

Customer:	Product Size:	4
Product Name:	Type:	Coni-Snap
Product Code	Print Type:	Non Print
BODY		CAP
Code:	V44.700	Code:
Name:	WHITE.OP.V700	Name:
IMPRINTING		

Qualitative and Quantitative composition *

Composition per unprinted capsule part

Body represents about 60% of the capsule weight

Name of excipient(s)	Function	Body (V44.700)		Cap (V44.700)		Total Capsule	
		%	mg/body	%	mg/cap	%	mg/capsule
Hypromellose	Structure	qsp100	21.2226	qsp100	14.1484	qsp100	35.3710
Gellan gum	Gelling agent	5.0000	1.1400	5.0000	0.7600	5.0000	1.9000
Titanium dioxide	Opacifier	1.9184	0.4374	1.9184	0.2916	1.9184	0.7290
		100	22.8000	100	15.2000	100	38.0000

*The quantities given are based on the theoretical calculations of the average specification weight of the capsules.

*Due to the nature of raw materials, their sourcing and technology improvements, the dyestuff content data indicated are target values and actual values may vary.

Additional information

Specifications :	These capsules conform to the specifications as defined in the current edition of the Capsugel "TECHNICAL REFERENCE FILE".
Packaging information :	Standard packaging consists of protective, food antistatic bags inside robust cardboard cartons.
Storage information :	Capsugel recommends that our capsules be stored in the closed containers in which they are dispatched in areas where the ambient temperature is 15°C to 25°C and the relative humidity 35% to 65%.
General commitment :	As the supplier of this product, Capsugel will notify of any significant changes that would affect the integrity of the product. Typically this is defined as Level II changes by the International Pharmaceutical Excipient Council's Significant Change Guide for Bulk Pharmaceutical Excipients.
Shelf life :	Capsugel continues a global stability program and maintains data supporting 5 years shelflife of our capsules.

Manufacturing Processes

No Addition Of Preservatives
 No Ethylene Oxide Treatment
 No Irradiation Treatment

Regulatory information

Name of excipient(s)	E Nr	C.I. Nr	Function	Reference / Monograph standard
Hypromellose	E464		Structure	(EU) 231/2012,, EP, JP, USP/NF
Gellan gum	E418		Gelling agent	(EU) 231/2012, JSFA, 21 CFR
Titanium dioxide	E171	77891	Opacifier	(EU) 231/2012, 21 CFR, EP, JP, USP/NF

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Date: Nov 18, 2019**Capsugel France SAS, Rue Timken 10 - F68027 Colmar - France****Capsugel Belgium NV, Rijksweg 11 - 2880 Bornem - Belgium**