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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. |