

Case #	Reaction description	Notes from narratives	Outcome	Primary Suspect Drug(s)	Secondary Suspect Drug(s)	Concomitant drugs	Indication	SGLT2i dose	Start date	End date	Event Date	Age, yr range*	Gender*	Report Date	Reported By	Reporter Country
Fournier's gangrene																
1	NECROTISING FASCIITIS; URINARY TRACT INFECTION;		Other	FORXIGA								60-69		07/23/15	Physician	GERMANY
2	NECROTISING FASCIITIS;		Hospitalization	FORXIGA										08/05/15	Physician	AUSTRALIA
3	NECROTISING FASCIITIS;		Other	INVOKANA		ENALAPRIL; GABAPENTIN; GLIPIZIDE; METFORMIN HYDROCHLORIDE; OMEPRAZOLE	TYPE 2 DIABETES MELLITUS	300				60-69		11/27/15	Physician	UNITED STATES
4	PERINEAL INFECTION; SEPTIC SHOCK; GENITOURINARY TRACT INFECTION; INFECTION; STREPTOCOCCUS TEST POSITIVE;	Death	Hospitalization, Life Threatening, Other	JARDIANCE		GLYBURIDE\METFO RMIN	DIABETES MELLITUS INADEQUATE CONTROL		12/01/14	10/03/15	10/03/15	70-79		12/17/15	Physician	UNITED STATES
5	NECROTISING FASCIITIS;		Other	FARXIGA										01/13/16	Physician	UNITED STATES
6	NECROTISING FASCIITIS;		Hospitalization	JARDIANCE		INSULIN GLARGINE		10	'2015		'201510	30-39		01/23/16	Consumer	UNITED STATES
7	NECROTISING FASCIITIS; SEPSIS; ACUTE KIDNEY INJURY;		Hospitalization	INVOKAMET			TYPE 2 DIABETES MELLITUS;							01/25/16	Physician	UNITED STATES

8	DEHYDRATION; ACUTE KIDNEY INJURY; RENAL FAILURE; SEPSIS; HAEMORRHAGE; NECROTISING FASCIITIS; SEPTIC ENCEPHALOPATHY; PULMONARY HYPERTENSION; MUSCLE ATROPHY; URINARY TRACT INFECTION; ACUTE RESPIRATORY FAILURE; DIABETIC KETOACIDOSIS; NECROTISING FASCIITIS; SEPTIC ENCEPHALOPATHY; SEPSIS; RENAL FAILURE; DEHYDRATION; ACUTE KIDNEY INJURY; POST-TRAUMATIC STRESS DISORDER; ACUTE RESPIRATORY FAILURE; URINARY TRACT INFECTION; DIABETIC KETOACIDOSIS;		Hospitalization, Life Threatening, Other	INVOKANA	LEVEMIR	FUROSEMIDE; LEVOTHYROXINE; LISINAPRIL; LORAZEPAM; ASPIRIN; INSULIN HUMAN	TYPE 2 DIABETES MELLITUS; FLUID RETENTION; THYROID DISORDER; BLOOD PRESSURE MEASUREMENT ; ANXIETY; CEREBROVASCULAR ACCIDENT PROPHYLAXIS	100	10/03/14		10/08/14	50-59		07/12/17	Consumer	UNITED STATES
9	NECROTISING FASCIITIS; SCROTAL ABSCESS; SCROTAL ABSCESS; NECROTISING FASCIITIS;		Hospitalization	FARXIGA		METFORMIN HYDROCHLORIDE; GLIPIZIDE; METFORMIN HYDROCHLORIDE; GLIPIZIDE; LIRAGLUTIDE	TYPE 2 DIABETES MELLITUS			02/21/16	02/21/16	60-69		05/31/16	Physician	UNITED STATES
10	NECROTISING FASCIITIS; SCROTAL ABSCESS;	"Fournier's syndrome"	Hospitalization	FARXIGA			DIABETES MELLITUS;		07/01/15	02/21/16	02/21/16	60-69		04/04/16	Physician	UNITED STATES
11	NECROTISING FASCIITIS; SCROTAL ABSCESS;		Hospitalization	XIGDUO XR								70-79		08/12/16	Physician	UNITED STATES
12	NECROTISING FASCIITIS;		Life Threatening	DAPAGLIFLOZIN			TYPE 2 DIABETES MELLITUS					60-69		08/27/16	Other Health Professional	AUSTRALIA

