Appendix 1-1

Prescription Drug's Package Insert Format

Package Insert Field
Name of The Pharmaceutical Product Number of Product-License Drug Categorization
Boxed Warning (Optional)
1. Description 1.1 Active Ingredients and Strengths 1.2 Excipients 1.3 Dosage Form (Note 1) 1.4 Appearance (Note 2) 2. Indication (Note 3) 3. Dosage and Administration 3.1 Dosage and Administration 3.2 Reconstitution methods (Note 4) 3.3 Specific Populations Dosage and Administration (Optional)
4. Contraindications 5. Warnings and Precautions 5.1 Warnings / Precautions 5.2 Drug Abuse and Dependence (optional) 5.3 Effects on ability to use machines (optional) (Note 5) 5.4 Laboratory tests (optional) 5.5 Other precautions (optional) 6. Warnings in Special Populations (optional) 6.1 Pregnancy (optional) 6.2 Lactation (optional) 6.3 Childbearing potential (optional) 6.4 Pediatric use (optional) 6.5 Geriatric use (optional) 6.6 Patients with Hepatic Impairment (optional) 6.7 Patients with Renal Impairment (optional) 6.8 Other Populations (optional) 7. Interactions (Note 6) 8. Adverse Reactions/ Undesirable effects 8.1 Clinically Significant Adverse Reactions 8.2 Clinical Trial Experience (Note 7) (optional) 8.3 Post-marketing Experience (optional) 9. Overdose (Note 7)

10. Clinical Pharmacology (Note 8)
10.1 Mechanism of action
10.2 Pharmacodynamics
10.3 Preclinical safety data
11. Pharmacokinetics (Note 8)
12. Clinical Studies (Note 8)
13. How Supplied/Storage and Handling
13.1 How Supplied
13.2 Shelf Life (Note 9)
13.3 Storage Condition
13.4 Special precautions for storage (optional)
14. Patient Counseling Information (optional)
15. References (optional) (Note 10)

Manufacturer (Note 11)
License Holder (Note 12)

Note：

1. The dosage form should be written according to the product license.
2. Appearance should be mainly described in text, supplemented by the presentation of pictures.
3. Indication should contain indication directions.
4. The dosage form must be reconstituted before use should describe the reconstitution methods, other dosage forms are exempted. (Dosage form must be reconstituted before use: parenteral preparations, powder for suspension, powder for syrup, powder for drop, powder for solution, powder for dialysis, etc.)
5. Effects on ability to use machines includes driving ability.
6. Interactions including drug and food interaction due to the characteristics of product, can fill in “no information” as approved.
7. Due to the characteristics of product, can fill in “no information” as approved.
8. If early package insert does not include the information, can fill in “no information”.
9. Shelf Life should fill in expiry date, effective period after reconstituted, or fill in contents as shown on the outer packaging.
10. References can fill in special precautions for disposal, references, date of revision of the text, etc.
11. Manufacturer includes manufacturer, packager, labeler, foreign license holders, etc.
12. License Holder includes domestic drug license holder and distributor.