

Potential side effects associated with esketamine nasal spray (Spravato™)

Below is the incidence of adverse events in patients treated with esketamine nasal spray plus an oral antidepressant at any dose in patients with “treatment-resistant depression”.

How did we decide what is or is not a "side effect" of the medication?

Adverse (undesirable) events that occurred during treatment with esketamine in placebo-controlled clinical trials are considered here to be side effects if they occurred at least twice as often as on placebo.

When do we call a side effect "common"?

A side effect is considered here to be “common” if the difference between its incidence on the combination of esketamine nasal spray and an oral antidepressant (SSRI or SNRI) versus on placebo and an oral antidepressant (SSRI or SNRI) was at least 5%.

What "other" or "less common" side effects will we consider on this page?

Other side effects included on this page (and in the handout provided on this website) are those for which the difference between its incidence on the combination of esketamine nasal spray and an oral antidepressant (SSRI or SNRI) versus on placebo and an oral antidepressant (SSRI or SNRI) was at least 1%.

Note: Side effects for which the difference between the two treatment groups was less than 1% are not discussed on this page.

Note: Symptoms reported by patients may be classified by the researchers into categories that could be considered to overlap, e.g., dizziness and vertigo; dissociation, “feeling abnormal”, and “mental impairment”.

Common side effects*	Drug-placebo difference	Percentage of patients on esketamine nasal spray plus antidepressant who reported it	Percentage of patients on placebo nasal spray plus antidepressant who reported it
Dissociation	32%	41%	9%
Dizziness	21%	29%	8%
Vertigo	20%	23%	3%
Nausea	19%	28%	9%
Decreased sense of touch or sensation	16%	18%	2%
Sedation	14%	23%	9%
Anxiety	7%	13%	6%
Blood pressure increased	7%	10%	3%
Vomiting	7%	9%	2%

Tiredness	6%	11%	5%
Other side effects*			
Feeling drunk	4.5%	5%	0.5%
Speech difficulty	4%	4%	0%
Euphoric mood	3%	4%	1%
Feeling abnormal	3%	3%	0%
Daytime urinary frequency increased	2.5%	3%	0.5%
Sweating increased	2%	4%	2%
Constipation	2%	3%	1%
Mental impairment	2%	3%	1%
Tremor	2%	3%	1%
Heart rate increased	1.5%	2%	0.5%

Important! The information in this handout is for general educational purposes only and is only a partial list of the potential side effects of this medication. If you are a patient, please consult the medical professional who prescribed this medication for further information about the potential side effects of this medication. For additional important information, including about potentially serious side effects of this medication, please make sure to review the page at the link below: <https://medlineplus.gov/druginfo/meds/a619017.html>