

## **Annex I**

### **List of nationally authorised medicinal products**

## **Annex IA**

### **List of nationally authorised medicinal products recommended for variation**

**A. List of nationally authorised medicinal products recommended for variation**

| <b>Member State in EEA</b> | <b>Marketing authorisation holder</b>        | <b>Product name</b>     | <b>INN/Active substance + Strength</b> | <b>Pharmaceutical form</b>        | <b>Route of Administration</b> |
|----------------------------|--|-------------------------|--|-----------------------------------|--------------------------------|
| Austria                    | Sandoz Gmbh                                  | Fosfomycin Sandoz       | Fosfomycin Disodium 10.56g Vial        | Powder For Solution For Infusion  | Intravenous Use                |
| Austria                    | Sandoz Gmbh                                  | Fosfomycin Sandoz       | Fosfomycin Disodium 5.28g Vial         | Powder For Solution For Infusion  | Intravenous Use                |
| Austria                    | Sandoz Gmbh                                  | Fosfomycin Sandoz       | Fosfomycin Disodium 1.32g Vial         | Powder For Solution For Injection | Intravenous Use                |
| Croatia                    | Infectopharm Arzneimittel Und Consilium Gmbh | Fomicyt                 | Fosfomycin 40mg/MI                     | Powder For Solution For Infusion  | Intravenous Use                |
| Denmark                    | Infectopharm Arzneimittel Und Consilium Gmbh | Fosfomycin Infectopharm | Fosfomycin 40mg/MI                     | Powder For Solution For Infusion  | Intravenous Use                |
| Finland                    | Infectopharm Arzneimittel Und Consilium Gmbh | Fosfomycin Infectopharm | Fosfomycin 40mg/MI                     | Powder For Solution For Infusion  | Intravenous Use                |
| France                     | Panpharma                                    | Fosfomycine Panpharma   | Fosfomycin 1g Bottle                   | Powder For Solution For Injection | Intravenous Use                |
| France                     | Panpharma                                    | Fosfomycine Panpharma   | Fosfomycin 1g Vial                     | Powder For Solution For Injection | Intravenous Use                |
| France                     | Panpharma                                    | Fosfomycine Panpharma   | Fosfomycin 4g Bottle                   | Powder For Solution For Injection | Intravenous Use                |

| <b>Member State in EEA</b> | <b>Marketing authorisation holder</b>        | <b>Product name</b>     | <b>INN/Active substance + Strength</b> | <b>Pharmaceutical form</b>                    | <b>Route of Administration</b> |
|----------------------------|--|-------------------------|--|---|--------------------------------|
| France                     | Sanofi-Aventis France                        | Fosfocine Iv            | Fosfomycin Sodium 1g Vial              | Powder And Solvent For Solution For Injection | Intravenous Use                |
| France                     | Sanofi-Aventis France                        | Fosfocine Iv            | Fosfomycin Sodium 4g Vial              | Powder And Solvent For Solution For Injection | Intravenous Use                |
| Germany                    | Infectopharm Arzneimittel Und Consilium Gmbh | Fosfomycin Infectopharm | Fosfomycin Sodium 10.56g/10.76g        | Powder For Solution For Infusion              | Intravenous Use                |
| Germany                    | Infectopharm Arzneimittel Und Consilium Gmbh | Infectofos              | Fosfomycin Sodium 10.56g/10.76g        | Powder For Solution For Infusion              | Intravenous Use                |
| Germany                    | Infectopharm Arzneimittel Und Consilium Gmbh | Infectofos              | Fosfomycin Sodium 2.64g/2.69g          | Powder For Solution For Infusion              | Intravenous Use                |
| Germany                    | Infectopharm Arzneimittel Und Consilium Gmbh | Infectofos              | Fosfomycin Sodium 3.96g/4.04g          | Powder For Solution For Infusion              | Intravenous Use                |
| Germany                    | Infectopharm Arzneimittel Und Consilium Gmbh | Infectofos              | Fosfomycin Sodium 6.6g/6.73g           | Powder For Solution For Infusion              | Intravenous Use                |
| Greece                     | Infectopharm Arzneimittel Und Consilium Gmbh | Fomicyt                 | Fosfomycin 40mg/MI                     | Powder For Solution For Infusion              | Intravenous Use                |
| Ireland                    | Infectopharm Arzneimittel Und Consilium Gmbh | Fomicyt                 | Fosfomycin 40mg/MI                     | Powder For Solution For Infusion              | Intravenous Use                |
| Italy                      | Infectopharm Arzneimittel Und Consilium Gmbh | Infectofos              | Fosfomycin 40mg/MI                     | Powder For Solution For Infusion              | Intravenous Use                |

