Intravenous (IV)
    - Intramuscular (IM)
    - Ophthalmic
    - Intranasal
    - Inhalation
    - Dermal
    - Vaginal
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## Factor Affecting Selection of Route and Method of Administration

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1. Drug Characteristics
  2. Ease of administration
  3. Site of action
  4. Onset of action
  5. Duration of action
  6. Quantity of drug administered
  7. Liver or kidney diseases
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## 1. Drug Characteristics

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- The **pH scale** measures the acidity or the alkalinity of a substance.
    - pH 7 is neutral (water).
  - Stomach is very acidic (pH 1-2).
  - Certain drugs are **degraded** or destroyed by stomach acid.
  - The **absorption** of many drugs is affected by the presence of food in the stomach.
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## 1. Drug Characteristics

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- Stomach is very acidic (pH 1-2).
  - Duodenal pH is higher, i.e. closer to neutral
  - Colonic pH is neutral to slightly alkaline
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## 1. Drug Characteristics

- In the drug research process the influence of drug characteristics is examined and the formulations approved will have compensated for this.

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## 2. Ease of Administration

- Prescribers assess patient characteristics to determine route of administration.
  - Difficulty in swallowing?
  - Very young or older adult patients might have difficulty swallowing.
    - **Consider liquid dose forms or non-oral routes of administration.**
  - PO route may be inadvisable for patients with nausea and vomiting.

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### 3. Site of Action

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- Route of administration may be influenced by desired site of action.
  - A **Local Effect**: Site of drug activity and site of administration are one in the same (e.g. eyes, ears, nose, skin).
  - A **Systemic Effect**: The drug is introduced into the circulatory system by any route of administration and carried by the blood to the site of action.
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### 4. Onset of Action

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Onset rate varies with formulation and route of administration.

- Since oral medications for systemic use need to go into solution to exert their effect, solutions or suspensions may work faster than oral tablets or capsules.
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#### 4. Onset of Action

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- Medications placed under tongue or between cheek and gums work quickly because they bypass stomach and liver and go directly into bloodstream.
  - Drugs given IV directly are carried immediately throughout the body.
  - Localized therapeutic effects, e.g. those applied to the skin, inhaled into the lungs or instilled into the eye.
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#### 5. Duration of Action

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- The length of time a drug gives the desired effect or is at the therapeutic level.
  - Controlled or extended-release
    - Drug effect lasts longer, e.g. 12 to 24 hours.
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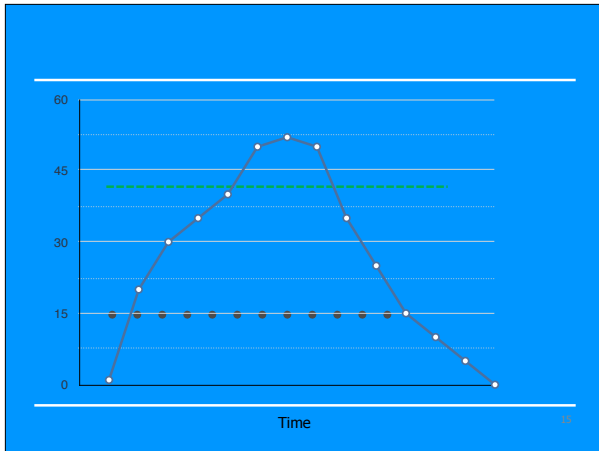
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## 5. Duration of Action

- Transdermal patches
  - Delivers small amounts of a drug steadily over many hours or even days.
- Sustained-duration effect can be achieved by means of intravenous (IV) infusion.
- Injections into the muscle and skin **last longer** than injections directly into the bloodstream.

