VOLUME 7 NUMBER 4

Secundum Artem

Current & Practical Compounding Information for the Pharmacist.

PACKAGING, STORAGE AND DISTRIBUTION OF COMPOUNDED PHARMACEUTICALS

INTRODUCTION

The outward appearance of the prescription drug package is often the only tangible basis for a patient's judgement of a pharmacist's care and skill. A package can be described as an economical means of providing protection, presentation, identification and convenience for a product until such time as it is completely used or consumed. The emphasis of packaging, for pharmaceuticals, is protection. If a drug product/preparation reacts with packaging materials or decomposes because of improper storage, it may become useless and even hazardous. The packaging, storage and distribution of compounded pharmaceuticals are very complex and diverse and directly impact the safety and efficacy of compounded medications. Terminology used in this issue will include the word "product" for a manufactured drug and the word "preparation" for one that is compounded.

Much information for this issue is derived from the process and products of the U.S. Pharmacopeia. The USP standards must be met by pharmacists, as well as by manufacturers; something many may not know. The USP seeks to establish standards appropriate to the packaging, storage and distribution of drugs to assure their continued quality. These standards are developed to be scientifically appropriate, economically feasible and socially responsible. It is the goal of the USP to provide safe, effective, high quality medicines from the manufacturer or the compounding pharmacist to the patient.

Historically, pharmacists have been involved primarily in "dispensing pharmacy" and the selection of the proper packaging has been more of a passive activity with minimal choices to routinely make. Until the mid-1900s, many pharmaceutical packages were made of paper and glass; foil and plastics made their way into pharmaceutical dispensing in the 1960s. In many cases, modern pharmacies stock primarily plastic vials for solid dosage forms, plastic oral liquid bottles (Rx ovals) for liquid dosage forms and plastic ointment jars and tubes. In the 1960s and 1970s, many manufacturers began putting their products in prepackaged, unit-of-use dosage forms. With these, the pharmacists would prepare the label and physically attach it to the container. Some products, such as antibiotic powders, would require the addition of water prior to labeling and dispensing. Today, a vast array of materials are commonly used in pharmacy, including numerous plastics, composites, papers, foils and several types of glass. Packaging is a very complex science and is rapidly changing.

"Manufactured products" must be exhaustively tested for compatibility and stability in the packaging materials. A primary reason for this is the materials will be in contact with the product for an extended period of time and may be exposed to extremes of storage conditions during transportation. "Compounded preparations", on the other hand, are designed for short term storage and minimal shipping exposure. There are, obviously, exceptions to this as some compounded pharmaceuticals are shipped throughout the country; however, these are generally shipped using a priority carrier whereas manufactured products are shipped using a trucking or land-based carrier. Pharmacists packaging compounded preparations, however, are required to properly package their preparations in accordance with the U.S. Pharmacopeia requirements to enhance stability. An example of packaging used for some compounded preparations is shown in Table 1.

Storage of pharmaceuticals is the pharmacist's responsibility from the time of receipt of the product and continues to the counseling of the patient on the proper storage of the medication at home or in an institution during the time of administration. Products are best stored at a uniform temperature for optimal results. However, it may be the common practice of many pharmacists to alter the thermostat setting when closing up for the night, such as increasing the temperature setting during the summer months and decreasing the temperature setting during the winter months, to help reduce utility costs. Wide temperature range variations should be discouraged as they may affect the stored drug products. Storage temperatures and Mean Kinetic Temperature will be discussed later in this issue.

Distribution of manufactured products under proper conditions is the responsibility of the pharmaceutical manufacturer. Distribution of compounded preparations is the responsibility of the compounding pharmacist. Today, we have many express delivery services available that enable pharmacists to provide delivery within 24 hours to almost anywhere in the U.S. under reasonably controlled conditions. Reference will be made to this in the discussion of Mean Kinetic Temperature.

