# Indexing - product concept - eculizumab injection Food and Drug Administration Reference Label Set Id: ebcd67fa-b4d1-4a22-b33d-ee8bf6b9c722

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## **Abstract Product Concept**

injection

#### **Product Information**

Product Type INDEXING - PRODUCT CONCEPT Item Code (Source) 16f3f311-ff6d-6601-9332-b567050035b0

## **Active Ingredient/Active Moiety**

| 8  |                   |                 |
|--|-------------------|-----------------|
| Ingredient Name  | Basis of Strength | Strength        |
| ECULIZUMAB (UNII: A3ULP0F556) (ECULIZUMAB - UNII:A3ULP0F556) | ECULIZUMAB        | 300 mg in 30 mL |

## **Application Product Concept**

### **Product Information**

Product Type INDEXING - PRODUCT CONCEPT Item Code (Source) 10618dae-d924-b570-041e-cfb26df9263c

## **Marketing Information**

|     | Marketing Category | Application Number or Monograph Citation |
|-----|--------------------|--|
| BLA |                    | BLA125166                                |
|     |                    |  |

## Labeler - Food and Drug Administration (927645523)

Revised: 12/2017 Food and Drug Administration