13	IMMUNOSUPPRESSION; NECROTISING FASCIITIS; GLYCOSURIA; GLYCOSURIA; NECROTISING FASCIITIS; SEPSIS; IMMUNOSUPPRESSION;	Necrotizing fasciitis of the perineum	Hospitalization, Life Threatening, Other	COSENTYX	DAPAGLIFLOZIN	CLOTRIMAZOLE; BETAMETHASONE; CALCIPOTRIENE; FLUCONAZOLE; INSULIN HUMAN; ; RAMIPRIL; ROSUVASTATIN; CLOTRIMAZOLE; BETAMETHASONE; CALCIPOTRIENE; FLUCONAZOLE; INSULIN HUMAN; ; RAMIPRIL; CLOTRIMAZOLE; ROSUVASTATIN;	PSORIASIS; INSULIN- REQUIRING TYPE 2 DIABETES MELLITUS	10	'201501		01/06/17	50-59		07/18/17	Other Health Professional	UNITED KINGDOM
14	NECROTISING FASCIITIS; WEIGHT DECREASED;		Hospitalization	EMPAGLIFLOZIN			TYPE 2 DIABETES MELLITUS;		03/22/16		'201702	50-59		06/06/17	Physician	BRAZIL
15	SCROTAL GANGRENE; SCROTAL GANGRENE; NECROTISING FASCIITIS; SEPSIS;		Hospitalization, Life Threatening	DAPAGLIFLOZIN.		; OMEGA-3-ACID ETHYL ESTERS; FENOFIBRATE; LISINOPRIL; ACETAMINOPHEN; GLICLAZIDE; SIMVASTATIN; ASPIRIN; PIOGLITAZONE; METFORMIN HYDROCHLORIDE; ; OMEGA-3-ACID ETHYL ESTERS; FENOFIBRATE; LISINOPRIL; ACETAMINOPHEN; GLICLAZIDE; SIMVASTATIN; ASPIRIN; PIOGLITAZONE; METFORMIN HYDROCHLORIDE			02/23/15	05/09/17	04/25/17	60-69		05/17/18	Other Health Professional	UNITED ARAB EMIRATES
16	NECROTISING FASCIITIS;		Hospitalization, Life Threatening	JARDIANCE		METFORMIN HYDROCHLORIDE	TYPE 2 DIABETES MELLITUS					40-49		09/14/17	Other Health Professional	AUSTRALIA

17	MYOCARDIAL INFARCTION; SEPSIS; ACUTE KIDNEY INJURY; NECROTISING FASCITIS; SEPSIS; MYOCARDIAL INFARCTION; ACUTE KIDNEY INJURY;		Hospitalization	INVOKANA			DIABETES MELLITUS		'201404		03/17/16	60-49		08/01/18	Consumer	UNITED STATES
18	PERINEAL ABSCESS; NECROTISING FASCITIS;		Disability, Hospitalization, Other	FORXIGA		ACARBOSE; ALLOPURINOL; ASPIRIN; GLICLAZIDE; INSULIN HUMAN; LISINAPRIL; METFORMIN HYDROCHLORIDE; INSULIN ASPART; OMEGA-3-ACID ETHYL ESTERS; PIOGLITAZONE; SIMVASTATIN	TYPE 2 DIABETES MELLITUS; GOUT; BLOOD CHOLESTEROL ABNORMAL		11/19/14	06/05/17	04/27/17	60-69		02/09/18	Physician	UNITED KINGDOM
19	NECROTISING FASCITIS;		Hospitalization, Other	JARDIANCE		GLIMEPIRIDE; FLUTICASONE FUROATE/VILANTE ROL TRIFENATATE; METFORMIN HYDROCHLORIDE; ALBUTEROL SULFATE; OMEPRAZOLE; ATORVASTATIN CALCIUM	TYPE 2 DIABETES MELLITUS			02/02/18	01/23/18			03/16/18	Other Health Professional	UNITED KINGDOM
20	NECROTISING FASCITIS; DIABETIC KETOACIDOSIS;		Hospitalization	INVOKANA	INVOKANA		TYPE 2 DIABETES MELLITUS		07/20/15	07/20/15	07/20/15	60-69		05/17/18	Consumer	UNITED STATES
21	SCROTAL ABSCESS; SCROTAL ABSCESS; NECROTISING FASCITIS;		Hospitalization	FORXIGA		METFORMIN HYDROCHLORIDE; GLIMEPIRIDE; DULAGLUTIDE; ROSUVASTATIN CALCIUM; METFORMIN HYDROCHLORIDE; GLIMEPIRIDE; DULAGLUTIDE; ROSUVASTATIN CALCIUM	TYPE 2 DIABETES MELLITUS		01/29/18	03/03/18	03/03/18	40-49		09/10/18	Physician	SAUDI ARABIA