| <b>Member State in EEA</b> | <b>Marketing authorisation holder</b>        | <b>Product name</b>                                | <b>INN/Active substance + Strength</b> | <b>Pharmaceutical form</b>                    | <b>Route of Administration</b> |
|----------------------------|--|--|--|---|--------------------------------|
| Netherlands                | Infectopharm Arzneimittel Und Consilium Gmbh | Fomicyt  | Fosfomicin 40mg/MI                     | Powder For Solution For Infusion              | Intravenous Use                |
| Norway                     | Infectopharm Arzneimittel Und Consilium Gmbh | Fosfomicin Infectopharm                            | Fosfomicin 40mg/MI                     | Powder For Solution For Infusion              | Intravenous Use                |
| Poland                     | Infectopharm Arzneimittel Und Consilium Gmbh | Infectofos   | Fosfomicin 40mg/MI                     | Powder For Solution For Infusion              | Intravenous Use                |
| Spain                      | Laboratorios Ern, S.A.                       | Fosfocina Intravenosa                              | Fosfomicin Disodium 1g Vial            | Powder And Solvent For Solution For Injection | Intravenous Use                |
| Spain                      | Laboratorios Ern, S.A.                       | Fosfocina Intravenosa                              | Fosfomicin Disodium 4g Vial            | Powder For Solution For Injection             | Intravenous Use                |
| Spain                      | Laboratorios Ern, S.A.                       | Fosfomicina Intravenosa Level                      | Fosfomicin 4g Vial                     | Powder For Solution For Injection             | Intravenous Use                |
| Sweden                     | Infectopharm Arzneimittel Und Consilium Gmbh | Fosfomicin Infectopharm                            | Fosfomicin 40mg/MI                     | Powder For Solution For Infusion              | Intravenous Use                |
| United Kingdom             | Infectopharm Arzneimittel Und Consilium Gmbh | Fomicyt  | Fosfomicin 40mg/MI                     | Powder For Solution For Infusion              | Intravenous Use                |
| United Kingdom             | Infectopharm Arzneimittel Und Consilium Gmbh | Fosfomicin Infectopharm Arzneimittel Und Consilium | Fosfomicin 40mg/MI                     | Powder For Solution For Infusion              | Intravenous Use                |

## **Annex IB**

**List of nationally authorised medicinal products recommended for variation and subject to conditions on the marketing authorisation**

**B. List of nationally authorised medicinal products recommended for variation and subject to conditions on the marketing authorisation**

| <b>Member State in EEA</b> | <b>Marketing authorisation holder</b>     | <b>Product name</b> | <b>INN/Active substance + Strength</b> | <b>Pharmaceutical form</b>    | <b>Route of Administration</b> |
|----------------------------|---|---------------------|--|-------------------------------|--------------------------------|
| Austria                    | Zambon S.P.A.                             | Monuril             | Fosfomycin Trometamol<br>5.631g Bag    | Granules For Oral<br>Solution | Oral Use                       |
| Austria                    | Dr. Friedrich Eberth<br>Arzneimittel Gmbh | Fosfomycin Eberth   | Fosfomycin Trometamol<br>5.631g/8g     | Granules For Oral<br>Solution | Oral Use                       |
| Austria                    | Aristo Pharma Gmbh (Art 57)               | Cystium             | Fosfomycin Trometamol<br>5631mg Sachet | Powder For Oral<br>Solution   | Oral Use                       |
| Belgium                    | Zambon Nv                                 | Monuril             | Fosfomycin Trometamol<br>5.631g Sachet | Granules For Oral<br>Solution | Oral Use                       |
| Bulgaria                   | Zentiva, K.S.                             | Фосфомицин Зентива  | Fosfomycin Trometamol<br>5.631g Sachet | Granules For Oral<br>Solution | Oral Use                       |
| Bulgaria                   | Adipharm Ead                              | Фосфосептик         | Fosfomycin Trometamol<br>5631mg Sachet | Granules For Oral<br>Solution | Oral Use                       |
| Bulgaria                   | Zambon S.P.A.                             | Монурал             | Fosfomycin Trometamol<br>5.631g Sachet | Granules For Oral<br>Solution | Oral Use                       |
| Bulgaria                   | Zentiva, K.S.                             | Фосфомицин Зентива  | Fosfomycin Trometamol<br>5.631g Sachet | Granules For Oral<br>Solution | Oral Use                       |
| Croatia                    | Pharmas D.O.O.                            | Urifos              | Fosfomycin 3g Sachet                   | Granules For Oral<br>Solution | Oral Use                       |
| Croatia                    | Jadran-Galenski Laboratorij<br>D.D.       | Fosfomicin Jgl      | Fosfomycin Trometamol 3g<br>Bag        | Granules For Oral<br>Solution | Oral Use                       |

