



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

10 June 2021  
EMA/344502/2021  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: epinephrine / lidocaine

Procedure no.: PSUSA/00001233/202009



| <b>Product Name (in authorisation country)</b>                                | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
|-------------------------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Lignospan 2% Special, oplossing voor injectie                                 | not available                       | RVG 12789                            | SEPTODONT NV-SA                           | NL                                              |
| LIGNOSPAN 20 mg/ml + 0,0125 mg/ml solution injectable.                        | not available                       | BE160352                             | SEPTODONT NV-SA                           | BE                                              |
| LIGNOSPAN 20 mg/ml + 0,0125 mg/ml Injektionslösung                            | not available                       | BE160352                             | SEPTODONT NV-SA                           | BE                                              |
| LIGNOSPAN 20 mg/ml + 0,0125 mg/ml oplossing voor injectie.                    | not available                       | BE160352                             | SEPTODONT NV-SA                           | BE                                              |
| LIGNOSPAN solution injectable.                                                | not available                       | 2007070018                           | SEPTODONT NV-SA                           | LU                                              |
| LIGNOSPAN SPECIAL                                                             | not available                       | MA 035/00101                         | SEPTODONT                                 | MT                                              |
| Lignospan Special (20 mg/12.5 microgram per ml) Solution for injection 1.8 ml | not available                       | PA 0196/013/001                      | SEPTODONT                                 | IE                                              |
| Lignospan Special (20 mg/12.5 microgram per ml) Solution for injection 2.2 ml | not available                       | PA 0196/013/002                      | SEPTODONT                                 | IE                                              |

| <b>Product Name (in authorisation country)</b>                                   | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
|----------------------------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| LIGNOSPAN SPECIAL,<br>Lignocaine Hydrochloride<br>2% and Adrenaline<br>1/80000   | not available                       | 46096/95/25-7-96                     | JOHN TSAPRAZIS S.A.                       | GR                                              |
| Xylocain adrenalin 10<br>mg/ml + 5 míkróg/ml<br>stungulyf, lausn                 | not available                       | 930153                               | ASPEN PHARMA TRADING<br>LIMITED           | IS                                              |
| Xylocain adrenalin 10<br>mg/ml+5 mikrogram/ml<br>injektionsvätska, lösning       | not available                       | 8318                                 | ASPEN PHARMA TRADING<br>LIMITED           | SE                                              |
| Xylocain adrenalin, 10<br>mg/ml + 5 mikrog/ml,<br>injeksjonsvæske,<br>oppløsning | not available                       | 2164                                 | ASPEN PHARMA TRADING<br>LIMITED           | NO                                              |
| Xylocain adrenalin, 5<br>mg/ml + 5 mikrog/ml,<br>injeksjonsvæske,<br>oppløsning  | not available                       | 2163                                 | ASPEN PHARMA TRADING<br>LIMITED           | NO                                              |
| Xylocain-Adrenalin,<br>injektionsvæske,<br>opløsning (Medicinal)                 | not available                       | 01111                                | ASPEN PHARMA TRADING<br>LIMITED           | DK                                              |
| XYLOCAINE 1 %<br>Adrénaline 1:200.000,<br>solution injectable                    | not available                       | BE371515                             | ASPEN PHARMA TRADING<br>LIMITED           | BE                                              |
| XYLOCAINE 1 %<br>Adrénaline 1:200.000,<br>solution injectable                    | not available                       | 2011030046                           | ASPEN PHARMA TRADING<br>LIMITED           | LU                                              |

