

Sacubitril/ Valsartan risks of psychiatric disorders as hallucinations , sleep and paranoia

[EDA performs label update to include the following:](#)

Special warnings and precautions for use

Psychiatric disorders

Psychiatric events such as hallucinations, paranoia and sleep disorders, in context of psychotic events, have been associated with sacubitril/valsartan use. If a patient experiences such events, discontinuation of sacubitril/valsartan treatment should be considered.

Interaction with other medicinal products and other forms of interaction

Lithium

Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with ACE inhibitors or angiotensin II receptor antagonists including sacubitril/valsartan. Therefore, this combination is not recommended. If the combination proves necessary, careful monitoring of serum lithium levels is recommended. If a diuretic is also used, the risk of lithium toxicity may be increased further.

Undesirable effects

Psychiatric disorders

Hallucinations**	Rare
Sleep disorders	Rare
Paranoia	Very rare

Background:

Therapeutic indications

Adult heart failure

Sacubitril/ Valsartan is indicated in adult patients for treatment of symptomatic chronic heart failure with reduced ejection fraction .

Paediatric heart failure

Sacubitril/ Valsartan is indicated in children and adolescents aged one year.

References: EMA ([Click here](#))