| <b>Member State in EEA</b> | <b>Marketing authorisation holder</b> | <b>Product name</b>              | <b>INN/Active substance + Strength</b> | <b>Pharmaceutical form</b>           | <b>Route of Administration</b> |
|----------------------------|---------------------------------------|----------------------------------|--|--------------------------------------|--------------------------------|
| Croatia                    | Sandoz D.O.O.                         | Urinex                           | Fosfomicin Trometamol 3mg Sachet       | Granules For Oral Solution           | Oral Use                       |
| Czech Republic             | Exeltis Czech S.R.O.                  | Urifos                           | Fosfomicin Trometamol 5631mg Sachet    | Granules For Oral Solution           | Oral Use                       |
| Czech Republic             | Apogepha Arzneimittel Gmbh            | Rapidnorm                        | Fosfomicin Trometamol 5631mg Sachet    | Granules For Oral Solution           | Oral Use                       |
| Denmark                    | Zambon S.P.A.                         | Monurol                          | Fosfomicin 2g Units                    | Granules For Oral Solution           | Oral Use                       |
| Denmark                    | Zambon S.P.A.                         | Monurol                          | Fosfomicin 3g Units                    | Granules For Oral Solution           | Oral Use                       |
| Estonia                    | Zentiva, K.S.                         | Fosfomicin Zentiva               | Fosfomicin Trometamol 5.631g Sachet    | Granules For Oral Solution           | Oral Use                       |
| Estonia                    | Zentiva, K.S.                         | Fosfomicin Zentiva               | Fosfomicin Trometamol 5.631g Sachet    | Granules For Oral Solution           | Oral Use                       |
| France                     | Mylan S.A.S                           | Fosfomycine Adultes Mylan Pharma | Fosfomicin Trometamol 5.631g Sachet    | Granules For Oral Solution           | Oral Use                       |
| France                     | Ranbaxy Pharmacie Generiques          | Fosfomycine Ranbaxy              | Fosfomicin Trometamol 5631mg           | Granules For Oral Solution In Sachet | Oral Use                       |
| France                     | Cristers                              | Fosfomycine Adultes Cristers     | Fosfomicin Trometamol 5.631g Sachet    | Granules For Oral Solution           | Oral Use                       |
| France                     | Therabel Lucien Pharma S.A.           | Uridoz                           | Fosfomicin Trometamol 5.631g Sachet    | Granules For Oral Solution In Sachet | Oral Use                       |



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|----------------------------|---------------------------------------|------------------------------|--|--------------------------------------|--------------------------------|
| France                     | Laboratoires Urgo Healthcare          | Fosfomycine Adultes Urgo     | Fosfomycin Trometamol 5.631g Sachet    | Granules For Oral Solution           | Oral Use                       |
| France                     | Eg Labo Laboratoires Eurogenerics     | Fosfomycine Eg               | Fosfomycin 3g/8g                       | Granules For Oral Solution           | Oral Use                       |
| France                     | Laboratoires Gerda                    | Fosfomycine Adultes Gerda    | Fosfomycin Trometamol 5.631g Sachet    | Granules For Oral Solution           | Oral Use                       |
| France                     | Arrow Generiques                      | Fosfomycine Adultes Arrow    | Fosfomycin Trometamol 5.631g Sachet    | Granules For Oral Solution           | Oral Use                       |
| France                     | Zentiva France                        | Fosfomycine Adultes Zentiva  | Fosfomycin Trometamol 3g Sachet        | Granules For Oral Solution           | Oral Use                       |
| France                     | Nexmed Pharma                         | Fosfopharm                   | Fosfomycin Trometamol 5.631g Sachet    | Granules For Oral Solution In Sachet | Oral Use                       |
| France                     | Evolupharm                            | Fosfomycine Adultes Evolugen | Fosfomycin Trometamol 5.631g Sachet    | Granules For Oral Solution           | Oral Use                       |
| France                     | Zambon France S.A.                    | Fostrofemge                  | Fosfomycin Trometamol 5.631g Sachet    | Granules For Oral Solution In Sachet | Oral Use                       |
| France                     | Zambon France S.A.                    | Gynofostrome                 | Fosfomycin Trometamol 5.631g Sachet    | Granules For Oral Solution In Sachet | Oral Use                       |
| France                     | Zambon France S.A.                    | Monuril                      | Fosfomycin Trometamol 5.631g Sachet    | Granules For Oral Solution In Sachet | Oral Use                       |
| France                     | Biogaran                              | Fosfomycine Biogaran         | Fosfomycin Trometamol 5.631g Sachet    | Granules For Oral Solution           | Oral Use                       |