PACKAGING

Packaging involves various types or categories of containers. The USP 23 has a number of definitions of various types of containers.

A *container* is defined as "that which holds the article and is or may be in direct contact with the article".

The *immediate container* is "that which is in direct contact with the article at all times".

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The *closure* is" a part of the container".

Materials for containers should protect the product from environmental conditions, not be reactive with the product, should not impart tastes or odors, should be nontoxic, FDA approved, meet the tamper-resistant requirements, and be adaptable to high speed packaging technology.

Containers are now being considered for further definitions by the USP Committee of Revision, Subcommittee on Packaging, Stability and Distribution, into primary containers, critical secondary containers and secondary containers, as follows.

A *primary container* is that which is in direct contact with the product. The purpose of a primary container is to provide the product protection from the environment during storage and handling. This primary container may also be a specialized delivery system, such as an aerosol or metered dose dispenser. Primary containers are primarily made of glass, plastic, single or laminated flexible materials, and metal.

A *critical secondary container* is not in direct contact with the product but does provide product stability protection. This includes an over-pack, over-wrap or pouch to provide moisture, gas, light or microbial protection that is not provided by the primary container.

A *secondary container* is defined as a container that encloses one or more primary containers, and may not always be present. It may be used for the final market presentation of the product and is often used to carry the required labeling for the product. It can also provide protection against damage in the handling and distribution system. This is commonly the folding paper carton, but may also include special trays for some products, including syringes, suppositories, etc.

Are compounding pharmacists involved in all these types of containers? Yes, they may be; consequently, it is important to understand their function, design and use. Prior to being used, a container must be "clean". Sometimes, special precautions and cleaning procedures may be necessary, as in the case of sterile products and others. Another important consideration is that the container must not interact physically or chemically with the preparation that is placed in it so as to alter the strength, quality or purity of the article beyond the official requirements. These requirements apply not only to manufacturers of drug products but also to dispensing pharmacists of drug products and to compounding pharmacists for drug preparations.

Packaging also includes film wrappers, blister packages, strip packages, bubble packages, nebules, etc. Blister-type packaging can be a thermo-formed tray with each cavity holding a single tablet and covered with a peelable lidding film. A blister protects a moisture-sensitive product up to the point of administration whereas a multiple unit bottle has the headspace moisture replaced every time the container is opened. Roll or "Life-saver" type packaging is used for convenience and portability for small quantities of some products, as in antacids.

It should be noted that the USP 23 contains a table as a reminder for the pharmacist engaged in the typical dispensing situation listing the capsules and tablets that are official in the USP and indicates the correct container to use in dispensing that product.

Additional USP Container Definitions

Other USP package definitions pharmacists must be aware of include the following.

A *light-resistant container* protects the contents from the effects of light by virtue of the specific properties of the material of which it is composed, including any coating applied to it. Another option is to make a clear and colorless or translucent container light-resistant by an opaque covering. In the latter case, the product must be retained within the opaque outer covering prior to dispensing.

A *well-closed container* protects the contents from extraneous solids and from loss of the article under the ordinary or customary conditions of handling, shipment, storage and distribution.

A *tight container* protects the contents from contamination by extraneous liquids, solids or vapors, from loss of the article, and from efflorescence, deliquescence, or evaporation under the ordinary or customary conditions of handling, shipment, storage and distribution and is capable of tight re-closure.

Closures

Closures often consist of a cap and a liner. Closures (caps) are generally either thermosetting or thermoplastic resins. They differ greatly in physical and chemical properties and are considered a part of the container.

A liner is any material that is inserted in a cap to effect a seal between the closure and the container. They are usually made of a resilient backing and a facing material. They must be sufficiently soft to smooth out any irregularities in the sealing surface and sufficiently elastic to recover its original shape when removed and replaced. Liners are generally attached to a cap using a suitable adhesive.

