

Prozac (fluoxetine)

Recommendations:

- **Amendments to the Product Information**

During the assessment of the information in the PSUR, it has been agreed that the following amendments to the Product Information are required:

- Section 4.3 Contraindications
to add a contra-indication with metoprolol used in cardiac failure
- Section 4.5 Interactions with other medicinal products and other forms of interactions
to add interactions with metoprolol, tamoxifen, atomoxetine, mequitazine, nebivolol, risperidone, oral anticoagulants, cyproheptamine, acetylsalicylic acid and non steroidal anti-inflammatory drugs
- Section 4.8 Undesirable effects
to replace the term “abnormal liver function tests” by “transaminases increased” and “gamma-glutamyltransferase increased”
to add the adverse effects “aggression”, “leucopenia” and “neutropenia” with the frequency category of rare
to mention “Stevens-Johnson syndrome” and “Toxic Epidermal Necrolysis” in the ADR table and not in the footnote