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25 February 2016

Important information:
Viekirax with or without Exviera not recommended in Child-Pugh B patients

Dear Healthcare Professional,

In agreement with the European Medicines Agency and the Maltese Medicines Authority, AbbVie would like to inform you of important new safety information related to the hepatic safety ofViekirax (ombitasvir, paritaprevir, ritonavir) with or without Exviera (dasubuvir) dasabuvir sodium

Summary and Recommendations

- Hepatic decompensation and hepatic failure, including liver transplantation or fatal outcomes, have been reported postmarketing in patients treated with Viekirax with Exviera
- Viekirax with or without Exviera is not recommended in patients with moderate hepatic impairment (Child-Pugh B) and remains contraindicated in patients with severe hepatic impairment (Child-Pugh C).
- Patients with cirrhosis should be monitored
    - for clinical signs and symptoms of hepatic decompensation
    - and with hepatic laboratory testing including direct bilirubin levels at baseline, during the first 4 weeks of starting treatment and as clinically indicated thereafter.
- Patients receiving Viekirax and Exviera should be informed to watch for early symptoms of liver inflammation, liver failure or hepatic decompensation and to consult their healthcare provider without delay if such symptoms occur.
- Patients with moderate hepatic impairment (Child-Pugh B) currently on

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treatment with Viekirax with and without Exviera may be continued on treatment after a discussion of the benefits and risks of continued treatment. Patients who continue on treatment should be monitored for evidence of hepatic decompensation as stated above.

- The Product Information for these products will be updated with the new recommendations.
- Patients who develop evidence of hepatic decompensation should discontinue treatment.

Further information on the safety concern

Viekirax is indicated in combination with other medicinal products for the treatment of chronic hepatitis C in adults

Exviera is indicated in combination with other medicinal products for the treatment of chronic hepatitis C in adults

- Twenty-six cases of hepatic decompensation and liver failure in patients treated with Viekirax with Exviera, with and without ribavirin, reported post-marketing have been assessed by a panel of independent hepatic experts as possibly or probably related to the treatment regimen.
- Most patients with these severe outcomes had evidence of advanced or decompensated cirrhosis prior to initiating therapy.
- Of these 26 cases, 10 led to severe outcomes, i.e. liver transplantation or death, and these severe outcomes were reported mostly in patients with evidence of advanced cirrhosis.
- It is estimated that 35,000 patient treatment courses of Viekirax with and without Exviera had been prescribed world-wide at the time these cases were reported.
- Although the specific role of antiviral therapy is difficult to establish due to background advanced liver disease, a potential risk cannot be excluded.

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Call for reporting

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals and patients are encouraged to report adverse events in patients taking Viekirax with or without Exviera are asked to report any suspected adverse reactions to the Medicines Authority at: www.medicinesauthority.gov.mt/adrportal or to the local representative of AbbVie Ltd.: V.J.Salomone Pharma Ltd., Upper Cross Road, Marsa MRS1542, Malta, Tel+356 21220174.

Company contact points

You and your patients may also contact our Medical Information department at the local representative of AbbVie Ltd.: V.J.Salomone Pharma Ltd., Upper Cross Road, Marsa MRS1542, Malta, Tel+356 21220174, if you have any questions about the information contained in this letter or the safe and effective use of Viekirax with and without Exviera.

Sincerely,

NEIL PUMFORD
UK Medical Director

February 2016