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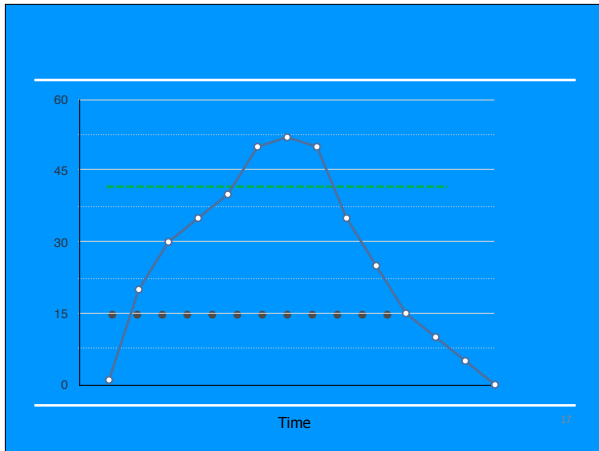
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## 6. Quantity of Drug

- Sometimes route of administration is chosen because of the amount of a drug that needs to given.
- IV infusion is an excellent method for systemic delivery of large quantities of material.
- IV injections and infusions can deliver a higher dose of medication to the target site.

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## Oral Dosage Forms

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- Disintegration
    - The breaking apart of a tablet into smaller pieces.
  - Dissolution
    - When the smaller pieces of a disintegrated tablet dissolve in solution.
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## Active vs. Inactive Ingredients

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- **Inactive Ingredients**
    - Include binders, lubricants, fillers, diluents, and disintegrates.
    - Added to help manufacture the formulation and to help the dosage form disintegrate and dissolve when administered.
    - If a drug X is a 50 mg tablet, then the actual weight is going to be more than 50 mg because of the inactive ingredients.
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## Oral Routes of Administration

- The **most frequently** used route of administration is PO (per os).
- Oral refers to two methods:
  - Applying topically to the mouth for local effect.
  - Swallowing for absorption through the GI tract into systemic circulation.

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## Solid Oral Dose Forms

Common dose forms for enteral administration are solid formulations.

- Tablets
- Capsules
- Bulk powders
- Rectal formulations

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## Other Tablet Types

- **Bulk powders:** contain the active drug in a small powder paper or foil envelope. The patient empties the envelope into a glass of water or juice and drinks the contents.
- **Chewable tablets** are flavored and are designed to be chewed.
- **Effervescent tablets** are granular salts that release gas and the active ingredient into solution when placed in water or juice.

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## Capsules

- A **capsule** is a solid dosage form consisting of a gelatin shell that encloses the drug.
  - usually swallowed whole.
  - tasteless and are easier to swallow than tablets.



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## Capsules

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- Contains powders, granules, liquids, or some combination with one or more active ingredients.
  - Flavorings are not common for this dose form.
  - **Soft or Soft-gel** are capsules that contain liquid instead of powders inside the gelatin shell.
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## Buccal Administration

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- **Buccal tablets** (and gum) are placed in the buccal pouch
    - Between the cheek and the gum.
    - Dissolved and absorbed by the buccal mucosa.
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## Oral Dose Forms Modified Release Formulation

- A **delayed-release** dose form does not release the active drug immediately after administration.
  - Avoid destruction in the stomach
  - Reduce GI upset
- An **extended-release** dose form allows reduced frequency of dosing.

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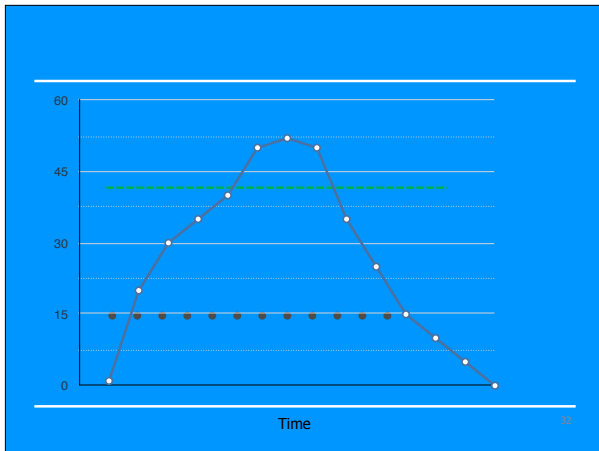
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## Liquid Formulations

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- **Solutions:** a clear liquid.
    - A **solvent** is a liquid that can dissolve another substance to form a solution.
    - **Aqueous solution** = water is the solvent.
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## Liquid Formulations