22	DEATH; PERINEAL INFECTION; GENITOURINARY TRACT INFECTION; DIABETIC KETOACIDOSIS; SEPTIC SHOCK;	Surgery to remove necrotic tissue from perineal area	Death, Hospitalization, Life Threatening, Other	JARDIANCE		GLYBURIDEMETFORMIN; PREDNISONE; LEVOTHYROXINE; ALENDRONATE SODIUM	TYPE 2 DIABETES MELLITUS; HYPOTHYROIDISM; OSTEOPOROSIS		12/01/14	10/03/15	10/03/15	70-79		09/05/18	Physician	UNITED STATES
23	NECROTISING FASCIITIS;	"Fournier's disease"	Life Threatening	INVOKANA			TYPE 2 DIABETES MELLITUS;		01/01/18		07/26/18	70-79		08/29/18	Other Health Professional	UNITED STATES
24	SCROTAL SWELLING; WOUND; NECROTISING FASCIITIS;		Hospitalization, Other	JARDIANCE		GABAPENTIN; INSULIN GLARGINE; DULAGLUTIDE	TYPE 2 DIABETES MELLITUS; NEUROPATHY PERIPHERAL		'201704	08/20/18	08/20/18	60-69		09/06/18	Other Health Professional	UNITED STATES
25	NECROTISING FASCIITIS;		Hospitalization, Life Threatening, Other	JARDIANCE			TYPE 2 DIABETES MELLITUS;		04/20/17	08/17/18	04/20/17	60-69		09/28/18	Other Health Professional	UNITED STATES
26	NECROTISING FASCIITIS;		Hospitalization, Other	JARDIANCE							'2018			09/06/18	Other Health Professional	UNITED STATES
27	COLON CANCER; NECROTISING FASCIITIS;		Disability, Hospitalization, Life Threatening, Other	METFORMIN	INVOKANA	MORPHINE; UNSPECIFIED INGREDIENT	DIABETES MELLITUS		12/01/08	10/14/15	10/14/15	40-49		08/30/18	Consumer	UNITED STATES
28	NECROTISING FASCIITIS;		Other	JARDIANCE										09/10/18	Other Health Professional	AUSTRALIA
29	PYREXIA; DIARRHOEA; VOMITING; GANGRENE; SEPSIS; NECROTISING FASCIITIS; ASTHENIA;	Necrotizing fasciitis of perineum	Disability, Hospitalization, Life Threatening	JARDIANCE		INSULIN NOS; SULFAMETHOXAZOLE; LEVITRIMETHOPRIM; SENNOSIDES A AND B; AMINO ACIDS; DEXTROSE; ELECTROLYTES NOS; SOYBEAN OIL; VITAMINS	DIABETES MELLITUS		11/30/17	08/10/18	08/24/18	60-69		09/03/18	Consumer	UNITED STATES
30	NECROTISING FASCIITIS; OSTEOMYELITIS;		Hospitalization, Other	FORXIGA	FORXIGA				07/22/15		'201707	50-59		09/18/18	Physician	CANADA
31	NECROTISING FASCIITIS; DEMENTIA; INCONTINENCE;		Other	FORXIGA										09/19/18	Physician	GERMANY

