

חברת AbbVie Biopharmaceuticals Ltd. שמחה להודיע על רישום התרופות הבאות בישראל:

Exviera 250 mg tablets

אקסוירה 250 מ"ג טבליות

Film coated tablets

dasabuvir 250 mg

Viekirax 12.5 mg/75 mg/50 mg tablets

ויקיראקס 12.5 מ"ג / 75 מ"ג / 50 מ"ג טבליות

Film coated tablets

ombitasvir 12.5 mg, paritaprevir 75 mg, ritonavir 50 mg

ההתוויה המאושרת לתכשירים:

Exviera is indicated in combination with other medicinal products for the treatment of chronic genotype 1 (GT1) hepatitis C (CHC) virus infection in adults.

Viekirax is indicated in combination with other medicinal products for the treatment of chronic genotype 1 (GT1) hepatitis C (CHC) virus infection in adults.

מינונים:

The recommended dose of Exviera is 250 mg (one tablet) twice daily (morning and evening). Exviera must not be administered as monotherapy. Exviera should be used in combination with other medicinal products for the treatment of HCV.

The recommended oral dose of Viekirax is two 12.5 mg / 75 mg / 50 mg tablets once daily with food. Viekirax should be used in combination with other medicinal products for the treatment of HCV.

Table 1. Recommended co-administered medicinal product(s) and treatment duration by patient population

Patient population	Treatment*	Duration
Genotype 1b, without cirrhosis	Exviera + Viekirax	12 weeks
Genotype 1b, with compensated cirrhosis	Exviera + Viekirax + ribavirin	12 weeks
Genotype 1a, without cirrhosis	Exviera + Viekirax + ribavirin*	12 weeks
Genotype 1a, with compensated cirrhosis	Exviera + Viekirax + ribavirin*	24 weeks** (see section 5.1. in the prescribing information)

*Note: Follow the genotype 1a dosing recommendations in patients with an unknown genotype 1 subtype or with mixed genotype 1 infection.

** Exviera + Viekirax administered with ribavirin for 12 weeks may be considered for some patients based on prior treatment history.



For specific dosage instructions for ribavirin, including dose modification, refer to the respective Prescribing Information leaflet.

Method of administration

The film-coated tablets are for oral use. Patients should be instructed to swallow the tablets whole (i.e. patients should not chew, break or dissolve the tablet). To maximise absorption, Viekirax and Exviera tablets should be taken with food, without regard to fat and calorie content.

העלונים המעודכנים לרופא והעלונים המעודכנים לצרכן נשלחו למאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום, AbbVie Biopharmaceuticals Ltd, רחוב החרש 4, הוד השרון או בטלפון 7909600 – 09.

בברכה,

נעמי רביב

רוקחת ממונה