

SpecializedRx 3787 95th Ave NE, Ste 100 Circle Pines, MN. 55014 USA 888.512.1209 www.specializedrx.com

Supposi-Plex[™] R36 Suppository Base



Supposi-Plex™ R36 is a highly versatile pellet form suppository base with a long history of use in a wide range of APIs. Easy to use suppository base that is 100% derived from vegetable origin. Stable at room temperature, non-irritating and generally recommended for rectal suppositories. Mold lubrication not required. Meets the requirements of USP-NF/EP.

Test	Specification
Appearance	Waxy Solid, pellets
Odor	Faint
Melting Point	34.0 to 38.0 °C
Hydroxyl Value (NV=25)	20 to 30 mgKOH/g
Acid Value	<= 0.50 mgKOH/g
Water Content	<= 0.50 %
Density	Average relative density at 40 °C = 0.905



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Technical Data Sheet

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CATEGORY	A semi-solid pellet base for use in suppository type preparations. Rectal drug delivery: Suppository base with medium hydroxyl value (20 - 30 mg KOH/g).
INGREDIENTS	Conforms to Hard Fat, USP-NF/EP Glycerides, C10-18; Triglycerides C10-C18 The product is manufactured from raw materials of strictly vegetable origin: Palm Kernel/Palm Oil
ALLERGY	Per the 2004 Food Allergen Labeling and Consumer Protection Act, no allergen declarations are required for this product as relating to milk, egg, tree nut, fish, crustacean shellfish, wheat, peanuts, corn, and soybeans. Gluten-free, non-GMO/vegan compliant.
TECHNICAL DATA	This product is a pharmaceutical ingredient. It is recommended for use in pharmaceutical formulations administered by rectal/vaginal routes. This ingredient must be used according to appropriate regulations. Specialized Rx accepts no responsibility for the use of this product in applications other than those recommended. **SOLUBILITIES AT 20°C** - Ethanol 96°: Not very soluble - Chloroform, Methylene chloride: Soluble - Water: Insoluble - Vegetable oils: Soluble - Mineral oils: Soluble
SAFETY	For information on the toxicology and safety of this product, please consult the material safety data sheet (MSDS).
HANDLING AND STORAGE	Store the product in its original packaging sealed tightly, protected from light and moisture. Store at a temperature inferior or equal to 30 °C. During storage at high temperature (> 35°C), there is a risk of pellets agglomeration. Product has a shelf-life of 4 years under the recommended storage conditions and should not be used after its expiry date.
COMMENTS	SpecializedRx makes no warranties or claims to the accuracy or completeness of the above information given the variations in use and formulations.