Elastomers for closures are complex materials containing from two to ten different raw materials. They must be impermeable to gases, resistant to coring, have good compression recovery, a good shelf life, solvent resistance, resilience, and resistance to interaction with the package contents. Examples are butyl rubber, halobutyl rubber, ethylene-propylene rubber, silicone rubber, fluoroelastomers, natural rubber, neoprene rubber, styrene butadiene rubber and polybutadiene. Many of these elastomers contain latex, an important consideration for latex-sensitive patients.

Materials for Containers

Glass: Glass is a commonly used packaging material, though it is rapidly being replaced by plastics. Glass does possess superior protective qualities, it is economical and containers are readily available in a variety of sizes and shapes. It is chemically inert, impermeable, strong and rigid. It has FDA clearance and does not deteriorate with age. There are generally four types of glass used in pharmaceuticals.

Type I Neutral or borosilicate. Is very chemically inert and is used for acids, alkalies and all types of solvents. It is widely used in parenterals and other sterile products.

Type II Soda glass with a surface treatment. Commercial soda-lime glass that has been de-alkalized or treated to remove the sur face alkali. It is a chemically resistant glass. It is widely used in parenterals and other sterile products.

Type III Soda glass of limited alkalinity. This is an untreated glass with good chemical resistance. It is only occasionally used in parenterals.

NP Soda glass (nonparenteral usage) for oral and topical use.

Plastics: Plastics have become the most popular material for packaging pharmaceuticals. It is strong, lightweight, reasonably inert, chemical resistant and can be made from various polymers for select applications. Most commonly used plastics include polyethylene (Low Density-LDPE; High Density-HDPE), polystyrene, polypropylene and polyvinyl chloride. Many of the characteristics of these plastics are summarized in Table 2. Plastics are a mixture of homologous compounds with a range of molecular weights. These plastics also contain other substances, such as residues from the polymerization process, plasticizers, stabilizers, antioxidants, pigments and lubricants.

Polyethylene is a good barrier against moisture, but a relatively poor one against oxygen and other gases. Most solvents do not attack it and it is unaffected by strong acids and alkalies. Low density and high

density polyethylene containers differ in their stiffness, moisture-vapor transmission, stress cracking and clarity or translucency. As the density increases, the material becomes stiffer. Odors, flavors and gases may permeate. Polyethylene terephthalate (PET and PETG) are now widely used for packaging liquids.

Polystyrene is rigid and may be crystal clear. It has been used for years for solid dosage forms.

Polypropylene is very popular. It is an excellent barrier to water and gases but may not be too clear. It does not stress-crack and has good resistance to almost all types of chemicals, including strong acids, alkalies, and most organic materials. Its main drawback is its lack of clarity. It is widely used for syringes.

Polyvinyl chloride (PVC) can be crystal clear. It is a good oxygen barrier but can be permeable to water. It can yellow when exposed to heat or ultraviolet light. PVC is very stiff but can be softened with the use of plasticizers. It does yellow when exposed to heat or ultraviolet light. It is widely used for soft intravenous solution bags.

Polycarbonate is a clear, transparent rigid container and has been considered as a replacement for glass. It is resistant to dilute acids, oxidizing or reducing agents, salts, oils (fixed and volatile) and aliphatic hydrocarbons. It can be attacked by alkalies, amines, ketones, esters, aromatic hydrocarbons and some alcohols.

Metal: Metal containers can be made from aluminum, tin, steel or tin-plate. They are generally strong, opaque, impervious to liquids, moisture vapor, gases, odors and bacteria, as well as being resistant to both high and low temperatures. A disadvantage of metals is the requirement for some type of coating to minimize their reactivity with drugs.

Laminates: Laminates are a way of using the convenient aspects of different materials to apply to a specific situation. Paper is often laminated to plastic and foil. Different types of plastic may be laminated together. Plastic may be laminated to foil.