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- **Suspensions:** are formulations in which the drug is not dissolved in the liquid.
    - Suspensions should be **shaken well** before dispensing or administration.
  - **Syrups** are concentrated solutions of sucrose (sugar) in water and are thicker than water.
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## Non-aqueous Liquid Formulations

- Solutions that contain solvent other than water.
- **Elixirs** are sweetened liquids that contain alcohol (5-40%).
  - They are less sweet and less effective in masking taste than syrup.
- **Spirits** are alcoholic solutions that contain volatile oils (alcohol 62-85%).
- **Tinctures** are alcoholic solutions (like Spirits) but of nonvolatile substances.

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## Liquid Formulations - Emulsions

- Liquid Formulations (Emulsions) are solutions of oil and water based substances.
- **Emulsifier** is a substance that disperses the oil in to water (o/w emulsion) or water into oil (w/o emulsion).
- **Creaming** occurs when dispersed droplets merge together; can be dispersed by shaking.
- **Coalescence** is irreversible separation of the dispersed phase.

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## Liquid Formulations - Gels

- Made using a substance called gelling agents.  
e.g.
  - Carbopols® 934P, methylcellulose, hydroxypropyl-methyl-cellulose, and sodium carboxymethyl-cellulose are recommended for oral administration.
- Usually take 12-24 hours to reach maximum viscosity.
- Add the active drug before the gel is formed.

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## Other Delivery Systems

- **Unit dose disposable syringes** are pre-filled syringes that contain a single pre-measured dose of medication and are thrown away after use.
- An **oral syringe** is a device without a needle to administer medication to pediatric or elderly patients unable to swallow tablets or capsules.

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## Effervescent Salts and Lozenges

- **Effervescent salts** contain one or more medicinal agents and:
  - Some combination of sodium bicarbonate with citric acid, tartaric acid, or sodium biphosphate.
  - Release carbon dioxide gas when dissolved.
- **Lozenges** contain active ingredients and flavorings that are dissolved in the mouth.
  - Also known as troches or pastilles.
  - Generally have local effects.

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## Other Delivery Systems

- Dropper
  - Contains a small, squeezable bulb at one end and a hollow glass or plastic tube with a tapering point.
  - Frequently incorporated into the cap of a vial or other container .
- **gtt** is the abbreviation for drops.
- Droppers are often used for otic or ophthalmic administration.

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## Sublingual Administration

- Designed to be dissolved under the tongue.
  - Medication dissolved under the tongue is absorbed very quickly.
- Nitroglycerin (NTG) is the best known example of SL formulation (for chest pain).
- Advise patients to take a sip of water first and not to eat food or beverages until the drug is fully absorbed.



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## Oral Dose Forms

- **Capsules** are preferred over **tablets** for patients with difficulty swallowing.
- **Water** preferred over beverages to aid in swallowing.
- Some dose forms are designed to be **sprinkled on food** when swallowing a solid is difficult.
- **Liquid doses** are swallowed more easily and are suitable for
  - Patients with swallowing difficulties.
  - Small children.

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## Advantages of the Oral Route

- Ease and safety of administration.
- Active ingredient is generally contained in powders or granules which dissolve in GI tract.
- Sublingual (and buccal) administration has a rapid onset (less than 5 minutes).

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## Disadvantages of the Oral Route

- Delayed onset
  - Dose form must disintegrate before absorption.
- Destruction or dilution of drug by
  - GI fluids and acid.
  - Food or drink in stomach or intestines.
- Not indicated in patients who
  - Have nausea or vomiting.
  - Are comatose, sedated, or unable to swallow.

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## Disadvantages of the Oral Route

- Unpleasant taste of some liquid dose forms
  - Must be masked by flavorings to promote compliance.
- Some drugs given SL or buccally have a short duration of action.
  - NTG less than 30 to 60 minutes.
- Buccal route may have
  - Medicinal taste.
  - Local mouth irritation.

