

Drug product name: Cysteamine Bitartrate (NM002/Nylexa®)

Box Label

SPONSOR: University Medical Center Utrecht Heidelberglaan 100 3584 CX Utrecht The Netherlands
REMAP-CAP Trial Contact <u>For country specific contact: Refer to Pharmacy guide</u>
REMAP-CAP Core Protocol V3.0
EudraCT Number: 2015-002340-14
DP name: Cysteamine Bitartrate (NM002) Administration route: Intravenous Strength: 500 mg/vial; 2.5 mL fill volume Contents: 30 vials
Directions for use— Use as directed in Pharmacy guide
Store in freezer at -15°C to -25°C Keep medicines in box till use
FOR CLINICAL TRIAL USE ONLY
Patient ID:
Batch number: P04620 Expiry date: Jun 2022

Vial Label

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Document history

Nylexa clinical label_Version1.0_25 Feb 2021

Nylexa clinical label_Version2.0_06 Apr 2021

Nylexa clinical label_Version3.0_27 May 2021

Nylexa clinical label_Version4.0_13 Jul 2021

Cysteamine (NM002) clinical label_Version5.0_20 Aug 2021