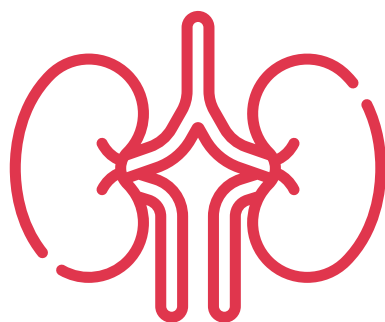


# ENTECAVIR for Hepatitis B

Reinforcing Renal Safety





“ENTECAVIR (ETV) DOES NOT AFFECT RENAL FUNCTION WHEN GIVEN IN HEPATITIS B VIRUS (HBV)-INFECTED PATIENTS WITH SEVERE RENAL DYSFUNCTION”



#### AIM

To evaluate safety and efficacy of ETV in HBV-infected patients with severe renal dysfunction, including hemodialysis patients

#### STUDY DESIGN

Retrospective, multicenter study



#### PATIENT CHARACTERISTICS

- 273 HBV-infected patients treated with ETV monotherapy for >1 year
- Age >20 years
- 85.3% had CKD stage G1/2; 9.2% had CKD stage G3; 1.8% had CKD stage G4/5, and 3.7% were on hemodialysis



#### ENTECAVIR POSOLOGY

- In patients with  $C_{cr} > 50$  mL/min: 0.5 mg once daily
- $C_{cr}$  30-50 mL/min: 0.5 mg once every 2 days
- $C_{cr}$  10-30 mL/min: 0.5 mg once every 3 days
- $C_{cr} < 10$  mL/min or on hemodialysis: 0.5 mg every 7 days

\*CKD, chronic kidney disease;  $C_{cr}$ , creatinine clearance

## METHODOLOGY



Patients assessed by physical examinations and blood tests at baseline and every 3 months



ETV efficacy and changes in renal function evaluated according to estimated glomerular filtration rate (eGFR) changes

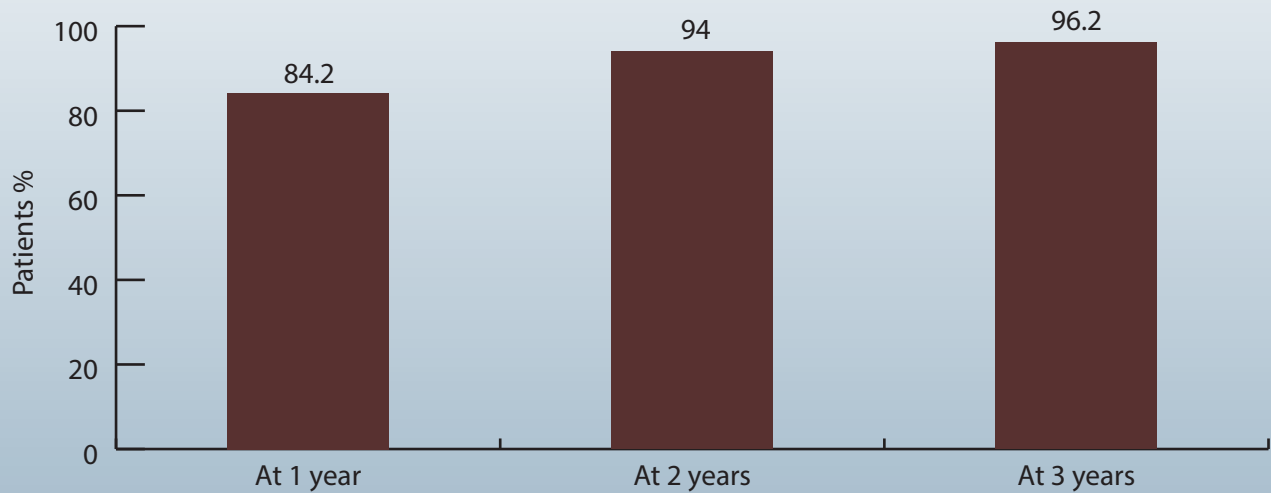
## RESULTS

Serum HBV-DNA disappearance was seen in 84.2%, 94.0%, and 96.2% of patients at 1, 2, and 3 years, respectively, post ETV initiation (see figure)

Rate of disappearance of serum HBV-DNA, alanine transaminase normalization, and virological breakthrough was similar in patients with or without renal dysfunction