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## Dispensing Oral Medications

- Patients need instruction on proper storage of nitroglycerin.
- SL nitroglycerin tablets should be stored in their original container (brown glass bottle).
  - Lid screwed on tightly to prevent loss of potency.
  - Pillboxes should be discouraged.
  - Refill nitroglycerin with a fresh bottle every 6 months.

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## Rectal Medications- Suppository

- Remove suppository from its package.
- Insert tapered end first with index finger for the full length of the finger.
- May need to be lubricated with a water-soluble gel to ease insertion.
- **Refrigeration** may make insertion of rectal medications easier in warm climates.



## Rectal Formulations

Rectal administration is **preferred** when:

- An oral drug might be destroyed by acidic fluids in the stomach.
- An oral drug might be too readily metabolized by the liver and eliminated from the body.
- The patient is unconscious and needs medication.
- N &/or V or severe acute illness in the GI tract make patient unable to take oral drugs.
- The site of action is local to the rectum.

## Parenteral Routes of Administration

- The term **parenteral** comes from Greek words.
  - Para (outside) and enteron (the intestine)
- **Parenteral administration** is an injection or infusion by means of a needle or catheter inserted into the body.
- Parenteral forms deserve special attention.
  - Complexity, potential for therapeutic benefit and danger including risk of infection.
- This route of administration bypasses the GI tract.

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## Parenteral Routes of Administration

### Injection Independent

- ophthalmic
- intranasal
- inhalation
- dermal
- vaginal
- otic

### Injection Dependent

- intravenous
- intramuscular
- intradermal
- subcutaneous
- epidural
- intrathecal

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## Parenteral Dosage Routes

- INTRA means INTO
  - Intravenous into the vein (IV)
  - Intradermal into the dermis (skin)
  - Intramuscular into a muscle(IM)
- Subcutaneous injections
  - Under the skin

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## Parenteral Forms for Injection

- Parenteral preparations must be
  - Sterile
- To ensure sterility, parenterals are prepared using
  - Aseptic techniques
  - Special clothing (gowns, masks, hair net, gloves)
  - Laminar flow hoods placed in special rooms.

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## Parenteral Dosage Forms

- IV route
  - Directly into a vein
- Prepared in hospitals and home healthcare pharmacies.
  - Antibiotics
  - Chemotherapy
  - Analgesics
  - Nutrition
  - Critical care medications

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## Needle Size Recommendations

Route	Gauge Length	
• Intravenous (IV)	16 - 20	1 - 1.5"
• Intramuscular (IM)	19 - 22	1 - 1.5"
• Subcutaneous (SC)	24 - 32	3/8 - 1"
• Intra-dermal (ID)	25 - 32	3/8"

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## Parenteral Route

- Disposable **syringes and needles** are used to administer drugs by injection .
  - Different sizes are available depending on the type of medication and injection needed .
- IV infusion can provide a **continuous amount** of needed medication.
  - Without fluctuation in blood levels of other routes.
- Infusion rate **can be adjusted**.
  - Provides more or less medication as the situation dictates.

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## Intravenous Formulations

- Administered directly into a vein.
- Takes about 20 seconds to circulate throughout the body.
- Aqueous solutions are the most common formulations.
- **Syringeability** – the ease with which a material can be drawn from container into a syringe.
- **Injectibility** is the ease of flow when a material is injected into a patient.

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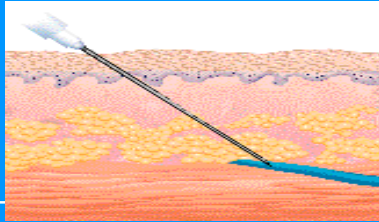
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## Intravenous Injections or Infusions

- Intravenous (IV) injections are injected directly into a vein and are administered at a 15- to 20-degree angle.



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## Intravenous Administration Devices

### • Infusion

- The gradual IV injection of a volume, usually 500 – 1000 ml, of fluid into a patient.
- E.g. dextrose in water 5% (D5W), 0.9% sodium chloride in water (NS).
- The solution bag has two ports: an **administration set port** and a **medication port**.

