

Disclaimer

The following report(s) provides findings from an FDA-initiated query using its Mini-Sentinel pilot. While Mini-Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Mini-Sentinel, and seeking to better understand the capabilities of the Mini-Sentinel pilot.

Data obtained through Mini-Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from the Mini-Sentinel pilot in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Mini-Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Scenario	Drug/Exposure			Event/Outcome						
	Incident Exposure	Washout (days)	Exposed Time Duration (days)	Event/Outcome	Care Setting/Principal Diagnosis Indicator	Time Window	Event Date	Washout (days)	Event De-duplication	Blackout Period (days)
23	Warfarin	183	30	INR lab test result ≥ 0	Inpatient	N/A	N/A	0	2	0
24	Warfarin	183	30	INR test procedure	Inpatient	N/A	N/A	0	2	0
25	Warfarin	183	30	INR lab test result ≥ 0 and INR test procedure	Inpatient	Same day	N/A	0	2	0
26	Warfarin	183	30	INR lab test result ≥ 0 and INR test procedure	Inpatient	+ 3 days	Result date	0	2	0
27	Warfarin	183	30	INR lab test result ≥ 0 and INR test procedure	Inpatient	- 3 days	Result date	0	2	0
28	Warfarin	183	30	INR lab test result ≥ 0 and INR test procedure	Inpatient	+/- 3 days	Result date	0	2	0
29	Warfarin	183	30	INR lab test result ≥ 0 without an INR test procedure	Inpatient	+/- 30 days	Result date	0	2	0
30	Warfarin	183	30	INR test procedure and INR lab test result ≥ 0	Inpatient	+ 3 days	Procedure Date	0	2	0
31	Warfarin	183	30	INR test procedure and INR lab test result ≥ 0	Inpatient	- 3 days	Procedure Date	0	2	0
32	Warfarin	183	30	INR test procedure and INR lab test result ≥ 0	Inpatient	+/- 3 days	Procedure Date	0	2	0
33	Warfarin	183	30	INR test procedure without an INR lab test result ≥ 0	Inpatient	+/- 30 days	Procedure Date	0	2	0

National Drug Codes (NDCs) were checked against First Data Bank's "National Drug Data File (NDDF®) Plus"

Healthcare Common Procedure Coding System (HCPCS) codes were checked against "Optum 2012 HCPCS Level II Data File" provided by OptumInsight

Current Procedural Terminology, Fourth Edition (CPT-4) codes were checked against "Optum 2012 Current Procedure Codes & Relative Values Data File" provided by OptumInsight