

2021 אוגוסט

רופא/ה נכבד/ה
חוקח/ת נכבד/ה

ברצוננו להביא לידיעתכם את העדכונים בעלון לרופא של התכשיר:

Edurant (Rilpivirine 25mg tablets)

המאושר להתוויה:

EDURANT in combination with other antiretroviral agents, is indicated for the treatment of Human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with HIV-1 RNA less than or equal to 100,000 copies/mL at the start of therapy.

השינויים המהותיים בעלון לרופא מופיעים בסעיפים הבאים:

4.1 Therapeutic indications

EDURANT™, in combination with other antiretroviral agents, is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in antiretroviral treatment-naïve adult patients with HIV-1 RNA less than or equal to 100,000 copies/mL at the start of therapy.

EDURANT is not recommended for patients less than 18 years of age.

4.2 Posology and method of administration

The recommended dose of EDURANT is one 25 mg tablet once daily. EDURANT must be taken orally with a meal [see section 5.2 Pharmacokinetic properties].

Dose adjustment

For patients concomitantly receiving rifabutin, the EDURANT dose should be increased to 50 mg (two tablets of 25 mg each) taken once daily, taken with a meal. When rifabutin co-administration is stopped, the EDURANT dose should be decreased to 25 mg once daily, taken with a meal [see section 4.5 Interaction with other medicinal products and other forms of interaction].

Missed dose

If the patient misses a dose of EDURANT within 12 hours of the time it is usually taken, the patient must take the medicine with a meal as soon as possible and resume the normal dosing schedule. If a patient misses a dose of EDURANT by more than 12 hours, the patient should not take the missed dose, but resume the usual dosing schedule.

If a patient vomits within 4 hours of taking the medicine, another EDURANT tablet should be taken with a meal. If a patient vomits more than 4 hours after taking the medicine, the patient does not need to take another dose of EDURANT until the next regularly scheduled dose.

Special populations

Elderly

There is limited information regarding the use of EDURANT in patients > 65 years of age. No dose adjustment of EDURANT is required in older patients (see section 5.2). EDURANT should be used with caution in this population.

Renal impairment

EDURANT has mainly been studied in patients with normal renal function. No dose adjustment of rilpivirine is required in patients with mild or moderate renal impairment. In patients with severe renal impairment or end-stage renal disease, rilpivirine should be used with caution.

In patients with severe renal impairment or end-stage renal disease, the combination of rilpivirine with a strong CYP3A inhibitor (e.g., ritonavir-boosted HIV protease inhibitor) should only be used if the benefit outweighs the risk (see section 5.2).

Treatment with rilpivirine resulted in an early small increase of mean serum creatinine levels which remained stable over time and is not considered clinically relevant (see section 4.8).

Hepatic impairment

There is limited information regarding the use of EDURANT in patients with mild or moderate hepatic impairment (Child-Pugh score A or B). No dose adjustment of EDURANT is required in patients with mild or moderate hepatic impairment. EDURANT should be used with caution in patients with moderate hepatic impairment. EDURANT has not been studied in patients with severe hepatic impairment (Child-Pugh score C). Therefore, EDURANT is not recommended in patients with severe hepatic impairment (see section 5.2).

Pediatric population

EDURANT is not indicated for children and adolescents under 18 years old.

Method of administration

EDURANT must be taken orally, once daily with a meal (see section 5.2). It is recommended that the film-coated tablet be swallowed whole with water and not be chewed or crushed.

העלון לרופא מצורף. הטקסט המודגש באדום הוסף לעלון ואילו הטקסט המחוקק הוסר.
כמו כן, העלון נשלח לפרסום במלאו למאגר התרופות שבאתר משרד הבריאות.

כמו כן, ניתן לקבל מודפס בפניה אלינו לטלפון 09-9591111.

להלן העדכונים.

בברכה,
אלינה ורמן
רוקחת ממונה