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## Parenteral Route Disadvantages

- Formulation is limited to:
  - solutions,
  - suspensions, and
  - Emulsions.
- Has to be **STERILE** (bacteria free).
- **pH** must match body fluid's using buffer system.
- Limited volume should be used to avoid pain and **necrosis**.

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## Parenteral Route Disadvantages

- Higher Cost: drug and auxiliary devices
- Require skilled personnel to administer them.
- Most difficult to remove once administered if there is an adverse or toxic reaction.
- Requires a needle for injection
- Potential for additional adverse events, e.g. infection or clot formation.

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## IV Formulation Complications

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- Thrombus formation
  - Phlebitis
  - Air emboli occur when air is introduced into the vein.
  - Particulate material can include small pieces of glass that chip from the product's vial or rubber pieces from the stopper.
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## Intramuscular Injections

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- Care must be taken with deep IM injections to avoid hitting a vein, artery, or nerve.
  - In adults, IM injections are given into upper, outer portion of the gluteus maximus.
  - For children and some adults, IM injections are given into the deltoid muscles of the shoulders.
  - Depot – the area in the muscle where the formulation is injected.
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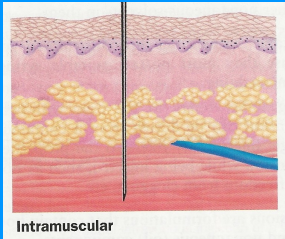
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## Intramuscular Injections



Typical needle is 22- to 25-gauge 1- to 1.5-inch needle..

IM injections are administered at a 90-degree angle

Volume limited to less than 3 mL

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## Advantages and Disadvantages of the IM Route

- Intramuscular (IM) and subcutaneous routes of administration are convenient ways to deliver medications compared with the IV route.
- Onset of response of the medication may be slower.
- Duration of action can be longer.
- Practical for use outside the hospital
- Used for drugs which are not active orally.

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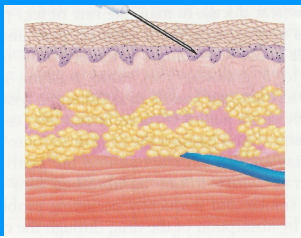
## Subcutaneous Injections Insulin

- Given using 30-32gauge short needles
  - in special syringe that measures in **UNITS**.
- Keep insulin **refrigerated**.
- Check expiration dates frequently.
  - Opened vials should be discarded **after 28 days**.
- A vial of insulin is mixed by **rolling between the hands** and **never be shaken**.
- The rubber stopper should be wiped with an alcohol wipe.

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## Intradermal Injections

- Given into capillary-rich layer just below epidermis for:
  - local anesthesia
  - immunizations
  - diagnostics



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## Intradermal Injections

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- Examples of ID injections include:
    - Skin test for tuberculosis (TB)
      - Typical site is the upper forearm, below the area where IV injections are given.
    - Allergy skin testing
      - Small amounts of various allergens are administered to detect allergies.
      - Usually on the back.
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## Implants and Plasters

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- **Implants**, or pellets, are dosage forms placed under the skin by means of minor surgery.
    - Used for long-term, controlled release of medications.
    - Enhanced patient compliance & convenience.
    - Complications at the site of insertion have limited use.
    - E.g: Viadur® - Duros® - Supperlin LA®
  - **Plasters** are solid or semisolid preparations that adhere to the body.
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## Topical Routes of Administration

- Topical administration is the application of a drug directly to the surface of the skin.
- Includes administration of drugs to any mucous membrane:
  - Nose
  - Ears
  - Vagina
  - Urethra
  - Colon
  - Lungs

## Ophthalmic Medications

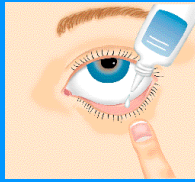
- Are administered for **local treatment**.
- **Must be at room temperature** or body temperature before application.
- Have to be **sterile**. Only preparations with preservatives can be repeatedly used.





## Ophthalmic Administration

- Before application, patient should wash hands.
  - Prevents contamination of application site.
- Tube or dropper should not touch the application site.
  - Medication may become contaminated.