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|----------------------------|---|-----------------------------------|--|---|--------------------------------|
| France                     | Sanofi-Aventis France                     | Fosfomycine Adultes<br>Zentiva    | Fosfomycin Trometamol<br>5.631g Sachet | Granules For Oral<br>Solution           | Oral Use                       |
| France                     | Teva Santé                                | Fosfomycine Adultes<br>Teva Sante | Fosfomycin Trometamol<br>5.631g Sachet | Granules For Oral<br>Solution           | Oral Use                       |
| France                     | Sandoz                                    | Fosfomycine Sandoz                | Fosfomycin Trometamol<br>5.631g Sachet | Granules For Oral<br>Solution In Sachet | Oral Use                       |
| France                     | Laboratoires Neitum                       | Urofast Adultes                   | Fosfomycin Trometamol<br>5.631g Units  | Oral Solution                           | Oral                           |
| Germany                    | Aliud Pharma Gmbh                         | Fosfomycin Al                     | Fosfomycin Trometamol<br>5.631g Dose   | Granules For Oral<br>Solution           | Oral Use                       |
| Germany                    | Zambon Gmbh                               | Monuril                           | Fosfomycin Trometamol<br>5.631g Sachet | Granules For Oral<br>Solution           | Oral Use                       |
| Germany                    | Uropharm Ag                               | Fosfomycin Uropharm               | Fosfomycin Trometamol<br>5.631g Sachet | Granules For Oral<br>Solution           | Oral Use                       |
| Germany                    | Dr. Friedrich Eberth<br>Arzneimittel Gmbh | Fosfomycin Eberth                 | Fosfomycin Trometamol<br>5.631g/8g     | Granules For Oral<br>Solution           | Oral Use                       |
| Germany                    | Aristo Pharma Gmbh (Art 57)               | Fosfomycin Aristo                 | Fosfomycin Trometamol<br>5631mg Bag    | Powder For Oral<br>Solution             | Oral Use                       |
| Germany                    | Apogepha Arzneimittel Gmbh                | Fosfuro                           | Fosfomycin Trometamol<br>5.631g Sachet | Granules For Oral<br>Solution           | Oral Use                       |
| Greece                     | Vocate Φαρμακευτική Αε                    | Fosfocin                          | Fosfomycin Trometamol<br>5.631g Sachet | Granules For Oral<br>Solution           | Oral Use                       |

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|----------------------------|---------------------------------------|---------------------------------|--|----------------------------|--------------------------------|
| Hungary                    | Exeltis Magyarország Kft.             | Fosfomicin Exeltis              | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral Solution | Oral Use                       |
| Hungary                    | Zambon S.P.A.                         | Monural                         | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral Solution | Oral Use                       |
| Ireland                    | Zambon S.P.A.                         | Monuril                         | Fosfomicin Trometamol 3g<br>Units      | Granules For Oral Solution | Oral Use                       |
| Italy                      | Mylan S.P.A.                          | Fosfomicina Adulti<br>Mylan     | Fosfomicin 3g Sachet                   | Granules For Oral Solution | Oral Use                       |
| Italy                      | Ranbaxy Italia S.P.A.                 | Fosfomicina Adulti<br>Ranbaxy   | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral Solution | Oral Use                       |
| Italy                      | Ranbaxy Italia S.P.A.                 | Fosfomicina Adulti<br>Ranbaxy   | Fosfomicin Trometamol<br>5.631g/MI     | Granules For Oral Solution | Oral Use                       |
| Italy                      | Ranbaxy Italia S.P.A.                 | Fosfomicina Bambini<br>Ranbaxy  | Fosfomicin Trometamol<br>3.754g Sachet | Granules For Oral Solution | Oral Use                       |
| Italy                      | Dymalife Pharmaceutical S.R.L.        | Interfos Adulti                 | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral Solution | Oral Use                       |
| Italy                      | Eg S.P.A.                             | Fosfomicina Eg                  | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral Solution | Oral Use                       |
| Italy                      | Aurobindo Pharma (Italia)<br>S.R.L.   | Fosfomicina Adulti<br>Aurobindo | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral Solution | Oral Use                       |
| Italy                      | Zentiva Italia Srl                    | Fosfomicina Zentiva             | Fosfomicin Trometamol<br>3.754g Sachet | Granules For Oral Solution | Oral Use                       |

