

## Interactive Adverse Drug Reaction (ADR) Overview

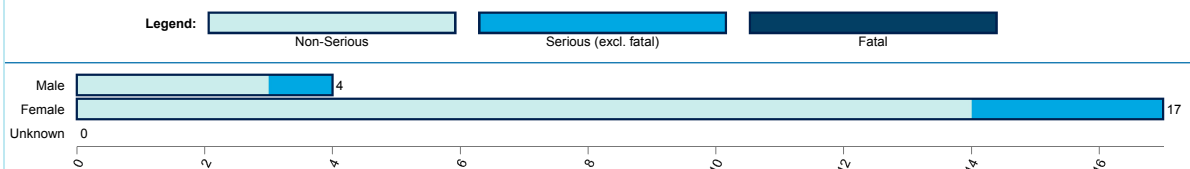
### Summary

This interactive ADR overview displays information from reports of Adverse Drug Reactions (ADRs). Please see the section at the bottom of the web page for essential context for understanding this interactive ADR overview. The information in the ADR overview can be very useful in helping to identify possible medicine safety issues. However, ADR overviews do not present a complete overview of the risks associated with specific medicines. Conclusions on the safety and risks of medicines can be made on the information in interactive ADR overviews alone.

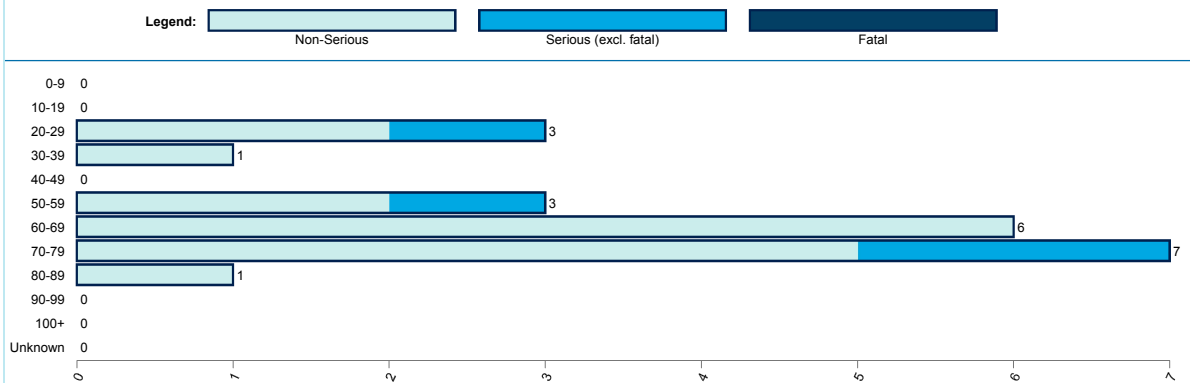
#### 1:1 DROPS 'STENOCARE'

- Single constituent brand names: 1:1 DROPS 'STENOCARE'
- Total number of ADR reports: 21 - Total number of reactions: 28
- Total number of serious ADR reports: 4 - Total number of fatal ADR reports: 0
- Displays show a breakdown of all 21 DK spontaneous reports received for 1:1 DROPS 'STENOCARE'.
- Reports processed up to: 6-May-2019

