

CapsOral®

Capsule Excipient

CapsOral® is an extremely versatile excipient that can be used in oral capsule formulations with numerous active pharmaceutical ingredients (APIs). It is particularly beneficial for static prone, hygroscopic, and drugs exhibiting poor solubility. It is an innovative SpecializedRx proprietary powder blend with several advantages over other traditional, more commonly used capsule fillers.

All ingredients are pharmaceutical grade excipients that meet or exceed current USP-NF monographs.

SKU	Size	NDC/Reference No.
B0225-40	100 g	72467-0225-40
B0225-50	500 g	72467-0225-50
B0225-55	1 kg	72467-0225-55
B0225-65	5 kg	72467-0225-65
B0225-70	10 kg	72467-0225-70
B0225-75	25 kg	72467-0225-75

Benefits:

- ✓ Even Particle Distribution: Consistent uniform particle size offers improved API distribution when blended with CapsOral®.
- ✓ Time Saving: Easily blends with numerous APIs and enables powders to fall easily and faster into the capsules, increasing efficiency and saving time spent compounding.
- ✓ Improved API Dissolution: Enhances the dissolution of many APIs, including poorly soluble drugs.
- ✓ Static Reduction: The physical properties exhibited in CapsOral® offer superior static reduction often found when working with many APIs, including progesterone.
- ✓ Effortless Spreadability: Easily spreads across capsule fill plates taking less time to compound versus lactose, microcrystalline cellulose, or many other traditional capsule excipients.
- ✓ Improved Stability: Formulated with very low hygroscopic ingredients that resist moisture lending to improved stability, especially for moisture-sensitive APIs.
- ✓ Classified GRAS status ingredients.
- ✓ Ideally suited for allergy sensitive patients.
- ✓ Pet Friendly: formulated without xylitol.

Formulated Without:

- Lactose
- Gluten
- Casein
- Soy
- Corn
- Tree Nuts
- Methylcellulose
- Sorbitol
- Dye
- Sugar
- Sodium Lauryl Sulfate (SLS)
- Magnesium Stearate

Capsule Packing Statistics

Capsule Size	#5	#4	#3	#2	#1	#0	#00	#000
CapsOral®	0.087	0.138	0.186	0.237	0.321	0.444	0.626	0.947
Hypromellose 2910/4000 cps (Methylcel E4M)	0.081	0.129	0.183	0.222	0.300	0.411	0.585	0.885
Hypromellose 2208/100,000 cps (Methylcel K100)	0.063	0.101	0.143	0.174	0.235	0.322	0.458	0.693
Microcrystalline Cellulose (Avicel Ph-105)	0.070	0.112	0.159	0.192	0.260	0.356	0.507	0.767

Results may vary slightly from person to person due to a variety of factors. Weights listed in grams (g) per capsule.

Category	Capsule Excipient
Appearance	White to off-white free-flowing powder
Description	CapsOral® is an easy to use, free-flowing, pharmaceutical grade powder formulated specifically as a capsule filling excipient with improved bioavailability potential for poorly soluble APIs. Anhydrous.
Ingredients	Proprietary pharmaceutical grade (USP-NF) blended capsule excipients that contains (Isomalt, glyceryl, poloxamer, sodium fumarate) selected specifically for their mean particle size, pharmaceutical grade, physical properties, amorphous surface characteristics, improved solubilization properties of poorly soluble APIs, and suitability for the intended application.
Allergy	Per the 2004 Food Allergen Labeling and Consumer Protection Act, no allergen declarations are required for this product as relating to corn, milk, egg, tree nut, fish, crustacean shellfish, wheat, peanuts, and soybeans. Gluten-free, non-GMO/vegan compliant.
Technical Data	Shelf Life: 2 years from date of manufacture when stored in original, unopened container. Density, at 25 °C approx. 0.46 g/cm ³
Safety Data	All ingredients classified as "Generally Recognized As Safe" (GRAS) and inactive excipient ingredients by the US FDA. For information on the toxicology and safety of this product, please consult the material safety data sheet (MSDS).
Handling & Storage	Comment: Due to some fine particles, this product is liable to become compacted or conglomerated. Storage Conditions: Product can be stored at ambient conditions for temperature, pressure, and humidity. Product should be kept in a tightly sealed container, under cool and dry conditions.
Comments	This information reflects US requirements for ingredients and allergy declarations. SpecializedRx makes no warranties or claims to the accuracy or completeness of the above information given the variations in use and formulations.