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| **Obrazac prijave o stavljanju lijeka u promet**  ***Notification of placing the medicinal product on the market*** |

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| **PODACI O LIJEKU**  ***PRODUCT DETAILS*** | |
| Naziv lijeka  *Product name* |  |
| Broj odobrenja lijeka  *Marketing authorisation number* |  |
| Pakiranje(a) stavljeno(a) u promet  *Packaging placed on the market* |  |
| Broj odobrenja pakiranja  *Authorisation number for packaging* |  |
| Datum odobrenja  *Marketing authorisation date* |  |
| Djelatna(e) tvar(i)  *Active substance(s)* |  |
| Farmaceutski oblik  *Pharmaceutical form* |  |
| Jačina  *Strength* |  |
| Naziv i adresa nositelja odobrenja  (naziv i adresa nositelja potvrde za paralelni promet lijeka, ako je primjenjivo)  *Marketing Authorisation Holder*  *(Parallel Distributor, if applicable)* |  |

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| **DATUM STAVLJANJA LIJEKA U PROMET**  prema definiciji u 1. poglavlju (odjeljak 2.4.2) volumena 2A [Uputa za podnositelje](https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-2/vol2a_chap1_en.pdf)  (za paralelni promet lijeka odgovara datumu unošenja lijeka u Republiku Hrvatsku)  ***DATE OF PLACING ON THE MARKET***  *as defined in Chapter 1 (section 2.4.2) of volume 2A of the* [*Notice to Applicants*](https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-2/vol2a_chap1_en.pdf)  *(for parallel distribution corresponds to the date of entry of the medicinal product into the Republic of Croatia)* |
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| **PODACI O PRIJAVITELJU**  ***DETAILS OF NOTIFYING PERSON*** | |
| Naziv i adresa tvrtke (nositelj odobrenja, predstavnik nositelja odobrenja za Republiku Hrvatsku, nositelj potvrde za paralelni promet lijeka)  *Company name and address (MAH, duly authorised representative, parallel distributor)* |  |
| Ime i prezime osobe koja ispunjava obrazac  *Name of the person completing the form* |  |
| Adresa e-pošte i telefon za kontakt  *E-mail and telephone number of contact person* |  |
| Datum prijave  *Date of notification* |  |

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| **U slučaju potrebe dostavljanja dodatnih podataka, molimo naznačiti privitke uz ovu prijavu**  (npr. Potvrda Europske agencije za lijekove za paralelni promet lijeka)  ***If applicable, please indicate all documents attached to this notification***  *(e.g. Notice for parallel distribution issued by EMA)* |
| 1.  2.  3. |