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|----------------------------|---------------------------------------|-------------------------------|--|----------------------------|--------------------------------|
| Italy                      | Zentiva Italia Srl                    | Fosfomicina Zentiva           | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral Solution | Oral Use                       |
| Italy                      | S.F. Group Srl                        | Infeur Adulti                 | Fosfomicin 3g Bag                      | Granules For Oral Solution | Oral Use                       |
| Italy                      | Doc Generici S.R.L.                   | Fosfomicina Adulti Doc        | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral Solution | Oral Use                       |
| Italy                      | Zambon Italia S.R.L.                  | Monuril                       | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral Solution | Oral Use                       |
| Italy                      | Zambon Italia S.R.L.                  | Monuril Bambini               | Fosfomicin Trometamol<br>3.754g Sachet | Granules For Oral Solution | Oral Use                       |
| Italy                      | Zambon Italia S.R.L.                  | Monuril Bambini               | Fosfomicin Trometamol<br>3.754g Sachet | Granules For Oral Solution | Oral Use                       |
| Italy                      | Pensa Pharma S.P.A.                   | Fosfomicina Pensa             | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral Solution | Oral Use                       |
| Italy                      | So.Se.Pharm S.R.L.                    | Berny                         | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral Solution | Oral Use                       |
| Italy                      | Aristo Pharma Gmbh (Art 57)           | Fosfomicina Adulti<br>Aristo  | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral Solution | Oral Use                       |
| Italy                      | Aristo Pharma Gmbh (Art 57)           | Fosfomicina Bambini<br>Aristo | Fosfomicin Trometamol<br>3.754g        | Granules For Oral Solution | Oral Use                       |
| Italy                      | Zentiva Italia Srl                    | Fosfomicina Zentiva           | Fosfomicin Trometamol<br>3.754g Sachet | Granules For Oral Solution | Oral Use                       |

| <b>Member State in EEA</b> | <b>Marketing authorisation holder</b> | <b>Product name</b>           | <b>INN/Active substance + Strength</b> | <b>Pharmaceutical form</b>           | <b>Route of Administration</b> |
|----------------------------|---------------------------------------|-------------------------------|--|--------------------------------------|--------------------------------|
| Italy                      | Zentiva Italia Srl                    | Fosfomicina Zentiva           | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral Solution           | Oral Use                       |
| Italy                      | Ratiopharm Gmbh                       | Fosfomicina Adulti Ratiopharm | Fosfomicin 3g Sachet                   | Granules For Oral Solution           | Oral Use                       |
| Italy                      | Sandoz S.P.A.                         | Fosfomicina Adulti Sandoz     | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral Solution           | Oral Use                       |
| Italy                      | Sandoz S.P.A.                         | Fosfomicina Bambini Sandoz    | Fosfomicin Trometamol<br>3.754g Sachet | Granules For Oral Solution           | Oral Use                       |
| Italy                      | C&g Farmaceutici                      | Danifos Adulti                | Fosfomicin Trometamol<br>5.631g Packet | Granules For Oral Solution           | Oral Use                       |
| Lithuania                  | Zentiva, K.S.                         | Fosfomicin Zentiva            | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral Solution           | Oral Use                       |
| Lithuania                  | Zentiva, K.S.                         | Fosfomicin Zentiva            | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral Solution           | Oral Use                       |
| Luxembourg                 | Zambon Nv                             | Monuril                       | Fosfomicin Trometamol<br>5.631g        | Granules For Oral Solution           | Oral Use                       |
| Malta                      | Zambon S.P.A.                         | Monuril                       | Fosfomicin Trometamol 3g Units         | Granules For Oral Solution           | Oral Use                       |
| Netherlands                | Zambon Nederland B.V.                 | Monuril                       | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral Solution           | Oral Use                       |
| Poland                     | Exeltis Poland Sp. Z O.O.             | Afastural                     | Fosfomicin Trometamol 3g Sachet        | Granules For Oral Solution In Sachet | Oral                           |