| <b>Product Name (in authorisation country)</b>                       | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
|----------------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| XYLOCAINE 1%<br>Adrenaline 1:200.000,<br>Injektionslösung            | not available                       | BE371515                             | ASPEN PHARMA TRADING LIMITED              | BE                                              |
| XYLOCAINE 1%<br>Adrenaline 1:200.000,<br>Injektionslösung            | not available                       | 2011030046                           | ASPEN PHARMA TRADING LIMITED              | LU                                              |
| XYLOCAINE 1%<br>Adrenaline 1:200.000,<br>oplossing voor injectie     | not available                       | BE371515                             | ASPEN PHARMA TRADING LIMITED              | BE                                              |
| Xylocaine 1% with<br>Adrenaline (Epinephrine)<br>1:200,000           | not available                       | PL 39699/0084                        | ASPEN PHARMA TRADING LIMITED              | UK                                              |
| XYLOCAINE 10 mg/ml<br>ADRENALINE 0,005<br>mg/ml, solution injectable | not available                       | 34009 551 659 9 6                    | ASPEN PHARMA TRADING LIMITED              | FR                                              |
| XYLOCAINE 10 mg/ml<br>ADRENALINE 0,005<br>mg/ml, solution injectable | not available                       | 34009 311 521 2 5                    | ASPEN PHARMA TRADING LIMITED              | FR                                              |
| XYLOCAINE 2 %<br>Adrénaline 1:200.000,<br>solution injectable        | not available                       | BE371524                             | ASPEN PHARMA TRADING LIMITED              | BE                                              |
| XYLOCAINE 2 %<br>Adrénaline 1:200.000,<br>solution injectable        | not available                       | 2011030047                           | ASPEN PHARMA TRADING LIMITED              | LU                                              |
| XYLOCAINE 2%<br>Adrenaline 1:200.000,<br>Injektionslösung            | not available                       | BE371524                             | ASPEN PHARMA TRADING LIMITED              | BE                                              |

| <b>Product Name (in authorisation country)</b>                                         | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
|----------------------------------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| XYLOCAINE 2%<br>Adrenaline 1:200.000,<br>Injektionslösung                              | not available                       | 2011030047                           | ASPEN PHARMA TRADING LIMITED              | LU                                              |
| XYLOCAINE 2%<br>Adrenaline 1:200.000,<br>oplossing voor injectie                       | not available                       | BE371524                             | ASPEN PHARMA TRADING LIMITED              | BE                                              |
| Xylocaine 2% with<br>Adrenaline (Epinephrine)<br>(1:200 000) Solution for<br>Injection | not available                       | PA 1691/027/001                      | ASPEN PHARMA TRADING LIMITED              | IE                                              |
| Xylocaine 2% with<br>Adrenaline (Epinephrine)<br>1:200,000.                            | not available                       | PL 39699/0085                        | ASPEN PHARMA TRADING LIMITED              | XI                                              |
| XYLOCAINE 20 mg/ml<br>ADRENALINE 0,005<br>mg/ml, solution injectable                   | not available                       | 34009 311 524 1 5                    | ASPEN PHARMA TRADING LIMITED              | FR                                              |
| XYLOCAINE 20 mg/ml<br>ADRENALINE 0,005<br>mg/ml, solution injectable                   | not available                       | 34009 551 657 6 7                    | ASPEN PHARMA TRADING LIMITED              | FR                                              |
| Xylocaine® 10 mg/ml + 5<br>microgram/ml adrenaline,<br>oplossing voor injectie         | not available                       | RVG 30237                            | ASPEN PHARMA TRADING LIMITED              | NL                                              |
| Xylocaine® 20 mg/ml + 5<br>microgram/ml adrenaline,<br>oplossing voor injectie         | not available                       | RVG 30238                            | ASPEN PHARMA TRADING LIMITED              | NL                                              |

| <b>Product Name (in authorisation country)</b>                                 | <b>MRP/DCP Authorisation number</b> | <b>National Authorisation Number</b> | <b>MAH of product in the member state</b> | <b>Member State where product is authorised</b> |
|--------------------------------------------------------------------------------|-------------------------------------|--------------------------------------|-------------------------------------------|-------------------------------------------------|
| Xylonor 2% Especial 20 mg/ml + 0,0125 mg/ml solución inyectable                | not available                       | 51081                                | SEPTODONT                                 | ES                                              |
| Xylonor 2% Special, Injektionslösung                                           | not available                       | 6433437.00.00                        | SEPTODONT GMBH                            | DE                                              |
| XYLONOR 20 mg/ml + 0,0125 mg/ml soluzione iniettabile                          | not available                       | 023787068                            | LABORATOIRES SEPTODONT                    | IT                                              |
| XYLONOR 20 mg/mL ADRENALINEE AU 1/80 000, solution injectable à usage dentaire | not available                       | 3400955762942                        | LABORATOIRES SEPTODONT                    | FR                                              |