Packaging Injections:
The commonly used "Large-Volume Parenteral" (LVP) and "Small-Volume Parenteral" (SVP) designations are based essentially on the size of their primary container. A large-volume injection is a single-dose injection that is intended for intravenous use and is packaged in containers labeled as containing more than 100 mL. A small-volume injection refers to an injection that is packaged in containers labeled as containing 100 mL or less.

A *pharmacy bulk package* is a container of a sterile preparation for parenteral use that contains numerous doses but is intended for use in a pharmacy admixture program and is restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. The closure of a pharmacy bulk package can only be penetrated one time after constitution and the container is only to be used in a suitable work area, such as a laminar flow hood or in an equivalent clean air compounding area.

Containers for injection, including closures, must not interact physically or chemically with the preparation in any way to alter it's strength, quality or purity. Also, the container must permit the inspection of its contents and be made of an appropriate material. If glass is used, the type of glass is generally specified in the articles monograph. Glass types used in parenterals include Type I, which is a highly resistant, borosilicate glass; Type II which is a treated soda-lime glass; and, Type III, a soda-lime glass, previously described.

Injections are limited in the volume they can contain. An intravenous solution is limited to 1000 mL volume and a multiple dose vial is limited to 30 mL. Solutions for irrigation and for parenteral nutrition are exempt from this limitation. Also, injections labeled for veterinary use are also exempt from these packaging and storage requirements concerning the limitation to single-dose containers and the limitation on the volume of multiple-dose containers.

Problems with Plastic Packaging Materials
General difficulties with plastics include permeation, leaching, sorption, chemical reactions and an alteration of the properties of the plastic.

Permeation is the transmission of gases, vapors or liquids through packaging materials. This can lead to hydrolysis and oxidation of the contained products.

Leaching is when an ingredient from the package migrates into the enclosed product. This is reasonably common in PVC containers using plasticizers, such as diethylhexylphthalate (DEHP). DEHP can actually migrate from plastic intravenous solution bags into the solution where it is administered to the patient. When paclitaxel came on the market, its vehicle was so lipophilic that leaching was a significant problem when pharmacists compounded the drug into an admixture using an LVP in a PVC container. DEHP-free containers and administration sets had to be developed and are now on the market.

Sorption results in the loss of a drug by sorbing onto (adsorption) or into (absorption) the plastic packaging material. This is especially important when the dose of the drug is small and may be insignificant in large dose products. Sorption to plastic has been reported for diazepam, nitroglycerin and other small-dosage, lipophilic drugs. This sorption can be minimized by pre-adding small amounts of several substances, including human serum albumin, to the solution, followed by the drug. In emulsions, there may also be the migration of some of the oil phase into the hydrophobic plastic bottle, as well as possibly some of the lipophilic preservatives.

Plastic tubes are low in cost, light in weight, durable, pleasant to touch, flexible, odorless and inert to most chemicals, unbreakable, leakproof, and retain their shape. They also have a characteristic "suckback" upon completion of administration which brings the product back into the tube and prevents oozing out of the container. One disadvantage to this involves ingredients that are easily oxidized.

STORAGE

Both manufactured and compounded products / preparations should be stored at the specified conditions required in the labeling or to enhance stability of the drug. Proper temperature monitoring of the storage environment may be required. This can be easily done by simply obtaining a thermometer and preparing a temperature monitoring log where the temperature is routinely manually read and recorded on the log. More sophisticated systems are also available that will monitor the temperature and store the data for later output.

Generally, storage conditions are described in terms of temperature and sometimes, light. Humidity is generally not specified as it is understood that the container will protect its contents from humidity excursions. Reasons to protect from freezing include the risk of container breakage, loss of strength or potency, especially of protein products, and the destructive alteration of the dosage form.

Patients should be advised to not store medications in the typical "Medicine Cabinet" in bathrooms due to the temperature variations and high humidities that may be experienced.