32	DIABETES MELLITUS INADEQUATE CONTROL; ANXIETY; SEPSIS; PAIN; WEIGHT DECREASED; SUPRAVENTRICULAR TACHYCARDIA; DEPRESSION; NECROTISING FASCIITIS;		Hospitalization, Life Threatening	INVOKANA		INSULIN GLARGINE; ATORVASTATIN CALCIUM; OMEPRAZOLE	DIABETES MELLITUS		04/05/16	08/03/17	08/05/17	60-69		09/18/18	Consumer	UNITED STATES
33	NECROTISING FASCIITIS; TESTICULAR PAIN; SEPSIS; EMOTIONAL DISTRESS; TESTICULAR SWELLING;		Disability, Hospitalization, Life Threatening	INVOKAMET		ATORVASTATIN; DOXEPIN; GABAPENTIN; INSULIN ASPART; INSULIN DEGLUDEC; MELOXICAM; SILDENAFIL CITRATE; TIZANIDINE	TYPE 2 DIABETES MELLITUS				01/25/18	40-49		09/19/18	Pharmacist	UNITED STATES
34	NECROTISING FASCIITIS;		Disability, Hospitalization, Life Threatening, Other	INVOKAMET XR			TYPE 2 DIABETES MELLITUS					50-59		09/20/18	Physician	UNITED STATES
35	NECROTISING FASCIITIS;		Hospitalization	INVOKANA										09/12/18	Physician	UNITED STATES
36	NECROTISING FASCIITIS;		Other	FARXIGA										09/20/18	Physician	UNITED STATES
37	NECROTISING FASCIITIS;		Hospitalization, Other	FORXIGA		INSULIN NOS	DIABETES MELLITUS					70-79		09/24/18	Physician	BRAZIL
38	NECROTISING FASCIITIS;		Other	VOKANAMET			TYPE 2 DIABETES MELLITUS							09/25/18	Physician	SPAIN
39	NECROTISING FASCIITIS;		Other	FARXIGA										09/26/18	Physician	UNITED STATES
40	NECROTISING FASCIITIS; RASH;		Other	FARXIGA										09/27/18	Physician	UNITED STATES
41	NECROTISING FASCIITIS;	Preferred term "Fournier's gangrene"	Hospitalization	DAPAGLIFLOZIN.		CANDESARTAN; METFORMIN HYDROCHLORIDE; AMLODIPINE BESYLATE	TYPE 2 DIABETES MELLITUS				08/17/18	30-39		09/27/18		GERMANY
42	NECROTISING FASCIITIS; DIABETIC KETOACIDOSIS;		Hospitalization, Life Threatening, Other, Required Intervent...	INVOKANA			TYPE 2 DIABETES MELLITUS		12/12/14	07/20/15	07/20/15	50-59			Consumer	UNITED STATES
43	NECROTISING FASCIITIS;		Hospitalization, Life Threatening, Other, Required Intervent...	INVOKANA			TYPE 2 DIABETES MELLITUS				'201710	50-59		09/21/18	Consumer	UNITED STATES

44	NECROTISING FASCIITIS;		Hospitalization, Life Threatening, Other, Required Intervent...	JARDIANCE			TYPE 2 DIABETES MELLITUS		'201803	07/28/18	07/28/18	40-49		09/19/18	Consumer	UNITED STATES
45	NECROTISING FASCIITIS;		Hospitalization, Life Threatening, Other, Required Intervent...	JARDIANCE			TYPE 2 DIABETES MELLITUS		'201410	'201501	'201501	50-59		09/19/18	Consumer	UNITED STATES
46	NECROTISING FASCIITIS;		Hospitalization, Life Threatening, Other, Required Intervent...	INVOKANA	JARDIANCE		TYPE 2 DIABETES MELLITUS		'2015		06/30/17	50-59		09/19/18	Consumer	UNITED STATES
47	NECROTISING FASCIITIS;		Hospitalization	INVOKANA	JANUMET						'201707			09/28/18	Physician	UNITED STATES
Other severe genital AEs																
1	HYPERSENSITIVITY VASCULITIS; CELLULITIS OF MALE EXTERNAL GENITAL ORGAN;		Hospitalization	INVOKANA			TYPE 2 DIABETES MELLITUS;							09/18/14	Physician	UNITED STATES
2	SCROTAL ABSCESS;		Other	FARXIGA			TYPE 2 DIABETES MELLITUS;	5						11/14/14	Consumer	UNITED STATES
3	STAPHYLOCOCCAL INFECTION; GLYCOSURIA; POST PROCEDURAL INFECTION; DEVICE RELATED INFECTION; SCROTAL ABSCESS; BACTERAEMIA;		Hospitalization, Other	CANAGLIFLOZIN			TYPE 2 DIABETES MELLITUS;		05/10/15		05/10/15	40-49		05/12/15	Physician	UNITED STATES
4	PYELONEPHRITIS; PERINEAL ABSCESS;		Other	INVOKANA										11/16/15	Consumer	UNITED STATES
5	VULVAL CELLULITIS;		Hospitalization	FORXIGA			DIABETES MELLITUS;	10						02/25/16	Physician	CANADA
6	CELLULITIS OF MALE EXTERNAL GENITAL ORGAN;		Hospitalization	CANAGLU		METFORMIN HYDROCHLORIDE; LINAGLIPTIN; INSULIN GLARGINE; ROSUVASTATIN CALCIUM; ZOLPIDEM TARTRATE; INSULIN LISPRO	TYPE 2 DIABETES MELLITUS; DYSLIPIDAEMIA; INSOMNIA	100	01/23/15		12/14/15	40-49		04/15/16	Other Health Professional	JAPAN

