

Domosedan injekció AUV  
 Gysz:1718737 Lej:17/12/31  
 Kisz:5ml Me.:darab  
 DR. SZÉKELY KFT. részére

2151 Főút  
 Keleti Márton u. 19.  
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DOMOSSEDAN 10MG/ML VETINJ SML HUEN

CERTIFICATE OF ANALYSIS

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Product Number: 133975  
 Batch Number: 1718737  
 Order Number: 80715647

Date of Manufacture: 30.12.2014  
 Date of Expiration: 12.2017  
 Storage: Room temp. +15...25°C  
 Specification: Hungary (109669) 22.10.2006

| TESTS                                       | METHOD   | REQUIREMENTS             | RESULTS                  | QTY CTRL SITE |
|---|----------|--------------------------|--------------------------|---------------|
| Volume in cont.                             | 100477-2 | 5,00 ml - 5,75 ml        | 5,30 ml                  | Espp0         |
| Clarity of solution                         | 100483-2 | clear                    | clear                    | Espp0         |
| Colour of solution                          | 100494-2 | colourless               | colourless               | Espp0         |
| Particulate matter, pres. of foreign partic | 100473-2 | practically no particles | practically no particles | Espp0         |
| pH  | 100432-2 | 4,0 - 5,5                | 4,3                      | Espp0         |
| Ident., detomidine HCl, HPLC                | 100642-4 | positive                 | positive                 | Espp0         |
| Assay, detomidine HCl                       | 100642-4 | 9,5 mg/ml - 10,5 mg/ml   | 10,3 mg/ml               | Espp0         |
| Ident., methyl parahydroxybenzoate, HPLC    | 100642-4 | positive                 | positive                 | Espp0         |
| Assay methyl parahydroxybenzoate            | 100642-4 | 0,8 mg/ml - 1,1 mg/ml    | 1,0 mg/ml                | Espp0         |
| Related substances                          | 100642-4 | nmt 1 %                  | nmt 1 %                  | Espp0         |
| Test for sterility                          | 113205-1 | sterile                  | sterile                  | Espp0         |
| Bacterial endotoxins                        | 100670-2 | nmt 25 EU/ml             | nmt 25 EU/ml             | Espp0         |

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Pharmacia Zrt.  
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 Tel: 0625 64292



CERTIFICATE OF ANALYSIS

DOMOSEDAN 10MG/ML VET INJ 5ML HUEN

Product Number: 133975  
Batch Number: 1718737  
Order Number: 80715547

| TESTS | METHOD | REQUIREMENTS | RESULTS | Q.LTY. CTRL. SITE |
|-------|--------|--------------|---------|-------------------|
|-------|--------|--------------|---------|-------------------|

The batch has been manufactured, including packaging and quality control, in accordance with the requirements of the Marketing Authorisation and in compliance with current Good Manufacturing Practices. The batch complies with the agreed specification and has been released for dispatch, sale and marketing by a Qualified Person.

Electronically approved 02.06.2016 10:30:03 by a Qualified Person Oho Lehtinen

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BATCH CERTIFICATE

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DOMOSÉDAN 10MG/ML VET INJ 5ML HUEN

Product Number: 133875  
Batch Number: 1718737  
Order Number: 89715547

The batch has been manufactured, including packaging and quality control, in accordance with the requirements of the Marketing Authorization and in compliance with current Good Manufacturing Practices. The batch complies with the agreed specification and has been released for dispatch, sale and marketing by a Qualified Person.

Electronically approved 02.08.2016 10:30:03 by a Qualified Person Oloho Lehtinen

|                                  |  |  |
|----------------------------------|--|--|
| Original Department              | Manufacturing, batch number 89715547, 02.08.2016 |  |
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| Fax: +358 (0)20 315              |  |  |
|                                  | Manufacturing, batch number 89715547, 02.08.2016 |  |
|                                  | Orionin lääketieteellinen osasto                 |  |
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|                                  | Manufacturing, batch number 89715547, 02.08.2016 |  |
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Min. biz. 2016/08/11  
sz. infocsi pontok  
20-03