



Valium kills 1,000 Australians every year, here are 8 reasons *why...**

What is it used for? Valium (Diazepam) is used to treat anxiety and belongs to a group of medicines called benzodiazepines. Valium is also used to relax muscles and to help people sleep. It is made by Roche Products.

Consumer Medicines Information (CMI) The CMI is the Australian Government warning document that is legally required to list all the serious risks and side effects of taking the medication, or a combination of medications.

What is the problem? Pharmaceutical companies have illegally excluded deadly side effects from Australian CMIs for over 20 years, as exposed in an independent report written with the assistance of doctors from Harvard and Yale universities. Here are **8 life threatening risks not contained in the [January 2020 Valium CMI](#)**

1. Addiction

The Australian Government Department of Health warns that prescription addiction is a significant issue and that *many patients are unaware that prescription medications such as benzodiazepines like Valium, can be highly addictiveⁱ ⁱⁱ*. They also warn that benzodiazepines should only be used for less than a month, and the shorter the safer, because they are addictiveⁱⁱⁱ. The reason why people are unaware of the risk of addiction is because it is not present in the benzodiazepine CMIs sourced from the TGA website. This is even though the TGA classes many benzodiazepines like Alprazolam (Xanax) as drugs of addiction. In fact, the Roche Valium CMI has not contained any warning of the risk of addiction since CMIs were introduced in 2000.

2. Dependence

The information given to health professionals by Roche warns that *the risk of dependence increases with higher doses and longer use^{iv}*. However, this warning is not included in the CMI for the consumers who take the medication. The Department of Health warns that dependence on pharmaceutical medicines can happen to anyone and often the person may not even be aware of it. This is an important warning as international experts warn that Valium dependence can lead to *addiction and abuse^v*. The Department of Health warns that dependence also means that if you stop taking the dose of medicine it can cause physical and mental *withdrawal symptoms^{vii}*.

3. Withdrawal Symptoms

The Valium CMI does not mention withdrawal symptoms, the risks or the side effects. However, Roche warn health professionals that after as little as one week of therapy, withdrawal symptoms can appear following the cessation of recommended doses. They also warn that withdrawal from Valium can take from 4 weeks to 4 months^{viii}. The Department of Health states that benzodiazepine withdrawal symptoms that can last up to a year^{ix}, and the risks include seizures and death^x.

4. Abuse

Prescription medication abuse is the use of the drug other than as prescribed by a doctor, it generally occurs when a person becomes dependent or addicted to the drug. 1 million Australians misuse a pharmaceutical drug every year, with benzodiazepines the leading medications abused^{xi}. As with dependence and addiction, the risk of abuse for benzodiazepines is a reason why they are classed as controlled drugs by the TGA. The TGA states that benzodiazepines must be used with caution because of the risk of dependence and abuse, even when used at therapeutic doses for short periods^{xii}, yet this risk is not present in the CMIs.

* Valium is used in the title to describe the class of medications known as benzodiazepines

5. Pregnancy

According to Roche, the safety of Valium for use in human pregnancy has not been established. Use during pregnancy can cause premature birth or miscarriage, and the baby may suffer from respiratory depression, withdrawal syndrome, congenital malformation, or delayed development.^{xiii} None of this information is contained in the Valium CMI.