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|----------------------------|--|---------------------------|--|--------------------------------------|--------------------------------|
| Poland                     | Exeltis Poland Sp. Z O.O.  | Afastural                 | Fosfomicin Trometamol<br>5631mg Sachet | Granules For Oral Solution           | Oral Use                       |
| Poland                     | Symphar Sp. Z O.O.   | Symural                   | Fosfomicin 3g Sachet                   | Granules For Oral Solution           | Oral Use                       |
| Poland                     | Zambon S.P.A.  | Monural                   | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral Solution           | Oral Use                       |
| Poland                     | Labiana Pharmaceuticals,<br>S.L.U.   | Uromaste                  | Fosfomicin 3g Sachet                   | Granules For Oral Solution           | Oral Use                       |
| Portugal                   | Pharma Bavaria Internacional<br>Portugal Unip. Lda                             | Fosmol                    | Fosfomicin Trometamol<br>5631mg Sachet | Granules For Oral Solution           | Oral Use                       |
| Portugal                   | Pharmakern Portugal –<br>Produtos Farmacêuticos,<br>Sociedade Unipessoal, Lda. | Fosfomicina<br>Pharmakern | Fosfomicin 3g Sachet                   | Granules For Oral Solution In Sachet | Oral Use                       |
| Portugal                   | Generis Farmacêutica, S.A.   | Fosfomicina Generis       | Fosfomicin 3000mg Sachet               | Granules For Oral Solution           | Oral Use                       |
| Portugal                   | Zambon - Produtos<br>Farmacêuticos, Lda.                                       | Monuril                   | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral Solution           | Oral Use                       |
| Portugal                   | Zambon - Produtos<br>Farmacêuticos, Lda.                                       | Monuril                   | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral Solution           | Oral Use                       |
| Portugal                   | Tolife - Produtos<br>Farmacêuticos, S.A.                                       | Fosfomicina Tolife        | Fosfomicin Trometamol<br>3000mg Sachet | Granules For Oral Solution           | Oral Use                       |

| <b>Member State in EEA</b> | <b>Marketing authorisation holder</b>  | <b>Product name</b>        | <b>INN/Active substance + Strength</b> | <b>Pharmaceutical form</b>             | <b>Route of Administration</b> |
|----------------------------|--|----------------------------|--|--|--------------------------------|
| Romania                    | Labiana Pharmaceuticals S.L.U.         | Fosfomicina Labiana        | Fosfomicin 3g Sachet                   | Granules For Oral Solution In Sachet   | Oral Use                       |
| Romania                    | Zambon S.P.A.                          | Monural                    | Fosfomicin Trometamol 5.631g Sachet    | Granules For Oral Solution             | Oral Use                       |
| Slovakia                   | Exeltis Slovakia                       | Afastural                  | Fosfomicin Trometamol 3g Sachet        | Granules For Oral Suspension In Sachet | Oral                           |
| Slovakia                   | Zambon S.P.A.                          | Monural                    | Fosfomicin 3g Units                    | Granules For Oral Solution             | Oral Use                       |
| Slovakia                   | Dr. Friedrich Eberth Arzneimittel GmbH | Fosfomicin Eberth          | Fosfomicin Trometamol 5.631g/8g        | Granules For Oral Solution             | Oral Use                       |
| Spain                      | Kern Pharma, S.L.                      | Fosfomicina Kern Pharma    | Fosfomicin Trometamol 5.631g Sachet    | Granules For Oral Solution             | Oral Use                       |
| Spain                      | Labiana Pharmaceuticals S.L.U.         | Fosfomicina Labiana Pharma | Fosfomicin 3g Sachet                   | Granules For Oral Solution             | Oral Use                       |
| Spain                      | Labiana Pharmaceuticals S.L.U.         | Fosfomicina Labiana        | Fosfomicin 3g Sachet                   | Granules For Oral Solution In Sachet   | Oral Use                       |
| Spain                      | Laboratorios Q Pharma S.L.             | Solufos                    | Fosfomicin Calcium 703mg Capsule       | Capsule, Hard                          | Oral Use                       |
| Spain                      | Laboratorio Stada, S.L.                | Fosfomicina Stada          | Fosfomicin 3g/8g                       | Granules For Oral Solution             | Oral Use                       |
| Spain                      | Farmalider, S.A.                       | Fosfomicina Farmalider     | Fosfomicin Trometamol 5.631g Sachet    | Granules For Oral Solution             | Oral Use                       |

