

Potential side effects associated with OROS methylphenidate extended-release (Concerta®)

Below is the incidence of adverse events in adult patients treated with OROS methylphenidate extended-release at doses up to 108 mg/day.

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

Adverse (undesirable) events that occurred during treatment with OROS methylphenidate extended-release 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 with OROS methylphenidate extended-release versus placebo was at least 5%.

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

Other side effects included on this page are those for which the difference between its incidence with OROS methylphenidate extended-release versus on placebo 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 postural hypotension.

Common side effects	Drug-placebo difference	Percentage of patients on OROS methylphenidate extended-release who reported it	Percentage of patients on placebo who reported it
Decreased appetite	18%	25%	7%
Dry mouth	10%	14%	4%
Nausea	10%	13%	3%
Difficulty sleeping	6%	12%	6%
Anxiety	6%	8%	2%

Increased heart rate	5%	5%	0%
Irritability	5%	6%	1%
Other side effects			
Increased sweating	4%	5%	1%
Depressed mood	3%	4%	1%
Restlessness	3%	3%	0%
Nervousness	2%	3%	1%
Pounding heart	2%	3%	1%
Uncontrollable movements	2%	3%	1%
Dizziness	2%	2%	0%
Loss of appetite	2%	2%	0%
Muscle tightness	2%	2%	0%
Aggression	1%	2%	1%
Agitation	1%	2%	1%
Decreased sexual desire	1%	2%	1%
Indigestion	1%	2%	1%
Upper respiratory tract infection	1%	2%	1%
Involuntary grinding or clenching of teeth	1%	2%	1%
Vision blurred	1%	2%	1%
Vomiting	1%	2%	1%
Drowsiness	1%	1%	0%

Numbness, pain or sensitivity to temperature	1%	1%	0%
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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/a682188.html>