

# Nystatin Micronized

## Therapeutical category:

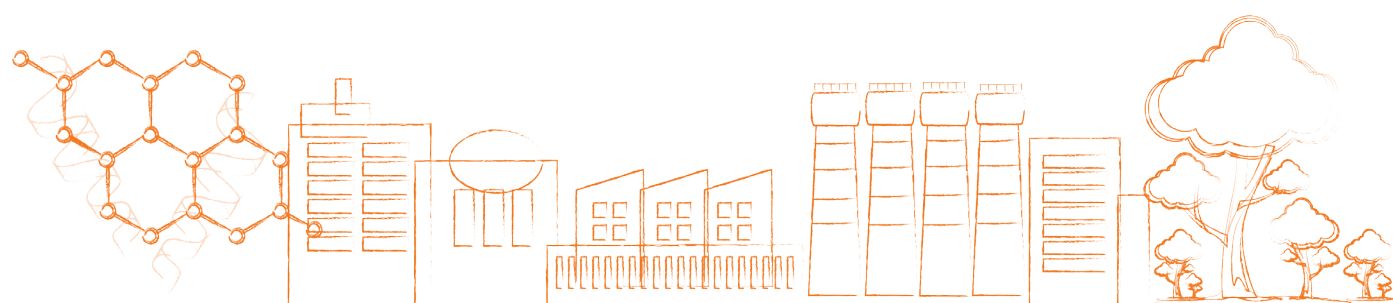
Polyene antibiotic with antifungal activity for oral use

## Characteristics:

A microfine crystalline powder

## Applications:

The product is suitable for the manufacture of (extemporaneous) oral suspensions



## Key parameters: Nystatin Micronized

<b>Pharmacopeia quality</b>	USP, EP	
<b>Regulatory information</b>	USA: FDA EU: EDQM Italy: AIFA	Canada: HPB Australia: TGA Japan: PMDA
<b>Appearance</b>	A yellow or slightly brownish powder	
<b>Potency</b>	≥ 5000 IU/mg (EP) ≥ 5500 U/mg (USP)	
<b>Loss on drying</b>	≤ 5.0%	
<b>Composition (by HPLC)</b>	Nystatin A1: ≥ 85% Any other compound: ≤ 4.0%	
<b>Residual solvents</b>	Acetone: ≤ 0.5% (EP) Acetone: ≤ 0.2% (USP) Methylisobutylketone: ≤ 0.05%	
<b>Shelf-life</b>	3 years in the original packaging under storage conditions	
<b>Batch size</b>	Approximately 200 kg	
<b>Storage conditions</b>	Below 25°C, protected from light and moisture	
<b>Packaging</b>	Primary packaging: polyethylene bag	
	Secondary packaging: thermo-sealed aluminum polyethylene bag	
	Outer packaging: corrugated box	
	Fixed quantity of the product (12.15 kg) equivalent to the desired total potency is packed in each box (71 BoU for EP or 82 BoU for the USP grade product)	

## Contact and information

For more information, please visit [www.dsm-sinochem.com](http://www.dsm-sinochem.com) or e-mail: [info@dsm-sinochem.com](mailto:info@dsm-sinochem.com) or contact us at one of the addresses below:

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