

DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT

1. DESCRIPTION

VALCYTE Powder for Oral Solution is a white to slightly yellow powder (granulate) intended for constitution with 91 mL of purified water to 100 mL.

A bottle of 12 g powder contains 5.5 g valganciclovir hydrochloride corresponding to 5 g of valganciclovir (free base).

1 ml of constituted solution contains 55 mg of valganciclovir hydrochloride corresponding to 50 mg of valganciclovir (free base).

2. COMPOSITION

1 bottle contains:

Components	Reference	Function	Amount [g]
Granulate ¹			
Valganciclovir HCl ²	Roche	Drug substance	5.51
Mannitol			
Fumaric Acid			
Povidone K30			
Sodium Benzoate			
Saccharin Sodium			
Tutti Frutti Flavour			

3. CONTAINER CLOSURE

VALCYTE Powder for Oral Solution is packed in amber glass bottles with child resistant plastic closure.

FCC = Food Chemicals Codex

¹ Purified water (Ph. Eur./USP) used as granulation liquid, is essentially removed during processing

² Equivalent to 5 g valganciclovir (free base) on dry basis per 12 g of powder blend

³ May be adjusted for assay to 100 %

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