Boehringer Ingelheim

Boehringer Ingelheim Pty Limited
ABN 52 000 452 308

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Direct Healthcare Professional Communication: Information on severe liver injury and the need for regular monitoring of liver function associated with the use of nintedanib (Ofev®) in patients with idiopathic pulmonary fibrosis (IPF)

Dear Healthcare Professional,

Boehringer Ingelheim would like to inform you of the following important information:

Summary

- **In the post-marketing period, non-serious and serious cases of drug-induced liver injury (DILI) have been reported, including a case of severe liver injury during treatment with Ofev® associated with a fatal outcome.**
- **The majority of hepatic events have occurred within the first three months of Ofev® initiation. Therefore, it is recommended that particular attention should be taken during this initial period.**
- **For patients prescribed Ofev®, transaminases and bilirubin levels should be investigated:**
  - **Upon initiation of treatment;**
  - **At regular intervals during the first three months of treatment;**
  - **Periodically thereafter (e.g. at each patient visit) or as clinically indicated.**
- **Dose reduction or treatment interruption is recommended for managing transaminase elevations according to the current product information.**

Further information on the safety concern

Increases of liver enzymes are very common (may affect more than 1 in 10 treated patients) side effects of Ofev®, whereas DILI is uncommon (may affect up to 1 in 100 treated patients). The majority of reported hepatic events were mild or moderate and reversible upon dose reduction or treatment interruption.

The product information is in the process of being updated to reflect the observed increased severity of DILI and to provide further guidance on the monitoring schedule of hepatic laboratory testing.

The overall benefit-risk balance of Ofev® for the treatment of patients with IPF remains positive.

Recommendations

For patients prescribed Ofev® for the treatment of IPF, hepatic transaminase and bilirubin levels should be investigated upon initiation of treatment, at regular intervals during the first three months of treatment and periodically thereafter (e.g. at each patient visit) or as clinically indicated.

Please be reminded to ensure that appropriate monitoring of hepatic function is performed in case patients are referred to their community / general practitioners.

Call for reporting

Healthcare professionals are reminded to continue to report suspected adverse reactions associated with these products to the Centre for Adverse Reactions Monitoring (CARM) at https://nzphvc.otago.ac.nz/reporting/.

Company contact point

If you have further questions or require additional information, please contact Boehringer Ingelheim Medical Information on 0800 802 461.

Yours Sincerely,

Dr Petra Moroni-Zentgraf
Medical Director
Boehringer Ingelheim Pty Limited