### Reports by Gender

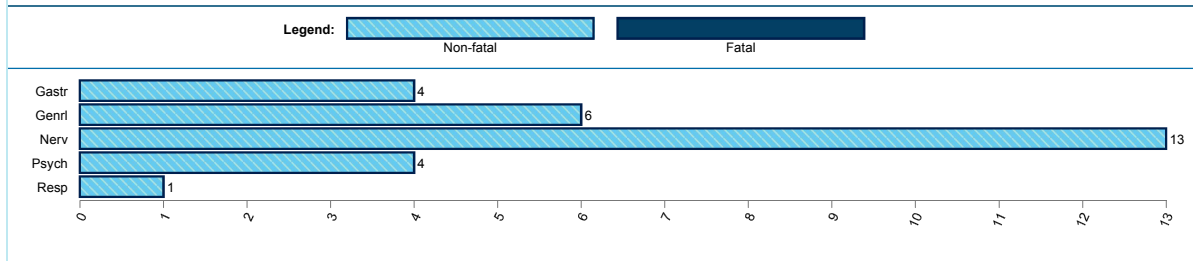


### Reports by Age Group

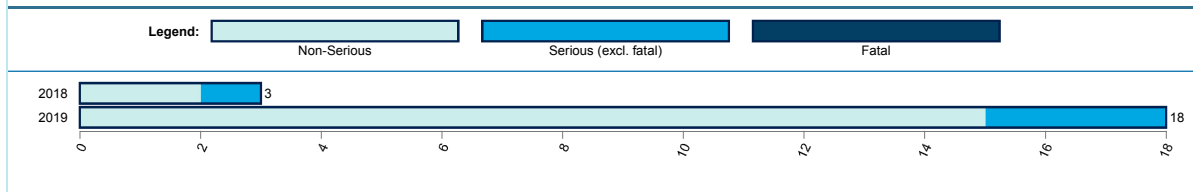




### Reactions by MedDRA System Organ Class



### Reports by Year



### Reactions by MedDRA System Organ Class

Reactions in MedDRA	Total reactions	
	All	Fatal
<b>Gastrointestinal disorders</b>	<b>4</b>	<b>0</b>
- <i>Gastrointestinal motility and defaecation conditions</i>	3	0
- <i>Diarrhoea (excl infective)</i>	2	0
Diarrhoea	2	0
- <i>Gastrointestinal atonic and hypomotility disorders NEC</i>	1	0
Constipation	1	0
- <i>Gastrointestinal signs and symptoms</i>	1	0
- <i>Nausea and vomiting symptoms</i>	1	0
Nausea	1	0
<b>General disorders and administration site conditions</b>	<b>6</b>	<b>0</b>
- <i>General system disorders NEC</i>	6	0
- <i>Asthenic conditions</i>	4	0
Fatigue	4	0
- <i>Feelings and sensations NEC</i>	1	0
Feeling abnormal	1	0



### Reactions by MedDRA System Organ Class

Reactions in MedDRA	Total reactions	
	All	Fatal
- <i>Pain and discomfort NEC</i>	1	0
Discomfort	1	0
- <b>Nervous system disorders</b>	<b>13</b>	<b>0</b>
- <b>Headaches</b>	<b>1</b>	<b>0</b>
- <i>Headaches NEC</i>	1	0
Headache	1	0
- <b>Mental impairment disorders</b>	<b>2</b>	<b>0</b>
- <i>Memory loss (excl dementia)</i>	1	0
Memory impairment	1	0
- <i>Mental impairment (excl dementia and memory loss)</i>	1	0
Disturbance in attention	1	0
- <b>Neurological disorders NEC</b>	<b>10</b>	<b>0</b>
- <i>Disturbances in consciousness NEC</i>	3	0
Depressed level of consciousness	1	0
Somnolence	1	0
Syncope	1	0
- <i>Neurological signs and symptoms NEC</i>	7	0
Dizziness	7	0
- <b>Psychiatric disorders</b>	<b>4</b>	<b>0</b>
- <b>Anxiety disorders and symptoms</b>	<b>1</b>	<b>0</b>
- <i>Anxiety symptoms</i>	1	0
Anxiety	1	0
- <b>Deliria (incl confusion)</b>	<b>1</b>	<b>0</b>
- <i>Confusion and disorientation</i>	1	0
Confusional state	1	0
- <b>Depressed mood disorders and disturbances</b>	<b>1</b>	<b>0</b>
- <i>Depressive disorders</i>	1	0
Depression	1	0
- <b>Disturbances in thinking and perception</b>	<b>1</b>	<b>0</b>
- <i>Hallucinations (excl sleep-related)</i>	1	0
Hallucination	1	0
- <b>Respiratory, thoracic and mediastinal disorders</b>	<b>1</b>	<b>0</b>



### Reactions by MedDRA System Organ Class

Reactions in MedDRA	Total reactions	
	All	Fatal
- <b>Respiratory disorders NEC</b>	1	0
- <i>Breathing abnormalities</i>	1	0
Hyperventilation	1	0
<b>Total reactions</b>	<b>28</b>	<b>0</b>

### Essential Context for Understanding this Interactive Adverse Drug Reaction (ADR) Overview

The data shown in the interactive ADR overviews can be very useful in helping to identify possible medicine safety issues. However, ADR overviews does not present overview of the risks associated with specific medicines. Conclusions on the safety and risks of medicines cannot be made on the data shown in ADR overview alone.

For more comprehensive information about the risks of particular medicines, you should refer to the patient information leaflet or the summary of product characteristic medicine.

When using interactive ADR overviews, you should remember that:

- The likelihood of experiencing an adverse drug reaction when taking a medicine cannot be estimated from the data in interactive ADR overviews.
- Reporters are asked to submit adverse drug reaction (ADR) reports even if they only have a suspicion that the medicine may have caused the ADR. The exister ADR report in the interactive ADR overview does not necessarily mean that the medicine has caused the reaction.
- Many factors have to be considered when assessing whether a medicine has caused a reported adverse drug reaction. When monitoring the safety of medicine: staff carry out careful analysis of these factors.
- It is not possible to compare the risks of different medicines by comparing the numbers presented in the interactive ADR overviews.

If you are concerned about the medicine you are taking, you should contact your doctor who prescribed the medicine or your pharmacist. You should not stop taking a prescribed medicine without first talking to your health professional.

For more information on this display please see [Interactive Adverse Drug Reaction \(ADR\) Overview \(http://laegemiddelstyrelsen.dk/en/sideeffects/side-effects-from-medicines/drug-analysis-prints-reported-adverse-reactions\)](http://laegemiddelstyrelsen.dk/en/sideeffects/side-effects-from-medicines/drug-analysis-prints-reported-adverse-reactions).

DAP version: 1.0.0  
MedDRA version: 22.0  
Report level: PBG

