

## 含 nintedanib 成分藥品中文仿單修訂內容

◎「5 警語與注意事項」應刊載以下內容：

### 5.3 Gastrointestinal disorders

#### Diarrhoea

Diarrhoea may lead to dehydration with or without electrolyte disturbances which may progress to renal function impairment.

#### Nausea and vomiting

Vomiting may lead to dehydration with or without electrolyte disturbances which may progress to renal function impairment.

### 5.8 Renal function

Cases of renal impairment/failure, in some cases with fatal outcome, have been reported with nintedanib use. Patients should be monitored during nintedanib therapy, with particular attention to those patients exhibiting risk factors for renal impairment/failure. In case of renal impairment/failure, therapy adjustment should be considered (see “Dose adjustment”).

◎「8 使用於特定族群時- 8.7 腎功能不全」應刊載以下內容：

Patients should be monitored during nintedanib therapy, with particular attention to those patients exhibiting risk factors for renal impairment/failure. In case of renal impairment/failure, therapy adjustment should be considered (see “Dose adjustment”).