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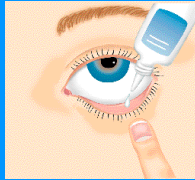
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## Ophthalmic Administration

- Only sterile ophthalmic solutions or suspensions should be used in the eye.
- Ear drops can **NEVER** be used in the eye, but eye drops **CAN** be used in the ear.



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## Ophthalmic Administration

- Patient's head should be tilted back.
- After administration, the patient should place a finger in the corner of the eye, next to the nose to close the lacrimal gently.
  - Prevents loss of medication through tear duct.
- Patient should also keep the eyes closed for 1 or 2 minutes after application .

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## Ophthalmic Administration



- When multiple drops of more than one medication are to be administered, the patient should wait 5 minutes between different medications.
  - The first drop may be washed away.
- If an ointment and a drop are used together, the drop is used first.
  - Wait 10 minutes before applying the ointment.

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## Contact Lenses & Ocular Inserts

- **Contact lenses**

- If the patient is allowed to wear contact lenses, the lens should be put in the eye 5 minutes after the solution is used.

- **Ocular Inserts**

- Ocusert® is an ocular insert designed to deliver pilocarpine at a controlled rate for up to 7 days.
- Lenses placed in a solution containing a drug and the lenses absorb the drug solution.

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## Intranasal Formulations

- Nasal cavity holds about 20 ml and has a very rich blood supply.
- May reach drug concentration similar when a drug is administered as IV.
- Nasal inhaler is a cylindrical tube with a cup that contains fibrous material impregnated with a volatile drug.



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## Intranasal Formulations

- Applied by:
  - drops (instillation)
  - sprays
  - aerosol (spray under pressure)
- Used for:
  - relief of nasal congestion or allergy symptoms
  - administration of flu vaccine

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## Intranasal Formulation

- Patient should:
  - Tilt head back.
  - Insert dropper or spray or aerosol tip into the nostril pointed toward the eyes.
  - Apply prescribed number of drops or sprays in each nostril.
- Breathing should be through mouth to avoid sniffing medication into the sinuses.
- Important not to overuse nasal decongestants.

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## Orally Inhaled Medications

- Intended to **deliver drugs to the lungs**.
  - Lungs are designed for exchange of gases from tissues into bloodstream.
  - Usual dose form is an aerosol.
  - “Environmental friendly” propellants now required to replace chlorofluorocarbons (CFCs) .

## Orally Inhaled Medications

- Avoids the problems of:
  - **Degradation** found with oral administration.
  - Minimizes potential **toxicity** associated with systemic administration.
- Most common examples are medications for respiratory illness including asthma.

## Inhaled Medications

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- **Metered-dose inhalers (MDI)**
    - Provide medication with compressed gas.
    - Deliver measured dose with each activation.
    - If a MDI contains a steroid, the patient should **RINSE** the mouth thoroughly after dose to prevent oral fungal infection.
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## Inhaled Medications

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- **Nebulizers**
    - Create a mist when a stream of air flows over a liquid.
    - Commonly utilized for young children or elderly patients with asthma or lung disease.
  - **A diskus**
    - A newer dosage form to administer drug to lungs as micronized powder.
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## Inhaled Medications

- Most inhalation dosage forms are MDI aerosols that depend on the power of compressed or **liquefied gas** to expel the drug from a container.
- **Particle size** of the aerosolized medication is a critical factor with MDIs.



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## Inhaled Medications

- **Spacer and adapters**
  - MDI requires coordination between breathing in and activation of the aerosol.
  - There are extension devices to assist the patient who can't coordinate these two processes.



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## Proper Administration of Aerosolized Medications

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1. Shake canister well.
  2. Insert canister into a mouthpiece and connect to spacer.
  3. Breathe out and hold spacer between lips making a seal.
  4. Activate MDI and take a deep slow inhalation.
  5. Hold breath briefly, and slowly exhale through the nose.
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## Transdermal

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- Delivers drug to bloodstream via absorption through the skin.
  - Therapeutic effects can last for up to 1 week.
    - across membranes of the skin.
    - into layer where absorption into bloodstream occurs.
  - Transdermal patches should be carefully discarded after use because they could cause serious side effects if ingested by young children or pets.
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## Basic Rule of Percutaneous Absorption

- More drug is **absorbed** when the formulation is applied to a larger surface area.
- Formulations or dressings (occlusive) that increase the **hydration** of the skin generally improve absorption.
- The greater the amount of **rubbing in (inunction)** of the formulation, the greater the absorption.
- The longer the formulation remains in contact with the skin, the greater will be the absorption.

