## Potential side effects of mixed salts of a single-entity amphetamine product extended-release (Mydayis®)

Below is the incidence of adverse events in adult outpatients treated with mixed salts of a singleentity amphetamine product extended-release capsules (up to 75 mg daily) versus placebo.

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

Adverse (undesirable) events that occurred during treatment with mixed salts of a single-entity amphetamine product XR 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 mixed salts of a single-entity amphetamine product XR 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 mixed salts of a single-entity amphetamine product XR 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 mixed salts of a single- entity amphetamine product XR who reported it (up to 75 mg daily)	Percentage of patients on placebo who reported it
Decreased appetite	26%	30%	4%
Sleeping difficulty	23%	31%	8%
Dry mouth	19%	23%	4%
Heart rate increased	9%	9%	0%
Weight decreased	9%	9%	0%

Other side effects				
Anxiety	<b>4%</b>	7%	3%	
Depression	3%	3%	0%	
Painful menstrual periods	2%	4%	2%	
Palpitations	2%	4%	2%	
Diarrhea	2%	3%	1%	
Agitation	2%	2%	0%	
Bruxism (clenching or grinding of teeth)	2%	2%	0%	
Erectile dysfunction	1%	2%	1%	
Feeling jittery	1%	2%	1%	

**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: <a href="https://medlineplus.gov/druginfo/meds/a601234.html">https://medlineplus.gov/druginfo/meds/a601234.html</a>