

TECHNICAL DATA SHEET

FEATURES & BENEFITS

- This low splatter formula offers fast stain removal, high polishing ability and is easy to rinse.
- Delivered in convenient unit doses to reduce the risk of cross-contamination or in an economic jar alternative.
- Available in many popular flavors and grits.

RECOMMENDED USE

- Dental prophylaxis treatment. Intended solely for use in a dentist office.

PRODUCT DETAILS

Product Name:	Medicom DentiCare® Pro-Polish Prophylaxis Paste with Fluoride
Product Type:	Dental Polish
Active Ingredient:	Sodium Fluoride, NaF 2.7% w/w (equivalent to 1.23% w/w fluoride ion)
Ounces per Jar:	See Appendix 1
Flavors:	See Appendix 1
Country of Origin:	USA



CHARACTERISTIC		SPECIFICATION
Description		Gritty, crumbly, and rubbery paste
Appearance		Firm and moist
Color		Consistent with flavor. Refer to Appendix 1.
Heavy Metal	Arsenic	< 3 ppm
	Cadmium	< 3 ppm
	Lead	< 10 ppm
	Total Mercury	< 1 ppm

CERTIFICATION & STANDARDS

ISO 13485 certified manufacturer.
Health Canada registered medical device manufacturer.
Health Canada Class NHP, NPN 80024656.
FDA Class 1 Medical Device.

STORAGE CONDITIONS

Store at temperature between 15°C to 25°C
(59°F – 77°F)
Shelf life of 2 years.

Appendix 1 (List of items)

Item Code	Description	Packaging Information	Size	Color	Specific Attribute	Treatment	Marketed in USA as	Marketed in Canada as
10031-CMUN	Medicom DentiCare Pro-Polish Prophylaxis Paste with Fluoride	1 Jar is plastic shrink-wrapped	12 oz (340g)/Jar	Consistent with Flavor	Flavor: Mint Grittiness: Coarse	Non-Sterile	Medical Device Class 1	NHP: NPN 80024656
10031-FBGUN	Medicom DentiCare Pro-Polish Prophylaxis Paste with Fluoride	1 Jar is plastic shrink-wrapped	12 oz (340g)/Jar	Consistent with Flavor	Flavor: Bubble Gum Grittiness: Fine	Non-Sterile	Medical Device Class 1	NHP: NPN 80024656
10031-MCHUN	Medicom DentiCare Pro-Polish Prophylaxis Paste with Fluoride	1 Jar is plastic shrink-wrapped	12 oz (340g)/Jar	Consistent with Flavor	Flavor: Cherry Grittiness: Medium	Non-Sterile	Medical Device Class 1	NHP: NPN 80024656
10031-MMUN	Medicom DentiCare Pro-Polish Prophylaxis Paste with Fluoride	1 Jar is plastic shrink-wrapped	12 oz (340g)/Jar	Consistent with Flavor	Flavor: Mint Grittiness: Medium	Non-Sterile	Medical Device Class 1	NHP: NPN 80024656
10047-CMUN	Medicom DentiCare Pro-Polish Prophylaxis Paste with Fluoride	200 Cups/BoxOuter Packaging: plastic shrink-wrap	0.07 oz (2g)/Cup	Consistent with Flavor	Flavor: Mint Grittiness: Coarse	Non-Sterile	Medical Device Class 1	NHP: NPN 80024656
10047-CRBUN	Medicom DentiCare Pro-Polish Prophylaxis Paste with Fluoride	200 Cups/BoxOuter Packaging: plastic shrink-wrap	0.07 oz (2g)/Cup	Consistent with Flavor	Flavor: Raspberry Grittiness: Coarse	Non-Sterile	Medical Device Class 1	NHP: NPN 80024656

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Item Code	Description	Packaging Information	Size	Color	Specific Attribute	Treatment	Marketed in USA as	Marketed in Canada as
10047-FBGUN	Medicom DentiCare Pro-Polish Prophylaxis Paste with Fluoride	200 Cups/BoxOuter Packaging: plastic shrink-wrap	0.07 oz (2g)/Cup	Consistent with Flavor	Flavor: Bubble Gum Grittiness: Fine	Non-Sterile	Medical Device Class 1	NHP: NPN 80024656
10047-MCHUN	Medicom DentiCare Pro-Polish Prophylaxis Paste with Fluoride	200 Cups/BoxOuter Packaging: plastic shrink-wrap	0.07 oz (2g)/Cup	Consistent with Flavor	Flavor: Cherry Grittiness: Medium	Non-Sterile	Medical Device Class 1	NHP: NPN 80024656
10047-MMUN	Medicom DentiCare Pro-Polish Prophylaxis Paste with Fluoride	200 Cups/BoxOuter Packaging: plastic shrink-wrap	0.07 oz (2g)/Cup	Consistent with Flavor	Flavor: Mint Grittiness: Medium	Non-Sterile	Medical Device Class 1	NHP: NPN 80024656

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