Storage Temperatures
Storage temperatures, as defined by the USP 23, include the following. A *freezer* is a place in which the temperature is maintained thermostatically between -20º C (-4ºF) and -10ºC (14ºF). Pharmacists should note this temperature range and not just assume that the setting on the freezer portion of the refrigerator-freezer in the pharmacy reaches this prescribed temperature range. If the freezer only reaches -7ºC (19.4ºF), it is not compliant with the USP requirements for a freezer.

A *cold place* is any temperature not exceeding 8ºC (46ºF). A refrigerator is a cold place in which the temperature is maintained thermostatically between 2ºC (36ºF) and 8ºC (46ºF).

A *cool place* is any temperature between 8ºC (46ºF) and 15ºC (59ºF). An item that is indicated for storage in a cool place may also be stored in the refrigerator.

Room temperature is defined as the temperature prevailing in a working area. *Controlled room temperature* is a temperature that is maintained thermostatically that encompasses the usual and customary working environment of 20ºC (68ºF) to 25ºC (77ºF); that results in a mean kinetic temperature calculated to be not more than 25ºC (77ºF); and that allows for excursions between 15ºC (59ºF) and 30ºC (86ºF) that are experienced in pharmacies, hospitals and warehouses. This includes items that are labeled for storage at either "controlled room temperature" or at temperatures "up to 25ºC (77ºF)". The mean kinetic temperature is a calculated value that can be used as an isothermal storage temperature that simulates the nonisothermal effects of storage temperature variations.

A warm place is any temperature between 30ºC (86ºF) and 40ºC (104ºF). Excessive heat is any temperature above 40ºC (104ºF). For items where no specific storage conditions are prescribed, it is to be understood that these items will be stored and distributed with protection from moisture, freezing and excessive heat.

Mean Kinetic Temperature

Mean Kinetic Temperature (MKT) is defined as the single calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures. In other words, as the degradation rates of drugs change with temperature, it is difficult to determine exactly how much a drug may have degraded when its storage temperature is not maintained constant. As the temperature decreases, the degradation rate decreases and as the temperature increases, the degradation rate increases. MKT is a concept of an integrated time:temperature function as it relates to degradation. It is similar to developing an area-under-the-curve (AUC) function for bioavailability, but this relates to time and temperature. As the temperature increases with time, the AUC increases, hence the extent of drug degradation would be greater as the AUC is greater. The opposite would also be true; with a decrease in temperature with time, the AUC decreases and the extent of drug degradation under these conditions would be less.

In summary, the mean kinetic temperature may be considered as an isothermal storage temperature that simulates the nonisothermal effects of storage temperature variation. It is not a simple arithmetic mean but involves exponential and logarithmic relationships. It is calculated from the average storage temperatures recorded over a time period and a running average calculated from the average of weekly high and low temperatures recorded over the preceding 52 weeks. The results from the equation (available upon request from the author), represent an approximation to the actual MKT and applies equally to all areas of pharmaceutical practice; namely, to manufacturers, warehousers, shippers, hospital and community pharmacies, emergency vehicles, sales representatives' vehicles, etc. In the future, it may become feasible to have integrating time:temperature indicators packaged with pharmaceuticals indicating an integrated "extent of degradation" of the drug product from the time of manufacturing or compounding, until the time of administration to the patient. This may become more critical and important as biotechnology-derived products make their way into the marketplace. The potential need for individualization of such products, and the possibility of short stability dating, makes this concept very important for the future.

DISTRIBUTION

Distribution of compounded pharmaceuticals may range from the patient picking them up, driving a few minutes home in their automobile, and carrying the package into the home to a scenario where the package is in a delivery vehicle for a few hours in the heat/cold, to where a commercial carrier must be used; and many situations in-between.The compounding pharmacist must consider the distribution of the preparation when determining the quantity to make, the containers to use, the packaging that would be required and whether or not temperature control may be an issue for delivery or shipping.