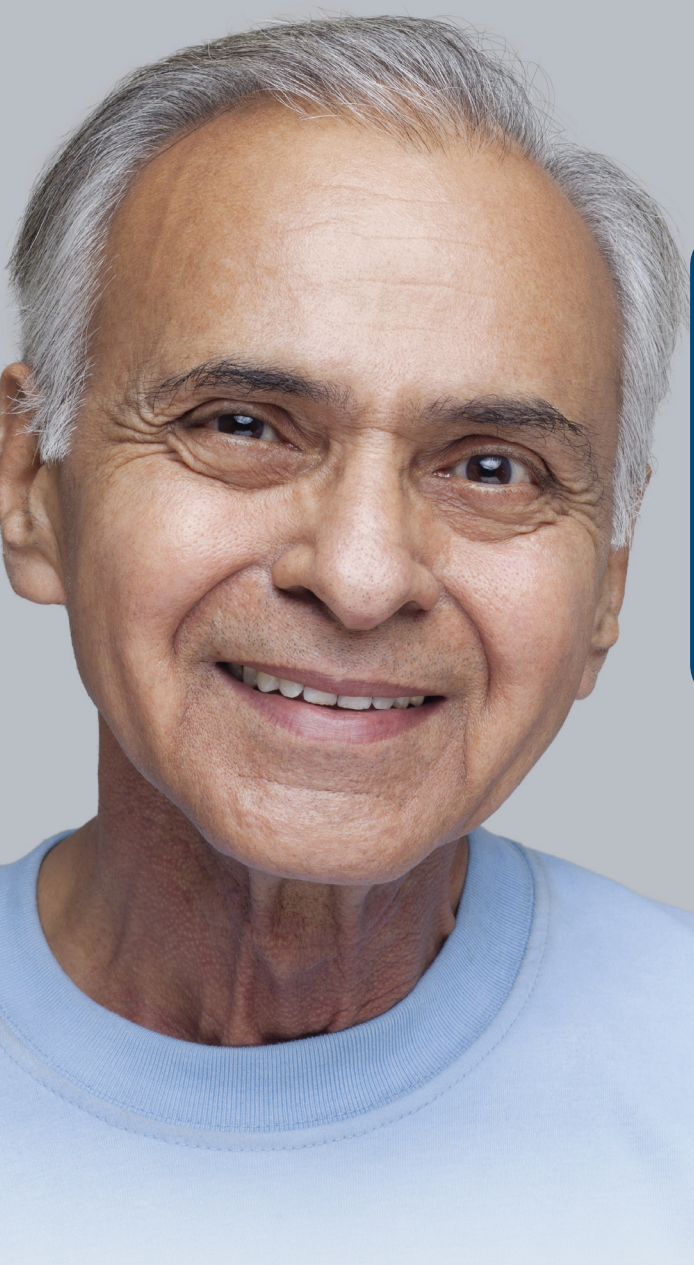
In patients with CKD stage G3–5, eGFR tended to restore with time post treatment initiation

ETV showed high efficacy in all hemodialysis patients without virological breakthrough



**Serum HBV-DNA disappearance with entecavir monotherapy**





## CONCLUSION



- ETV for HBV-infected patients with moderate-to-severe renal dysfunction, including hemodialysis patients, is highly effective
- ETV is effective in renal dysfunction patients and does not reduce renal function.

**Source:** Suzuki K, Suda G, Yamamoto Y, Furuya K, Baba M, et al. Entecavir treatment of hepatitis B virus-infected patients with severe renal impairment and those on hemodialysis. *Hepatol Res.* 2019;49(11):1294-1304.

### Entecavir dosing as per creatinine clearance ( $C_{cr}$ ):

$C_{cr} > 50$  mL/min: 0.5 mg once daily

$C_{cr} 30-50$  mL/min: 0.5 mg once every 2 days

$C_{cr} 10-30$  mL/min: 0.5 mg once every 3 days

$C_{cr} < 10$  mL/min or on hemodialysis: 0.5 mg every 7 days

Expiry Date June 2021

For the use of Registered Medical Practitioners/Hospitals & Laboratories only.

I20210229947

In Chronic Hepatitis B,

<sup>Rx</sup>  
**Entavir**  
Entecavir 0.5/1 mg  
**It's Persistent**



Prescribing information available on request.

All claims are based on evidences, available on request.

For any further information, please contact: Cipla Ltd. Regd. Office, Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India,

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