

TGA DAEN DATA ANALYSIS @ 10.2023



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Database of Adverse Event Notifications (DAEN) - medicines

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Inclusion in DAEN - medicines does not mean that the adverse event has been confirmed or that it was caused by a medicine or vaccine.

Tables and graphs | Graphs

Advanced search options ?

MedDRA system organ class

(All selected)

- Search
- Select all
 - Blood and lymphatic system disorders
 - Cardiac disorders
 - Congenital, familial and genetic disorders
 - Ear and labyrinth disorders
 - Endocrine disorders

MedDRA reactions

(All selected)

- Search
- Select all
 - 11-beta-hydroxylase deficiency
 - 5q minus syndrome
 - Abdominal abscess
 - Abdominal adhesions
 - Abdominal cavity drainage

Age (years)

- Select all
- Less than 5
- 5 to 11
- 12 to 17
- 18 to 64
- 65 and above
- Unknown

Gender

- Select all
- Female
- Male
- Not Specified

Filters

From: 1/01/1971 To: 9/10/2023

Search medicines - (10,094) Medicines selected...

(Search by [trade name/s](#) or an [active ingredient/s](#). Select one or multiple medicines from the list below to include in your search.)

Search

- Select all
- 100% Pure bee pollen (active ingredients: Pollen)
- 123Diet Drops - AUST L 301834 (active ingredients: Glutamine; Ornithine monohydrochloride; Alanine; Lysine hydrochloride; Histidine; Gymnema sylvestr...
- 1300 SEASICK (Escape Travel Sickness) compounded sea sickness product - Not on ARTG (active ingredients: caffeine; Chlorphenamine maleate (Chlorphe...
- 30 Plus (active ingredients: calcium; chromium picolinate; Cimicifuga racemosa; cyanocobalamin; folic acid; pyridoxine; tyrosine)
- 35 Billion Probiotic 10 - AUST L 292340 (active ingredients: Lactobacillus plantarum; Lactobacillus brevis; Lactobacillus salivarius ssp salivarius; Bifidobacter...
- 3TC (active ingredients: lamivudine)

Search summary counter

Reports (cases) 609,205	Single suspected medicine 497,920	Reported deaths 14,418
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Medicine summary - (16,166)

Hover over the table to view exporting data and other options. Click on the dots to see more options. →

MedDRA system organ class	MedDRA reaction term	Number of cases	Cases with a single suspected medicine	Cases where death was a reported outcome
Nervous system disorders	Headache	51,946	48,562	123
General disorders and administration site conditions	Pyrexia	42,272	34,054	266
Gastrointestinal disorders	Nausea	41,415	36,660	222
Skin and subcutaneous tissue disorders	Rash	34,887	27,064	113
General disorders and administration	Injection site reaction	32,698	28,293	8

List of reports - (609,205)

Hover over the table to view exporting data and other options. Click on the dots to see more options. →

Case number	Report entry date	Age (years)	Gender	Medicines reported as being taken	MedDRA reaction terms
7314	29/07/1971	15	Female	<ul style="list-style-type: none"> • Disprin (aspirin) - Suspected • Trade name not specified (ampicillin sodium) - Suspected • Trade name not specified (erythromycin) - Suspected 	<ul style="list-style-type: none"> • Pruritus • Rash maculo-papular
7310	25/09/1971	18	Female	<ul style="list-style-type: none"> • Penicillin (Penicillin) - Suspected • Trade name not specified (ampicillin sodium) - Suspected 	<ul style="list-style-type: none"> • Rash
7311	12/10/1971	14	Female	<ul style="list-style-type: none"> • Trade name not specified (ampicillin sodium) - Suspected 	<ul style="list-style-type: none"> • Rash erythematous
7312	16/10/1971	16	Female	<ul style="list-style-type: none"> • Trade name not specified (ampicillin) 	<ul style="list-style-type: none"> • Rash erythematous

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From: 21/12/2020 To: 9/10/2023

Search medicines - (11) Medicines selected

(Search by trade name/s or an active ingredient/s. Select one or multiple medicines from the list below to include in your search.)

Covid

- Select all
- COMIRNATY COVID-19 vaccine (active ingredients: tozinameran)
- COMIRNATY Original/Omicron BA (TNS) COVID-19 Vaccine - (tozinameran/not specified) (active ingredients: tozinameran)
- COMIRNATY ORIGINAL/OMICRON BA.1 COVID-19 Vaccine - (tozinameran/ritozinameran) (active ingredients: ritozinameran, tozinameran)
- COMIRNATY ORIGINAL/OMICRON BA.4-5 COVID-19 Vaccine - (tozinameran/famtozinameran) (active ingredients: famtozinameran, tozinameran)
- COVID-19 Vaccine (TNS) (active ingredients: COVID-19 Vaccine (Type not specified))
- COVID-19 Vaccine AstraZeneca (active ingredients: ChAdOx1-S (Viral vector))

Search summary counter

Reports (cases)	Single suspected medicine	Reported deaths
139,389	135,721	1,003

Medicine summary - (139,389)

Hover over the table to view exporting data and other options. Click on the dots to see more options.