6. Alcohol

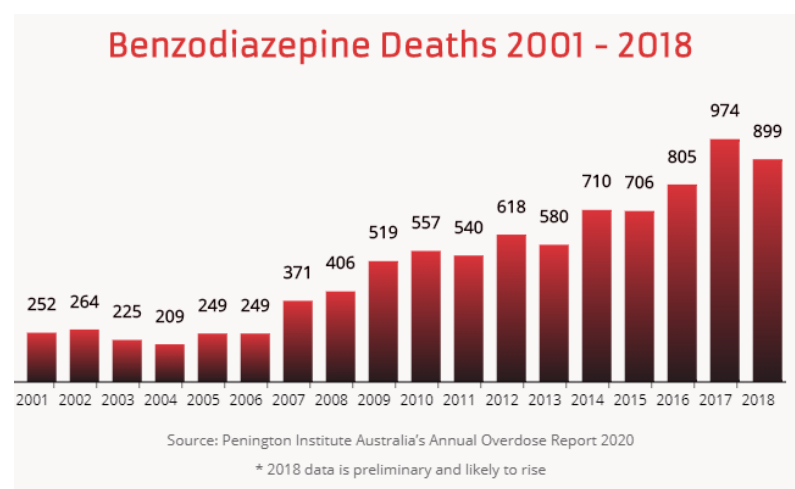
Combining Valium with alcohol can cause severe sedation, respiratory depression, cardiovascular depression, coma, and death, according to Roche^{xv}. However, they only warn consumers in the CMI about the risk of drowsiness, confusion, dizziness and unsteadiness which may increase the risk of a fall. The risk of coma or death has never been included.

7. Prescription Opioids

ABS data shows that the combination of opioids (e.g. Endone) and benzodiazepines is one of the leading causes of drug deaths in Australia over the last decade^{xvi}. The Endone CMI^{xvii} warns that combining it with benzodiazepines can result in severe drowsiness, decreased awareness, breathing problems, coma and death. However, this warning is not included in the Valium CMI, in fact it has never even mentioned opioids or these risks, once in 20 years. The same issue exists for antidepressants, a medication commonly prescribed with Valium.

8. Death

Benzodiazepines are the most common substance found in intentional and accidental drug deaths in Australia^{xviii}. **No prescription medication kills more Australians each year.** The risk of death is not mentioned once in the Valium CMI or any one of the other benzodiazepine CMIs reviewed on the TGA website.



The 2020 Penington Institute Annual Overdose Report^{xix} shows that benzodiazepine related deaths continue to increase. The total number of deaths from 2001-2018 is **9,133** and the annual number of deaths is almost **1,000**.

It is uncommon for benzodiazepines to be the sole medication in drug deaths. The ABS states that in over 97% of drug-induced deaths where benzodiazepines were present, they were taken in conjunction with other drugs like *prescription opioids, antidepressants and alcohol*^{xx}. 3 deadly risks not included in the Valium CMI.

Due to the increase in anxiety related mental health conditions during COVID-19, there are reports of an increase in benzodiazepine prescriptions by as much as 31%^{xxi}. Based on PBS data, that would see the total number of prescriptions increase from 6 million to around 8 million a year. Potentially that could see the loss of life due to benzodiazepines increase by several hundred Australians, to around **1,200-1,300** each year.

TGA fails and refuses to act



Professor
John
Skerritt

The Department of Health advises that for information about diazepam you can read the [CMI leaflet](#) which is regulated by the TGA. Professor John Skerritt the head of the TGA stated that the TGA would not review the CMIs to include these 8 warnings. The written reason he gave was that *Australians have a low level of medical literacy and including these risks could confuse consumers and delay treatment*. However, Professor Skerritt could not explain why these risks are contained in Roche Valium health professional warnings and the Roche [US consumer warning guide](#) (as required by the FDA). In fact, on World Mental Health Day 2020 it was reported that the FDA is now

increasing the information on these risks for consumers. These risks will now be part of a *Boxed Warning*, the FDA's most prominent warning. The reason is due to the increase in use of benzodiazepines for anxiety conditions due to COVID-19^{xxii}. In Australia, these risks will remain excluded to consumers, as they have for 20 years and over 50 million prescriptions.

Help us to make a change.

If you believe the CMI should have these warnings included, please email Professor Skerritt john.skerritt@health.gov.au and support our [change.org](https://www.change.org/prescribeddeaths) petition <https://www.change.org/prescribeddeaths>

A summary of the report that details the failure of the TGA to regulate Australian CMI warnings and the letter of complaint to the TGA can be found [here](#).

This summary was produced by Patrick O'Connor – author, *Prescribed Deaths – Life in The Killing Zone*.

