

## Potential side effects associated with doxepin (Silenor®)

Below is the incidence of adverse events in patients with chronic insomnia treated with doxepin.

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

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

### What side effects did we consider on this page?

We considered those side effects that occurred at a rate of 2% or more in any doxepin treated group.

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

### I. Incidence of adverse events in patients with chronic insomnia treated with doxepin 3 mg

Side effects	Drug-placebo difference	Percentage of patients on doxepin 3 mg who reported it	Percentage of patients on placebo who reported it
Hypertension (high blood pressure)	3	3	0
Upper respiratory tract infection and nasopharyngitis (nasal congestion and sore throat)	2	4	2
Gastroenteritis (stomach upset)	2	2	0
Nausea	1	2	1

### II. Incidence of adverse events in patients with chronic insomnia treated with doxepin 6 mg

Side effects	Drug-placebo difference	Percentage of patients on doxepin 6 mg who reported it	Percentage of patients on placebo who reported it
Somnolence (sleepiness)	5	9	4
Nausea	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: <https://medlineplus.gov/druginfo/meds/a617017.html>