Temperature-sensitive preparations that require refrigeration, can be packaged with frozen gel-packs. In the packing container, the prescription medication should not directly contact the frozen gel-pack as it may freeze the medication. Rather, a cloth, plastic bubbles or some insulator can be wrapped around the medication prior to placing it in the shipping container.

Temperature-sensitive preparations that require freezing can be packaged with dry-ice. Special containers are required for this as well as special labeling on the outside of the box. Dry-ice is not commercially available in most locations at a reasonable cost. Arrangements can also be made for routine delivery where it can be stored in insulated boxes for later use.

In cases where these temperature-sensitive preparations are shipped, it is wise to call the recipient and inform them of the shipping schedule with instructions that, if the package is not received, to immediately notify the shipping pharmacist.

General freight carriers and the US Postal Service are less consistent in their shipping conditions as compared to the express companies and those that specialize in small package distribution.

Several different chemical and electronic devices that are very reasonably priced are available to monitor temperature in transit. When these are placed inside a package, it is wise to notify the patient to observe the color of the device and to notify the shipping pharmacist of any color change that signifies temperature extreme exposure. There are many of these commercially available for different purposes. Some function using a chemical melting point, a freezing indicator or a polymerization reaction that may result in a color-change. Although not perfect, they do provide some valuable feedback information. Contact the author for a list of manufacturers/sources for these products.

Pharmacies should have, and follow, written procedures that specify packing techniques and materials for the different types of preparations that may be shipped. This includes the use of coolants, wrapping material, insulation, space-filler material, temperature-monitoring devices, and the final outer wrapping.

Hints and Suggestions for Packaging for Shipping

1. Place cotton in the tops of bottles of solid dosage forms to minimize the effects of vibrations, and shocks.
2. Make sure the closures are tight on all containers.
3. Use bubbles, "peanuts", shredded or tightly crumpled paper to fill voids and spaces in cartons to minimize movement of the containers in the shipping cartons.
4. Never assume that the container will stay in an upright position during shipping.
5. Never assume that the container will not be dropped at some point during shipping.
6. Call the recipient prior to shipping for assurance the package will be received and taken care of in a timely manner.

Table 1. List of Preparations and Suggested Packaging

Dosage Form	Containers / Packaging
Tablets / Capsules	Vials. Wide-mouth bottles, glass or plastic, with screw-on or snap caps. Mostly HDPE with others, in order of decreasing frequency are Polyvinyl chloride, Polyethylene, Polypropylene, Polyethylene Terephthalate and Polystyrene.
Liquids	Rx Ovals. Wide-mouth bottles (viscous liquids). Oral liquids that are flavored may experience a loss in flavor over time due to the volatilility of the flavoring component and permeation through the container. Plastic oral syringes.
Bulk Powders	Wide-mouth bottles, commonly plastic.
Divided powder	Papers. Individual pouches. Plastic bags.
Powders, Topic	Sifter-type boxes. Puffer units.
Ophthalmic liquids	Plastic dropper bottles. Syringes (No needles).
Ophthalmic ointment / gel	Ophthalmic tubes. Syringes (No needles).
Otics	Dropper bottles (Glass / Plastic)
Nasal Solutions	Dropper bottles (Glass / Plastic). Spray bottles (Plastic)
Ointments / Creams	Jars. Tubes. Syringes. Toothpaste-type pump.
Enemas	Squeezable plastic tubes.
Suppositories	Vials. Cartons. Plastic bags. Greaseproof cardboard boxes with a means of separating each item. They may be individually wrapped with foil. An alternative is the mold-package combination unit where they are dispensed in their disposable mold that is slipped into a cardboard sleeve.
Popsicles	Plastic bags.