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ⁱ Australian Government Department of Health, Healthdirect website, *Prescription Medication* see <https://www.healthdirect.gov.au/blog/prescription-medicine-addiction-can-happen-to-anyone>

ⁱⁱ Australian Government Department of Health, Healthdirect website, *Medicines and Addiction* see <https://www.healthdirect.gov.au/medicines-and-addiction>

ⁱⁱⁱ Australian Government Department of Health, Healthdirect website, *Anxiety Medication* see <https://www.healthdirect.gov.au/anxiety-medication>

^{iv} Roche Pharma, Valium Product Information, January 2020 see <https://www.nps.org.au/medicine-finder/valium-tablets#full-pi>

^v *Prescribed Deaths Life in The Killing Zone*, Chapter two www.prescribeddeaths.com.au

^{vi} Australian Government Department of Health, Healthdirect website, *Medicines and Addiction* see <https://www.healthdirect.gov.au/medicines-and-addiction>

^{vii} Australian Government Department of Health, Healthdirect website, *Substance Abuse* see <https://www.healthdirect.gov.au/substance-abuse>

^{viii} Roche Pharma, Valium Product Information, January 2020 see <https://www.nps.org.au/medicine-finder/valium-tablets#full-pi>

^{ix} Australian Government Department of Health, *Benzodiazepines*, see <https://adf.org.au/drug-facts/benzodiazepines/>

^x Australian Government Department of Health, *Benzodiazepines*, see <https://sydney.edu.au/content/dam/corporate/documents/research/matilda-centre/benzodiazepines-factsheet.pdf>

^{xi} Australian Government Department of Health, Healthdirect website, *Drug abuse* see <https://www.healthdirect.gov.au/drug-abuse>

^{xii} Therapeutic Goods Administration, *Scheduling delegate's final decisions*, June 2016, see <https://www.tga.gov.au/book-page/21-benzodiazepine-derivatives>

^{xiii} Roche Pharma, Valium Product Information, January 2020 see <https://www.nps.org.au/medicine-finder/valium-tablets#full-pi>

^{xiv} Australian Government Department of Health, *Drugs During Pregnancy*, see <https://www.sydney.edu.au/content/dam/corporate/documents/research/matilda-centre/substance-use-in-pregnancy.pdf>

^{xv} Roche Pharma, Valium Product Information, January 2020 see <https://www.nps.org.au/medicine-finder/valium-tablets#full-pi>

^{xvi} Australian Government, Australian Institute of Health and Welfare, *Alcohol, tobacco & other drugs in Australia*, see <https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/contents/drug-types/non-medical-use-of-pharmaceutical-drugs>

^{xvii} Alphapharm, Endone CMI April 2020, see <https://www.nps.org.au/assets/medicines/6c069f2f-c075-4d85-829a-a53300fede83-reduced.pdf>

^{xviii} Australian Government, Australian Institute of Health and Welfare, *Alcohol, tobacco & other drugs in Australia*, see <https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/contents/drug-types/non-medical-use-of-pharmaceutical-drugs>

^{xix} Pennington Institute, *Annual Overdose Report 2020*, see <https://www.pennington.org.au/publications/2020-overdose-report/>

^{xx} Australian Government, Australian Institute of Health and Welfare, *Alcohol, tobacco & other drugs in Australia*, see <https://www.aihw.gov.au/reports/alcohol/alcohol-tobacco-other-drugs-australia/contents/drug-types/non-medical-use-of-pharmaceutical-drugs>

^{xxi} Outcome Health, *Mental Health Impacts of COVID-19*, see https://www.digitalhealthcra.com/wp-content/uploads/2020/07/5_COVID19-Paper-5-Mental-Health.pdf

^{xxii} US Food and Drug Administration, *Boxed label changes for safe benzodiazepine use*, see <https://www.fda.gov/drugs/drug-safety-and-availability/fda-requiring-boxed-warning-updated-improve-safe-use-benzodiazepine-drug-class>