Prescriber Update

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Systemic fluoroquinolone antibiotics: Safety reminder

Key messages

- Only prescribe fluoroquinolones when other antibiotics normally used for the infection are inappropriate.
- Fluoroquinolones have been associated with prolonged, disabling, and potentially persistent/irreversible serious adverse reactions, including tendonitis/tendon rupture, peripheral neuropathy and psychiatric reactions.
- These reactions can affect any patient, regardless of their age and personal risk factors, and can involve multiple organ systems. Advise patients to seek medical attention if they experience signs/symptoms of serious adverse reactions during or after treatment.

In March 2025 the Medicines Adverse Reactions Committee (MARC) reviewed several safety concerns related to systemic fluoroquinolone antibiotics. The MARC recommended that the data sheets for these medicines be updated. See the Medsafe website for the meeting minutes and the report to the MARC.

The data sheets of available products have been updated to state that serious, prolonged, and disabling adverse reactions, such as tendonitis/tendon rupture, peripheral neuropathy and psychiatric reactions, are potentially irreversible.

Fluoroquinolones

Systemically acting fluoroquinolone antibiotics currently available include ciprofloxacin, moxifloxacin and norfloxacin. All fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions and antibiotic resistance.[1,2]

The data sheets for these products have been updated to state that fluoroquinolones should only be prescribed when other antibiotics normally used to treat the infection are inappropriate (ie, these medicines should only be used second line).

Refer to local guidelines for information on antimicrobial prescribing.

Key safety concerns

Table 1 provides a summary of key safety concerns associated with fluoroquinolones.

Reports of serious, prolonged, disabling and potentially irreversible adverse reactions include (but are not limited to) tendonitis/tendon rupture, peripheral neuropathy and psychiatric reactions.

Patients of any age and without pre-existing risk factors have experienced these adverse reactions. These reactions can occur shortly after initiation of treatment, or in the case of tendon rupture, may occur months after stopping therapy.[1,3,4] Remind patients to seek medical attention if they experience signs/symptoms during or following treatment.

Table 1: Safety concerns with systemic fluoroquinolone antibiotics[a]

Body system	Adverse reactions
Cardiac	QT prolongation Aortic aneurysm and dissection Kounis syndrome
Hepatobiliary	Fulminant hepatitis leading to liver failure
Musculoskeletal	Tendonitis Tendon rupture Exacerbation of symptoms of myasthenia gravis
Nervous system	Peripheral neuropathy Seizures
Psychiatric	Anxiety reactions Depression* Psychotic reactions* *which may progress to suicidal ideation
Skin/subcutaneous tissue	Photosensitivity reactions Toxic epidermal necrolysis Stevens-Johnson syndrome Acute generalised exanthematous pustulosis Drug reaction with eosinophilia and systemic symptoms

a. Not an exhaustive list. Refer to the data sheets for full information.

Sources: Moxifloxacin, norfloxacin and ciprofloxacin data sheets, available at: www.medsafe.govt.nz/Medicines/infoSearch.asp (accessed 27 June 2025).

New Zealand case reports

The New Zealand Pharmacovigilance database continues to receive adverse reaction reports associated with fluoroquinolones. Since January 2015, the majority of reports are for ciprofloxacin and relate to tendon adverse reactions. Table 2 shows the top five adverse reactions reported with a fluoroquinolone antibiotic.

Table 2: Top five adverse reaction terms reported with fluoroquinolone antibiotics, 1 January 2015 to 27 June 2025

Adverse reaction (MedDRA preferred term)	Number of reports
Tendonitis	62
Tendon disorder	21
Tendon rupture	12
Arthralgia	12
Paraesthesia	10

Source: New Zealand Pharmacovigilance database (accessed 27 June 2025).

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MARC's remarks: June 2025 meeting

The Medicines Adverse Reaction Committee (MARC) convened for their 202nd meeting on 12 June 2025.

The Committee reviewed the safety of **macrolide antibiotics** (**azithromycin, erythromycin, clarithromycin, roxithromycin**) in regard to cardiovascular death. The Committee noted the warning in the clarithromycin data sheet about the risk of adverse cardiovascular outcomes. To ensure consistency across the medicine class, the Committee recommended updates to the macrolide data sheets to include this warning.

The Committee discussed the risk of Guillain-Barré Syndrome (GBS) following vaccination with **Arexvy**, a **respiratory syncytial virus (RSV) vaccine**. They noted that the risk of GBS was higher following RSV infection compared to vaccination. The Committee considered that the information on GBS in the Australian product information was balanced and reflected the available evidence. This includes that there is insufficient evidence to establish a causal relationship between GBS and Arexvy. The Committee recommended updates to the New Zealand data sheet to align with the Australian product information.

The Committee reviewed the risk of renal adverse events with **nintedanib.** They agreed that there was sufficient evidence for an association and recommended updates to the nintedanib data sheet to include proteinuria, renal failure and thrombotic microangiopathy as undesirable effects.

See the Medsafe website for the MARC meeting minutes and the reports presented to the MARC.

Attention: Safety of medicines used to treat ADHD in adults

Key messages

- Stimulant medicines (eg, lisdexamfetamine, methylphenidate) and non-stimulant medicines (eg, atomoxetine) are indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in adults.
- Psychiatric effects, cardiovascular effects, and risk of seizures should all be considered when prescribing these medicines.

