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**Report № _____/_____**
❑ initial ❑ final
*(filled by Pharmacovigilance service)*

# REPORT ON UNEXPECTED THERAPEUTIC EFFECT OF MEDICINAL PRODUCT

**ALL THE INFORMATION GIVEN BY YOU IS CONFIDENTIAL AND NON-DISCLOSABLE EXCEPT AS OTHERWISE PERMITTED BY LAW**

## INFORMATION ABOUT PATIENT

| | | | |
|---|---|---|---|
| **Full name:** | | **Hepatic diseases** | ❑ yes ❑ no ❑ no information |
| **№ of medical treatment record / case history:** | | **Renal diseases** | ❑ yes ❑ no ❑ no information |
| **Sex:** | ❑ male ❑ female | **Pregnancy** | ❑ yes **Duration** _____ weeks |
| **Age**: | | **Allergy** (please specify): | ❑ yes ❑ no |
| **Weight** (kg): | | | |

## MEDICINAL PRODUCT (-S) (MP)

| Trademark | International Nonproprietary Name | Pharmaceutical form | Batch | Dosage, frequency and route of administration | Indications for use | Start date of administration | End date of administration |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

## OTHER MEDICINAL PRODUCTS (administered in the last 3 months)

| Trademark | International Nonproprietary Name | Pharmaceutical form | Batch | Dosage, frequency and route of administration | Indications for use | Start date of administration | End date of administration |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

## UNEXPECTED THERAPEUTIC EFFECT (-S) OF MP (UTE MP)

| Description of UTE MP (including results of laboratory and instrumental tests) | Start date of UTE | End date of UTE |
|---|---|---|
| | | |

**Did MP withdrawal result in UTE disappearance?** ❑ yes ❑ no ❑ no withdrawal of MP

**Did rechallenge of MP cause repeated UTE?** ❑ yes ❑ no ❑ no rechallenge of MP

**Measures taken:**
❑ no measures
❑ some measures (please specify):

**Result:**
❑ no information
❑ changes in patient health (please specify):

## INFORMATION ABOUT REPORTER (person that informs about UTE)

| | | | |
|---|---|---|---|
| **Full name:** | | | |
| **Occupation:** | ❑ doctor ❑ pharmacist ❑ medical representative ❑ patient ❑ other (please specify): | | |
| **Address:** | | | |
| **Phone:** | | **E-mail:** | |
| **Date of UTE information receiving:** | | **Filling date:** | |

**SIGNATURE** _____