

Bulevirtide: Adis Evaluation

Clinical Considerations

- **First entry inhibitor approved for chronic hepatitis D**
- **Self-administered as a daily subcutaneous injection**
- **Reduces HDV RNA levels and normalizes ALT levels**
- **Generally well tolerated; increases in bile salt levels are asymptomatic and reversible**

Plain Language Summary

Background and rationale

- Chronic hepatitis D is caused by an infection with the hepatitis delta virus (HDV). It is a fast-progressing and severe form of viral hepatitis that can lead to liver damage, cirrhosis and liver cell cancer.
- HDV cannot multiply in cells unless the hepatitis B virus is also present. Consequently, all patients with hepatitis D also have hepatitis B. Hepatitis D occurs in $\approx 4.5\%$ of patients with hepatitis B.
- Treatment options for chronic hepatitis D are limited (no other approved therapy to date) and generally ineffective.
- Bulevirtide (HEPCLUDEX®), a drug that is self-administered as a daily subcutaneous injection, blocks the entry of HDV into liver cells and limits the ability of HDV to multiply.

Clinical findings

- It is the first drug to be approved for the treatment of chronic hepatitis D in adults with compensated liver disease (the liver is damaged, but can still work).
- By reducing the amount of HDV in the body, bulevirtide improves liver function in these patients.
- Bulevirtide is also generally well tolerated.

Conclusion

Bulevirtide is a new treatment option for patients with chronic hepatitis D who have compensated liver disease.

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