7	VOMITING; CELLULITIS OF MALE EXTERNAL GENITAL ORGAN; NAUSEA;		Hospitalization	FORXIGA		ASPIRIN; ATORVASTATIN CALCIUM; BETAMETHASONE VALERATE; METFORMIN HYDROCHLORIDE/S ITAGLIPTIN PHOSPHATE; PERINDOPRIL; ACETAMINOPHENIC ODEINE PHOSPHATE	TYPE 2 DIABETES MELLITUS;	10				60-69	11/25/16	Pharmacist	CANADA
8	TINEA CRURIS; CELLULITIS OF MALE EXTERNAL GENITAL ORGAN;		Hospitalization	FORXIGA			TYPE 2 DIABETES MELLITUS;					70-79	03/01/17	Physician	AUSTRALIA
9	CELLULITIS OF MALE EXTERNAL GENITAL ORGAN; PENILE OEDEMA; BLOOD UREA INCREASED; SCROTAL OEDEMA; TENDERNESS; ERYTHEMA; WHITE BLOOD CELL COUNT INCREASED; PENILE SWELLING;		Hospitalization	COSENTYX	COSENTYX	HYDROXYCHLORO QUINE SULFATE; HYDROXYCHLORO QUINE SULFATE; ASPIRIN; NAPROXEN; OMEPRAZOLE; VALSARTAN; CANAGLIFLOZIN; METOPROLOL SUCCINATE; ALBUTEROL	PSORIATIC ARTHROPATHY; SPONDYLOART HROPATHY; CARDIOVASCUL AR EVENT PROPHYLAXIS; GASTROESOP HAGEAL REFLUX DISEASE; HYPERTENSION ; TYPE 2 DIABETES MELLITUS; HYPERTENSION				10/30/16	04/11/17	Other Health Professional	UNITED STATES	
10	BACK PAIN; URINARY TRACT INFECTION; CELLULITIS OF MALE EXTERNAL GENITAL ORGAN;	Posthitis	Hospitalization	JARDIANCE		METFORMIN HYDROCHLORIDE; ANAGLIPTIN; MITIGLINDE CALCIUM HYDRATE/VOGLIBO SE; GLICLAZIDE; EZETIMIBE	TYPE 2 DIABETES MELLITUS	01/10/17	10/23/17	10/21/17	40-49	03/01/18	Physician	JAPAN	
11	PERINEAL ABSCESS; URINARY TRACT INFECTION;	Treated with surgery	Disability, Hospitalization	JARDIANCE		TELMISARTAN; GLIMEPIRIDE; SITAGLIPTIN	TYPE 2 DIABETES MELLITUS			11/07/17	'201710	50-59	02/02/18	Physician	JAPAN



12	GANGRENE; NECROTISING FASCIITIS; LEG AMPUTATION; SEPSIS; OSTEOMYELITIS; DIABETIC KETOACIDOSIS; ABSCESS; DIABETIC ULCER; CELLULITIS; NEUROPATHIC ARTHROPATHY;	Necrotizing fasciitis of the pelvis	Disability, Hospitalization	INVOKANA		METFORMIN HYDROCHLORIDE; INSULIN GLARGINE; INSULIN LISPRO					'201503	40-49		02/14/18	Consumer	UNITED STATES
13	SEPSIS; URINARY TRACT INFECTION; ACUTE KIDNEY INJURY; PERINEAL INFECTION; SKIN ABRASION;		Hospitalization, Other	FORXIGA					04/26/18	05/05/18	05/05/18	50-59		05/15/18	Physician	MALAYSIA
14	ACUTE KIDNEY INJURY; TREATMENT NONCOMPLIANCE; DIABETIC KETOACIDOSIS; SEPSIS; CELLULITIS OF MALE EXTERNAL GENITAL ORGAN;		Hospitalization	INVOKANA	GLUCOPHAGE, VICTOZA		TYPE 2 DIABETES MELLITUS		02/09/15		'201710	30-39		06/20/18	Consumer	UNITED STATES
15	NECROTISING FASCIITIS;	Defined "negative for Fournier's gangrene"	Other	FORXIGA										09/12/18		AUSTRALIA
16	PERINEAL ABSCESS;		Hospitalization	SYNJARDY					03/27/18	09/14/18	09/06/18	40-49		09/26/18	Physician	SPAIN
17	NECROTISING FASCIITIS;	Pubic necrotizing fasciitis	Other	FORXIGA										09/25/18	Other Health Professional	CHINA

\* According to GB Data Protection Act, only age range can be shown and gender cannot be shown