



Interactive Adverse Drug Reaction (ADR) Overview

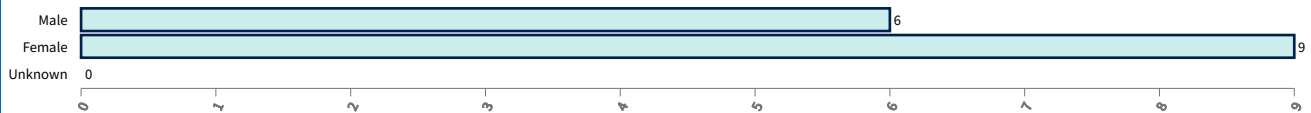
Summary

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 cannot be made on the information in interactive ADR overviews alone.

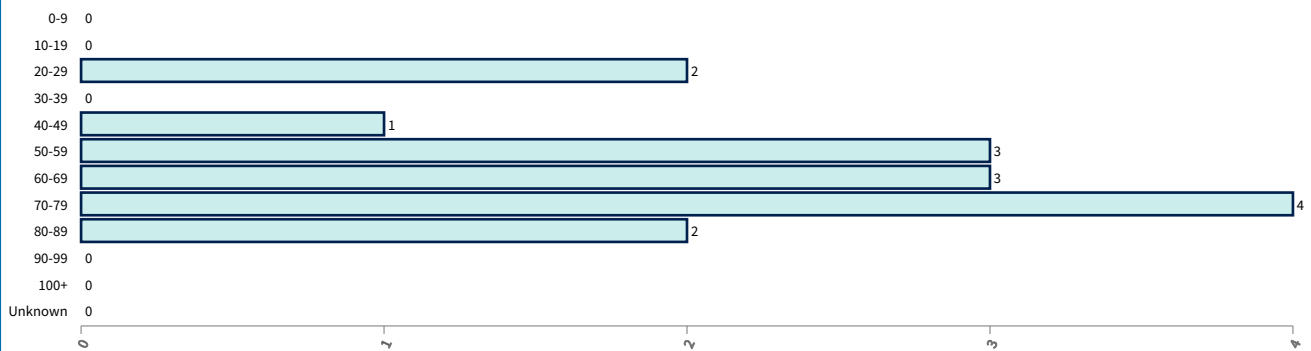
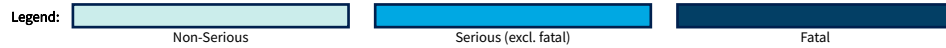
SEDEMEN 'AURORA NORDIC CANNABIS'

- Single constituent brand names: SEDEMEN 'AURORA NORDIC CANNABIS'
- Total number of ADR reports: 15 - Total number of reactions: 23
- Total number of serious ADR reports: 0 - Total number of fatal ADR reports: 0
- Displays show a breakdown of all 15 DK spontaneous reports received for SEDEMEN 'AURORA NORDIC CANNABIS'.
- Reports processed up to: 31-Jul-2023

Reports by Gender

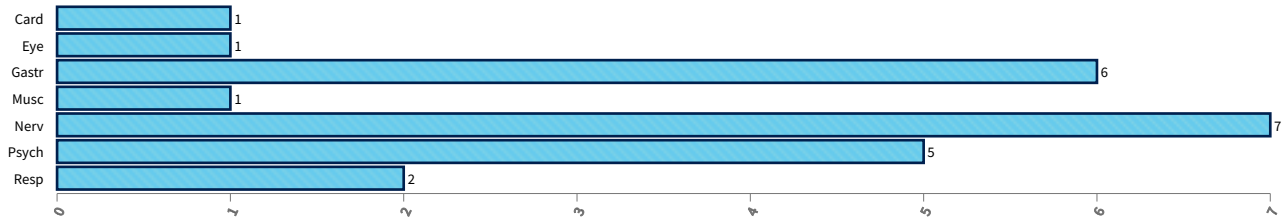


Reports by Age Group

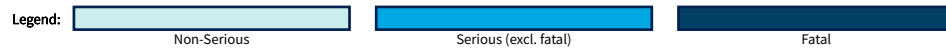




Reactions by MedDRA System Organ Class



Reports by Year



Reactions by MedDRA System Organ Class

Reactions in MedDRA	Total reactions	
	All	Fatal
+ Cardiac disorders	1	0
+ Eye disorders	1	0
+ Gastrointestinal disorders	6	0
+ Musculoskeletal and connective tissue disorders	1	0
+ Nervous system disorders	7	0
+ Psychiatric disorders	5	0
+ Respiratory, thoracic and mediastinal disorders	2	0
Total reactions	23	0

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 a complete 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 characteristics for the 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 existence of an 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 medicines, DKMA 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 any 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>).

DAP version: 1.0.0
MedDRA version: 26.0
Report level: PBG