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## Topical Dose Forms

- Dose forms for topical administration include:
- Skin:
  - creams
  - ointments
  - lotions
  - gels
  - transdermal patches



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## Ointments, Creams, Lotions, & Gels

- Dose forms should be applied as directed to the skin.
  - lotions, creams, and gels are worked into the skin.
  - ointments stay on the surface.
- When using some topicals, e.g. nitroglycerin ointment, the patient or caregiver should wear gloves to avoid being dosed with the drug.

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## Ointments, Creams, Lotions, & Gels

- When using topical corticosteroids:
  - Apply sparingly to affected areas for short periods of time.
  - Affected area should not be covered up with a bandage unless directed by the physician.
    - Occlusive dressings can significantly increase drug absorption and risk of side effects.
  - Overuse of potent topical corticosteroids can lead to serious systemic side effects.

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## Transdermal Patches

- Site of administration should be rotated and relatively hair free.
- Should not be placed over a large area of scar tissue.

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## Topical Formulations Advantages

- Local therapeutic effects.
- Lower risk of side effects.
- Not well absorbed into the deeper layers of the skin or mucous membrane.
- Offers steady level of drug in the system.

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## Vaginal Formulations



- **Vaginal tablets** also called **inserts**, they are inserted in the same manner as vaginal suppositories.
  - Patients should be instructed to dip the tablet into water before insertion.
  - Patients may want to wear a sanitary napkin to protect nightwear and bed linens.

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## Vaginal Formulations

- Ointments, Creams, and Aerosol Foams
  - Contain antibiotics, estrogenic hormonal substances, or contraceptive agents.
  - Creams and foams are placed in a special applicator tube, and the tube is then inserted high in the vaginal tract.

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## Intrauterine Devices (IUDs)



- A device placed in the uterus.
- Have a lower rate of vaginal expulsion due to their similarity to the uterine shape.
- ParaGard® is an IUD that has been shown to be effective for up to 12 years.
- Mirena® is another category of IUDs that is based on the release of the hormone progesterone

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## The Vaginal Ring

- A hormone based system used in one month cycles.
- The ring is inserted in the vagina for 3 weeks, removed for 7 days, and then reinserted.
- **NuvaRing®** is an example of such a device.



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## Toxic Shock Syndrome (TSS)

- A rare and potentially fatal disease that results from a severe bacterial infection of the blood.
- Though primarily associated with the use of super absorbency tampons, it has also been associated with various vaginal dosage forms.
- TSS symptoms include a high fever, nausea, skin rash, faintness, and muscle ache. It is treated with antibiotics and other medicines.

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## Otic Medications

- Must be at room temperature or body temperature.
  - Heated drops may cause rupturing of the eardrum.
  - Cold drops can cause vertigo and discomfort.
- Old medication should be removed along with any drainage before applying fresh medication.
- Alcohol causes pain and burning sensation.
  - Should not be used if the patient has a ruptured tympanic membrane (eardrum).

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## Otic Medications

- Tilt head to side with ear facing up for 2 to 5 minutes.
- Cotton balls placed in the ear after administration of drops will prevent excess medication from dripping out of the ear.
  - Balls will not reduce drug absorption.
  - Patients under 3 should have lobes pulled down and back.
  - Patients over 3 should have lobes pulled up and back.

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## Terms to Remember

- |                            |                    |
|----------------------------|--------------------|
| 1. alveolar sacs (alveoli) | 7. conjunctiva     |
| 2. aqueous                 | 8. contraceptive   |
| 3. biocompatibility        | 9. depot           |
| 4. buccal                  | 10. diluent        |
| 5. buffer system           | 11. disintegration |
| 6. colloids                | 12. dissolution    |

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