

CORTIZEME KÜLSŐLEGES SZUSZPENZIÓ 125 ML  
Gysz:53C1/PC300728 Lej:16/03/31  
Kisz:1X Me.:Darab  
SZÉKELY KFT részére

Medimpex Gy. Zrt.  
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**Certificat d'analyse / Analysis certificate**  
**Certificat de libération / Release certificate**

PRODUIT / PRODUCT : CORTIZEME 125ML HU  
Code produit / Code product : 300728  
Lot N° / Batch N° : 53C1  
Quantité / Quantity : 1,299 P  
Date de fabrication / Manufacturing date : January 2015  
Date de validité / Expiry date : March 2016

Lot informatique / IT batch number : 2316538

Date d'édition / printed on  
March 25 2015

| ANALYSES / ANALYSIS              | RESULTATS / RESULTS | NORMES / STANDARDS                 |
|----------------------------------|---------------------|------------------------------------|
| <b>CHARACTERS</b>                |                     |                                    |
| Appearance                       | Passed              | Homogeneous fluid white suspension |
| pH at 20°C                       | 4.8                 | 4.0 to 6.0                         |
| Contents                         | Passed              | According to specifications        |
| <b>IDENTIFICATIONS</b>           |                     |                                    |
| Prednisolone                     | Passed              | Identical to the standard          |
| Neomycin                         | Passed              | Identical to the standard          |
| <b>ASSAYS</b>                    |                     |                                    |
| Prednisolone                     | 100.1 mg/100ml      | 95.0 to 105.0 mg/100ml             |
| Neomycin (as sulfate)            | 514.9 mg/100ml      | 475.0 to 525.0 mg/100ml            |
| <b>PRESERVATIVES</b>             |                     |                                    |
| Benzyl alcohol                   | 0.51 ml/100ml       | 0.45 to 0.55 ml/100ml              |
| Sodium hydroxy methane sulfinate | 55.9 mg/100ml       | 20.0 to 110.0 mg/100ml             |

Je certifie que le lot ci-dessus a été fabriqué, analysé et contrôlé selon les BPF et les exigences de l'AMM. Ce lot est conforme pour la mise sur le marché.  
I certify that above mentioned product has been manufactured and checked in compliance with the GMP requirements and the specifications in the marketing authorization, and is satisfactory for release for sale.

DECISION : Accepté par / Released by

Personne habilitée / Qualified Person

Date de libération / release date : 24/3/2015

LARCHER Sandrine

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Kiadva: 15/08/06

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