Table 3. Plastic Container Materials and Their Characteristics

	Polyethylene		**Polypropylene**	**Polystyrene**	**Polyvinyl Chloride**
	HDPE	LDPE			
Clarity	Hazy, Transparent	Hazy, Translucent	Clear	Clear	Clear
Water absorption	Low	Low	Low	Mod-High	Low
Water-vapor permeability	Low	Very low	Very low	High	Low
Oxygen Permeability	High	Mod-High	Mod-High	High	Low
CO_2 Permeabililty	High	Mod-High	Mod-High	High	Low
Resistance to: Acids	Fair to very good	Fair to very good	Fair to very good	Fair to good	Very good
Alcohol	Good	Good	Very good	Poor	Very good
Alkalies	Good	Good	Very good	Good	Good
Mineral oil	Poor	Fair	Fair	Fair	Good
Solvents	Good	Good	Good	Poor	Fair
Heat	Poor	Fair	Good	Fair	Fair to poor
Cold	Excel	Excel	Poor-Fair	Poor	Very poor
High Humidity Excel	Excel	Excel	Excel	Excel	Excel
Impact Resistance	Excel	Good	Fair-Good	Poor-good	Fair-Excel
Inertness	Outstdg	Excel	Good-Excel	Very poor	Poor

HDPE = High Density Polyethylene **LDPE =** Low Density Polyethylene
Mod = Moderate **Excel =** Excellent **Outstdg =** Outstanding

Extemporaneous Formulations and Stability Studies Available For:

- Acetazolamide
- Allopurinol
- Alprazolam
- Azathioprine
- Baclofen
- Bethanechol
- Captopril
- Chloroquine Phosphate
- Cisapride
- Clonazepam
- Diltiazem HCl
- Dipyridamole
- Enalapril Maleate
- Flecainide Acetate
- Flucytosine
- Hydralazine HCl
- Ketoconazole
- Labetalol
- Metolazone
- Metoprolol Tartrate
- Metronidazole
- Procainamide
- Pyrazinamide
- Quinidine Sulfate
- Rifampin
- Spironolactone
- Spironolactone/HCTZ
- Tetracycline HCl
- Verapamil HCl

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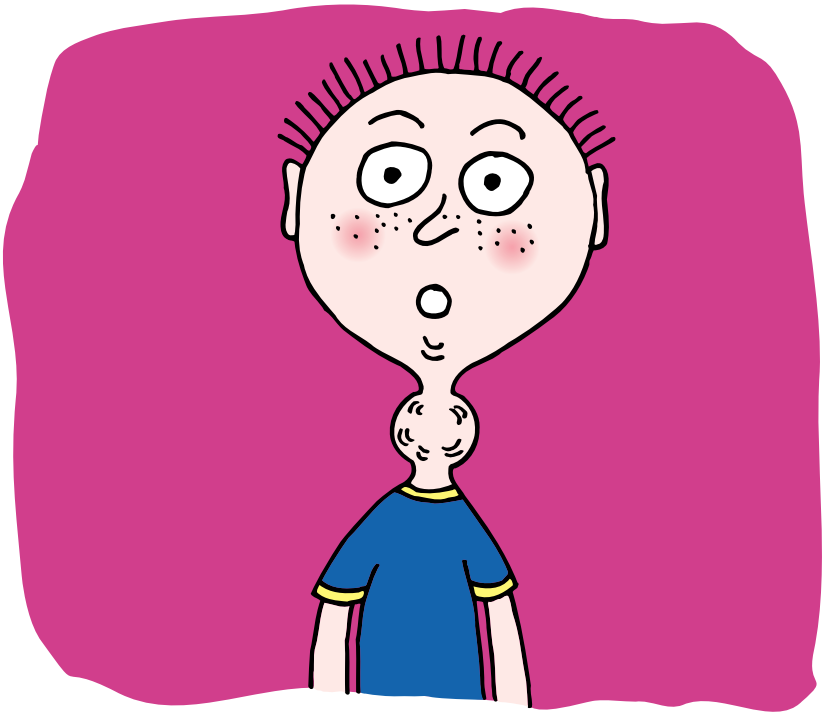

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