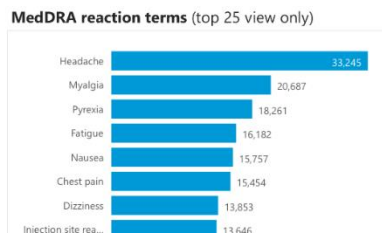
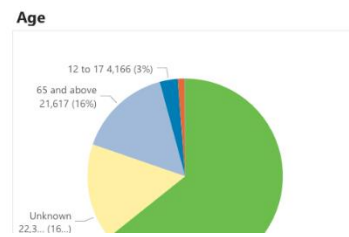
MedDRA system organ class	MedDRA reaction term	Number of cases	Cases with a single suspected medicine	Cases where death was a reported outcome
Nervous system disorders	Headache	33,245	32,645	46
Musculoskeletal and connective tissue disorders	Myalgia	20,687	20,348	14
General disorders and administration site conditions	Pyrexia	18,261	17,923	39
General disorders and administration site conditions	Fatigue	16,182	15,806	33

List of reports - (139,389)

Hover over the table to view exporting data and other options. Click on the dots to see more options.

Case number	Report entry date	Age (years)	Gender	Medicines reported as being taken	MedDRA reaction terms
515141	21/12/2020	46	Female	<ul style="list-style-type: none"> • COMIRNATY COVID-19 vaccine (tozinameran) - Suspected • Revestive (teduglutide) - Suspected 	<ul style="list-style-type: none"> • Abdominal discomfort • Abdominal distension • Abdominal pain • Adverse event following immunisation • Arthritis • Arthritis bacterial • Bacteraemia • Drug ineffective • Dyspnoea exertional • Endocarditis • Fatigue

Data visual representation



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609,205 ALL CASES (including COVID jabs) TGA DAEN from 7.1971 to 10.2023 = Average 11,659 cases per annum over 52.25 years.

609,205 cases less COVID Jab cases 139,389 = 469,816 cases divided by 52.25 yrs = Average 8,992 cases (non-COVID jabs) per annum.

139,389 COVID jabs by 2.75 years (2.2021 - 10.2023) = Avg. 50,687 cases p.a.

50,687 (C-19 jabs) compare to 8,992 (non-C-19 jabs) p.a. = 464% increase in cases p.a.!!

Now - apply underreporting factor of x 30.

Avg. COVID jabs 50,687 cases p.a. x 30 = 1,520,610 (estimate) COVID jab cases p.a.

TGA DAEN Deaths Data, Jab deaths & Maths

14,418 deaths reported ALL cases (incl. COVID jabs) 1971-2023 = Avg. 276 p.a.

14,418 deaths less COVID jab deaths 1,003 = 13,415 by 52.25 yrs = Avg. 257 p.a.

1,003 **C-19 jab reported deaths** (12.2020-10.2023) by 2.75yrs = **Avg. 365 deaths p.a.**

365 COVID jab deaths by 257 Non-C-19 jab deaths = 42% increase DAEN deaths p.a

Underreporting factor 365 C-19 jab deaths p.a. x 30 = 10,950 deaths estimate p.a.

LOST PREGNANCIES – MISCARRIAGES, FOETAL DEATHS & STILLBIRTHS

Search the DAEN - medicines ?

Date range ?

From: 1/01/1971 To: 9/10/2023

Search medicines - (455) Medicines selected
(Search by trade name/s or an active ingredient/s. Select one or multiple medicines from the list below to include in your search.)

Search:

- Select all
- 30 Plus (active ingredients: calcium; chromium piccolinate; Cimicifuga racemosa; cyanocobalamin; folic acid; pyridoxine; tyrosine)
- 3TC (active ingredients: lamivudine)
- 5FU (active ingredients: fluorouracil)
- Abilify (active ingredients: aripiprazole)
- Acetylsalicylic acid (active ingredients: Acetylsalicylic acid)
- Aclasta (active ingredients: zoledronic acid; zoledronic acid monohydrate)

Search summary counter

Reports (cases)	Single suspected medicine	Reported deaths
1,153	985	60

Medicine summary - ra@s ?
Hover over the table to view exporting data and other options. Click on the dots to see more options. →

MedDRA system organ class	MedDRA reaction term	Number of cases	Cases with a single suspected medicine	Cases where death was a reported outcome
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	890	781	1
Pregnancy, puerperium and perinatal conditions	Foetal death	178	136	34
Pregnancy, puerperium and perinatal conditions	Stillbirth	93	73	26

List of reports - ra@s ?
Hover over the table to view exporting data and other options. Click on the dots to see more options. →

Case number	Report entry date	Age (years)	Gender	Medicines reported as being taken	MedDRA reaction terms
7827	6/06/1973	28	Female	<ul style="list-style-type: none"> • Provera (medroxyprogesterone acetate) - Suspected • F.G.F. (ferrous sulfate heptahydrate; folic acid) - Not suspected 	<ul style="list-style-type: none"> • Congenital hydrocephalus • Stillbirth
8324	27/08/1973	20	Female	<ul style="list-style-type: none"> • Calvita (Calcium phosphate; Cholecalciferol; ferrous sulfate heptahydrate; Thiamine hydrochloride) - Suspected • F.G.F. (ferrous sulfate heptahydrate; folic acid) - Suspected • Trade name not specified (Product not coded) - Suspected 	<ul style="list-style-type: none"> • Anencephaly • Spine malformation • Stillbirth

Data visual representation

Tables and graphs | **Graphs**

Advanced search options ?