| <b>Member State in EEA</b> | <b>Marketing authorisation holder</b> | <b>Product name</b>                | <b>INN/Active substance + Strength</b> | <b>Pharmaceutical form</b>              | <b>Route of Administration</b> |
|----------------------------|---------------------------------------|------------------------------------|--|---|--------------------------------|
| Spain                      | Arafarma Group, S.A                   | Uroseptic                          | Fosfomicin Trometamol<br>5.631g Sachet | Powder For Oral<br>Solution In Sachet   | Oral Use                       |
| Spain                      | Zambon, S.A.U.                        | Monurol                            | Fosfomicin 3g Sachet                   | Granules For Oral<br>Solution In Sachet | Oral Use                       |
| Spain                      | Qualigen, S.L.                        | Fosfomicina Qualigen               | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral<br>Solution           | Oral Use                       |
| Spain                      | Laboratorios Ern, S.A.                | Fosfocina                          | Fosfomicin Calcium 500mg<br>Capsule    | Capsule, Hard                           | Oral Use                       |
| Spain                      | Laboratorios Ern, S.A.                | Fosfocina                          | Fosfomicin Calcium<br>250mg/5ml        | Powder For Oral<br>Suspension           | Oral Use                       |
| Spain                      | Abamed Pharma, S.L.                   | Fosfomicina Abamed<br>Pharma       | Fosfomicin 3g Sachet                   | Granules For Oral<br>Solution           | Oral Use                       |
| Spain                      | Abamed Pharma, S.L.                   | Fosfomicina Abamed                 | Fosfomicin 3g Sachet                   | Granules For Oral<br>Solution In Sachet | Oral Use                       |
| Spain                      | Pensa Pharma, S.A.U.                  | Fosfomicina Pensa                  | Fosfomicin Trometamol<br>5.631g Sachet | Granules For Oral<br>Solution           | Oral Use                       |
| Spain                      | Tarbis Farma, S.L.                    | Fosfomicina Tarbis                 | Fosfomicin Trometamol 3g<br>Sachet     | Granules For Oral<br>Solution In Sachet | Oral Use                       |
| Sweden                     | Zambon S.p.A                          | Monurelle                          | Fosfomicin 3g Dose                     | Granules For Oral<br>Solution           | Oral Use                       |
| United Kingdom             | Exeltis Poland Sp. Z O.O.             | Fosfomicin<br>Temapharm Sp. Z O.O. | Fosfomicin Trometamol<br>5631mg Sachet | Granules For Oral<br>Solution           | Oral Use                       |



| <b>Member State in EEA</b> | <b>Marketing authorisation holder</b> | <b>Product name</b>                | <b>INN/Active substance + Strength</b> | <b>Pharmaceutical form</b> | <b>Route of Administration</b> |
|----------------------------|---------------------------------------|------------------------------------|--|----------------------------|--------------------------------|
| United Kingdom             | Mercury Pharmaceuticals Ltd.          | Fosfomicin Mercury Pharmaceuticals | Fosfomicin Trometamol 5631mg Sachet    | Granules For Oral Solution | Oral Use                       |
| United Kingdom             | Zambon S.P.A.                         | Monuril                            | Fosfomicin Trometamol 5.631g Sachet    | Granules For Oral Solution | Oral Use                       |

