



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

8 February 2024  
EMA/61133/2024  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: misoprostol (gastrointestinal indication)

Procedure no.: PSUSA/00010291/202306

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**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

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An agency of the European Union



| Product full name<br>(in authorisation country) | MRP/DCP or CP Authorisation<br>number | National Authorisation<br>Number | MAH of product in the member state                | Member State<br>where product<br>is authorised |
|-------------------------------------------------|---------------------------------------|----------------------------------|---------------------------------------------------|------------------------------------------------|
| Cyprostol® - Tabletten                          | not available                         | 1-19557                          | PFIZER CORPORATION AUSTRIA<br>GESELLSCHAFT M.B.H. | AT                                             |
| Cytotec 0,2 mg comprimidos                      | not available                         | 8628636                          | LABORATÓRIOS PFIZER, LDA.                         | PT                                             |
| Cytotec 0,2 mg comprimidos                      | not available                         | 8628628                          | LABORATÓRIOS PFIZER, LDA.                         | PT                                             |
| Cytotec 0,2 mg tabletit                         | not available                         | 10710                            | PFIZER OY                                         | FI                                             |
| Cytotec 0,2 mg tabletter                        | not available                         | 10710                            | PFIZER OY                                         | FI                                             |
| Cytotec 0,2 mg tabletter                        | not available                         | 00-8063                          | PFIZER AS                                         | NO                                             |
| Cytotec 0,2 mg tabletter                        | not available                         | 11033                            | PFIZER AB                                         | SE                                             |
| Cytotec 0,2 mg töflur.                          | not available                         | 880109                           | PFIZER APS                                        | IS                                             |
| CYTOTEC 200 mcg compresse                       | not available                         | 026488015                        | PFIZER S.R.L.                                     | IT                                             |
| Cytotec 200 mcg δισκία                          | not available                         | 40410/07/19-5-2008               | PFIZER HELLAS, A.E.                               | GR                                             |
| Cytotec 200 microgram tablets                   | not available                         | PL 00057/0956                    | PFIZER LIMITED                                    | XI                                             |
| Cytotec 200 microgram Tablets.                  | not available                         | PA 822/118/1                     | PFIZER HEALTHCARE IRELAND                         | IE                                             |
| CYTOTEC 200 microgram tabletten.                | not available                         | BE134093                         | PFIZER S.A. (BELGIUM)                             | BE                                             |
| CYTOTEC 200 microgrammes,<br>comprimés.         | not available                         | BE134093                         | PFIZER S.A. (BELGIUM)                             | BE                                             |
| CYTOTEC 200 microgrammes,<br>comprimés.         | not available                         | 2007079404                       | PFIZER S.A.                                       | LU                                             |

|                                     |               |            |                       |    |
|-------------------------------------|---------------|------------|-----------------------|----|
| Cytotec 200 microgramos comprimidos | not available | 58.403     | PFIZER, S.L.          | ES |
| Cytotec 200 Mikrogramm Tabletten    | not available | BE134093   | PFIZER S.A. (BELGIUM) | BE |
| Cytotec 200 Mikrogramm Tabletten    | not available | 2007079404 | PFIZER S.A. (BELGIUM) | LU |
| Cytotec, 200 µg, tabletki           | not available | R/2716     | PFIZER EUROPE MA EEIG | PL |
| Cytotec, tabletten 200 microgram    | not available | RVG 13724  | PFIZER B.V.           | NL |
| Cytotec, tabletter                  | not available | 11978      | PFIZER APS            | DK |