MedDRA system organ class
(All selected)

Search:

Select all
 Pregnancy, puerperium and perinatal condi...

MedDRA reactions
(1 selected)

Search:

Stillbirth
 Stillbirth
 Abortion spontaneous
 Foetal death

Age (years)

Select all
 Less than 5
 12 to 17
 18 to 64
 Unknown

Gender

Select all
 Female
 Male
 Not Specified

Data visual representation

Age

Less than 5 6 (1%)

MedDRA reaction terms (top 25 view only)

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Search the DAEN - medicines

Date range

From 1/01/2021 To 9/10/2023

Search medicines - (5) Medicines selected

(Search by trade name/s or an active ingredient/s. Select one or multiple medicines from the list below to include in your search.)

- Select all
- COMIRNATY COVID-19 vaccine (active ingredients: tozinameran)
- COVID-19 Vaccine (TNS) (active ingredients: COVID-19 Vaccine (Type not specified))
- COVID-19 Vaccine AstraZeneca (active ingredients: ChAdOx1-S (Viral vector))
- NUVAXQVID COVID-19 Vaccine (active ingredients: SARS-CoV-2 rS (NVX-CoV2373))
- Spikevax COVID-19 vaccine - (elasomeran) (active ingredients: elasomeran)

Search summary counter

Reports (cases)	Single suspected medicine	Reported deaths
335	325	0

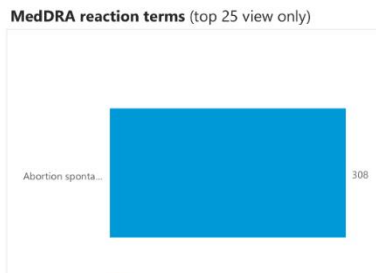
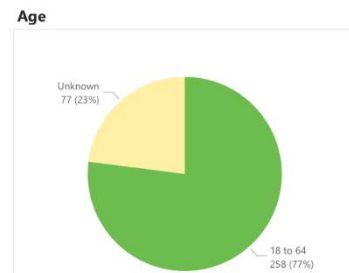
Medicine summary -

MedDRA system organ class	MedDRA reaction term	Number of cases	Cases with a single suspected medicine	Cases where death was a reported outcome
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	308	298	0
Pregnancy, puerperium and perinatal conditions	Stillbirth	17	17	0
Pregnancy, puerperium and perinatal conditions	Foetal death	12	12	0

List of reports -

Case number	Report entry date	Age (years)	Gender	Medicines reported as being taken	MedDRA reaction terms
544763	28/04/2021	-	Female	• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected	• Abortion spontaneous
545665	30/04/2021	36	Female	• COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector)) - Suspected	• Abortion spontaneous
549660	7/05/2021	32	Female	• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected	• Abortion spontaneous
550251	10/05/2021	27	Not Specified	• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected	• Abortion spontaneous
552136	13/05/2021	35	Female	• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected	• Abortion spontaneous • Menstruation irregular
552803	14/05/2021	35	Female	• COMIRNATY COVID-19 vaccine (tozinameran) - Suspected	• Abortion spontaneous

Data visual representation



Data visual representation

Tables and graphs

Advanced search options

MedDRA system organ class

(All selected)

Search

Select all

Pregnancy, puerperium and perinatal condi...

MedDRA reactions

(1 selected)

Search

Stillbirth

Abortion spontaneous

Foetal death

Age (years)

Select all

18 to 64

Unknown

Gender

Select all

Female

Male

Not Specified

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LOST PREGNANCIES – MISCARRIAGES, FOETAL DEATHS & STILLBIRTHS

TGA DAEN all lost pregnancies (incl. COVID jabs) 6.1973 - 10.2023 = 1,153 cases.
 1,153 divided by 50.25 years = Avg. 23 lost pregnancies per annum.
 1,153 cases less C-19 jab lost pregnancies 335 = 818 by 50.25yrs = 16 p.a. (non-C-19).
335 COVID jabs lost pregnancies (4.2021-10.2023) divided by 2.5yrs = Avg. 134 p.a.
 134 p.a. jabs lost pregnancies compare to 16 p.a. = **737.5% increase lost pregnancies p.a.**
 Apply **underreporting factor 30** x 335 DAEN 'lost pregnancies' following COVID jabs = **10,050 (estimate) of 'deaths in the wombs'**. Not so 'safe and effective'. Sharon Cousins 10.2023