## **Annex IC**

### **List of nationally authorised medicinal products recommended for suspension**

**C. List of nationally authorised medicinal products recommended for suspension**

| <b>Member State in EEA</b> | <b>Marketing authorisation holder</b>                                    | <b>Product name</b>    | <b>INN/Active substance + Strength</b> | <b>Pharmaceutical form</b>           | <b>Route of Administration</b> |
|----------------------------|--|------------------------|--|--------------------------------------|--------------------------------|
| Croatia                    | Pharmas D.O.O.   | Urifos                 | Fosfomicin 2g Sachet                   | Granules For Oral Solution           | Oral Use                       |
| Estonia                    | Zentiva, K.S.  | Fosfomicin Zentiva     | Fosfomicin 2g Sachet                   | Granules For Oral Solution In Sachet | Oral Use                       |
| Lithuania                  | Zentiva, K.S.  | Fosfomicin Zentiva     | Fosfomicin Trometamol 3.754g Sachet    | Granules For Oral Solution           | Oral Use                       |
| Lithuania                  | Zentiva, K.S.  | Fosfomicin Zentiva     | Fosfomicin Trometamol 3.754g Sachet    | Granules For Oral Solution           | Oral Use                       |
| Netherlands                | Zambon Nederland B.V.  | Monuril                | Fosfomicin Trometamol 3.754g Sachet    | Granules For Oral Solution           | Oral Use                       |
| Poland                     | Labiana Pharmaceuticals, S.L.U.  | Uromaste               | Fosfomicin 2g Sachet                   | Granules For Oral Solution           | Oral Use                       |
| Poland                     | Zambon S.P.A.  | Monural                | Fosfomicin Trometamol 3.754g Sachet    | Granules For Oral Solution           | Oral Use                       |
| Portugal                   | Pharmakern Portugal – Produtos Farmacêuticos, Sociedade Unipessoal, Lda. | Fosfomicina Pharmakern | Fosfomicin 2g Sachet                   | Granules For Oral Solution In Sachet | Oral Use                       |
| Portugal                   | Generis Farmacêutica, S.A.   | Fosfomicina Generis    | Fosfomicin 2000mg Sachet               | Granules For Oral Solution           | Oral Use                       |

| <b>Member State in EEA</b> | <b>Marketing authorisation holder</b> | <b>Product name</b>        | <b>INN/Active substance + Strength</b> | <b>Pharmaceutical form</b>           | <b>Route of Administration</b> |
|----------------------------|---------------------------------------|----------------------------|--|--------------------------------------|--------------------------------|
| Portugal                   | Zambon - Produtos Farmacêuticos, Lda. | Monuril                    | Fosfomicin Trometamol<br>3.754g Sachet | Granules For Oral Solution           | Oral Use                       |
| Romania                    | Labiana Pharmaceuticals S.L.U.        | Fosfomicina Labiana        | Fosfomicin 2g Sachet                   | Granules For Oral Solution In Sachet | Oral Use                       |
| Romania                    | Zambon S.P.A.                         | Monural Pediatric          | Fosfomicin Trometamol<br>3.754g Sachet | Granules For Oral Solution           | Oral Use                       |
| Spain                      | Labiana Pharmaceuticals S.L.U.        | Fosfomicina Labiana Pharma | Fosfomicin 2g Sachet                   | Granules For Oral Solution           | Oral Use                       |
| Spain                      | Labiana Pharmaceuticals S.L.U.        | Fosfomicina Labiana        | Fosfomicin 2g Sachet                   | Granules For Oral Solution In Sachet | Oral Use                       |
| Spain                      | Arafarma Group, S.A                   | Uroseptic                  | Fosfomicin Trometamol<br>3.754g Sachet | Powder For Oral Solution In Sachet   | Oral Use                       |
| Spain                      | Zambon, S.A.U.                        | Monurol                    | Fosfomicin 2g Sachet                   | Granules For Oral Solution In Sachet | Oral Use                       |
| Spain                      | Abamed Pharma, S.L.                   | Fosfomicina Abamed         | Fosfomicin 2g Sachet                   | Granules For Oral Solution In Sachet | Oral Use                       |
| Spain                      | Abamed Pharma, S.L.                   | Fosfomicina Abamed Pharma  | Fosfomicin 2g Sachet                   | Granules For Oral Solution In Sachet | Oral Use                       |
| Spain                      | Tarbis Farma, S.L.                    | Fosfomicina Tarbis         | Fosfomicin Trometamol 2g Sachet        | Granules For Oral Solution In Sachet | Oral Use                       |

| <b>Member State in EEA</b> | <b>Marketing authorisation holder</b> | <b>Product name</b>             | <b>INN/Active substance + Strength</b>                         | <b>Pharmaceutical form</b>                    | <b>Route of Administration</b> |
|----------------------------|---------------------------------------|---------------------------------|--|---|--------------------------------|
| Spain                      | Laboratorios Ern, S.A.                | Fosfocina Intramuscular         | Fosfomicin Disodium 1g Vial, Lidocaine Hydrochloride 30mg Vial | Powder And Solvent For Solution For Injection | Intramuscular Use              |
| Spain                      | Laboratorios Ern, S.A.                | Fosfomicina Intramuscular Level | Fosfomicin 1g Vial   | Powder And Solvent For Solution For Injection | Intramuscular Use              |