The number of adverse reaction reports for attention-deficit hyperactivity disorder (ADHD) medicines in adults increased in 2024 compared to previous years. In addition, on 1 February 2026, changes to who can prescribe stimulant medicines for ADHD will come into effect.[1] These changes are expected to increase access to ADHD medicines.

With these circumstances in mind, we considered it timely to discuss the safety of medicines used to treat ADHD in adults.

ADHD in adults[2]

Attention deficit hyperactivity disorder (ADHD) in adults is characterised by symptoms of inattention, impulsivity and restlessness resulting in functional impairment. Functional impairment includes difficulties performing everyday tasks, and reduced ability to engage in work, education or social activities.

Executive dysfunction (difficulties with planning, organising, and prioritising and completing tasks) and emotional dysregulation (difficulties responding to and managing emotions) are also commonly seen.

The predominant feature of ADHD in adults is inattention, which differs from children, where hyperactivity and impulsivity are more typical features.

Medicines used to treat ADHD in adults

Stimulant medicines block the reuptake of noradrenaline and dopamine.[3-7] In New Zealand, lisdexamfetamine and methylphenidate are the stimulant medicines approved for the treatment of ADHD in adults. They are indicated as an integral part of a total treatment programme that may include other measures (psychological, educational and social) for patients with this syndrome.[3-9]

Atomoxetine is a non-stimulant medicine that inhibits the reuptake of noradrenaline.[10-12] It is indicated for the treatment of ADHD in adults particularly if stimulants are contraindicated, following treatment failure with stimulants (eg, inadequate response, problematic adverse effects), or when there is a significant risk of misuse of stimulants.[9,12]

Lisdexamfetamine, methylphenidate and atomoxetine have similar safety considerations. These are summarised in Table 1 and include psychiatric effects, cardiovascular effects, risk of seizures and serotonin syndrome.

Table 1: Safety considerations when prescribing lisdexamfetamine, methylphenidate, or atomoxetine in adults for ADHD*

Warning or precaution	Comments
Psychiatric disorders	
Comorbid psychiatric disorders	Comorbidity of psychiatric disorders in ADHD is common. Consider the patient's personal and family psychiatric history when prescribing. For example, treatment of ADHD with stimulants should not be initiated in patients with acute psychosis, acute mania or acute suicidality.
Suicidal tendency	Do not initiate treatment in patients with signs of suicidal tendency. Monitor patients for signs of suicidality, particularly during the first few months of treatment and with any dose changes.
Tics or Tourette's syndrome	Do not use lisdexamfetamine in individuals with tics or Tourette's syndrome. Methylphenidate is associated with the onset or exacerbation of motor and verbal tics, including worsening of Tourette's syndrome. There have been reports of tics with atomoxetine.
Aggressive behaviour	Monitor patients for onset or exacerbation of aggressive behaviour which may occur during treatment. Dose increases or decreases may be needed.
Cardiovascular disease	
Cardiovascular disorders	Sudden deaths have been reported with the use of stimulant medicines in patients with structural cardiac abnormalities, but a causal relationship has not been established. Adults with structural cardiac abnormalities or other serious cardiac problems (eg, cardiomyopathy, heart rhythm abnormalities) should not be treated with these medicines. Before prescribing, assess for pre-existing cardiovascular disorders, family history of sudden death and arrythmias, and measure blood pressure and heart rate. Regularly review blood pressure and cardiovascular status during treatment.
Increases in blood pressure or heart rate	Some patients can have clinically relevant increases in blood pressure or heart rate. Be careful when treating patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate.

Continues

Warning or precaution	Comments
Other	
Seizures	Stimulant medicines may lower the convulsive threshold in patients with or without prior history of seizure. Seizures have been reported during atomoxetine treatment.
Serotonin syndrome	Serotonin syndrome may occur following coadministration with serotonergic medicines, including selective serotonin reuptake inhibitors (SSRIs) and serotonin and noradrenaline reuptake inhibitors (SNRIs). If coadministration cannot be avoided, exercise caution and monitor for signs and symptoms of serotonin syndrome.
Risk of abuse (stimulant medicines)	There is potential for misuse, abuse, dependence, or diversion of stimulant medicines. Assess the risk of abuse before prescribing and monitor for signs of abuse and dependence during treatment.
Liver injury (atomoxetine)	Reports indicate atomoxetine may cause severe liver injury, including acute liver injury, elevated hepatic enzymes, and bilirubin with jaundice.

* Not an exhaustive list. Refer to the data sheets for full information.

Sources: Lisdexamfetamine, methylphenidate and atomoxetine data sheets, available at www.medsafe.govt.nz/Medicines/infoSearch.asp (accessed 25 June 2025).

New Zealand case reports

Between 1 January 2021 and 30 June 2025, there were 20 adverse reaction cases reporting methylphenidate (15 cases), atomoxetine (4 cases), or lisdexamfetamine (1 case) as the suspect medicine in an adult aged 18 years or older.

In these 20 cases:

- the median age was 34.5 years (range 19 to 66 years)
- there was a peak of 10 cases reported during 2024
- nine cases reported reactions in the psychiatric disorders group, including two cases reporting anxiety, two cases reporting both suicidal ideation and depression, and one case reporting suicidal ideation
- other reactions with two or more reports were headache, hyperhidrosis, and therapeutic response decreased.

Further information

More information on ADHD in adults is available from the following links:

- Medicine data sheets
- ADHD in adults | Arorereti ki ngā pakeke (Healthify)
- Medicines for ADHD in adults (Healthify)
- Changes to the regulatory and funding restrictions for stimulant medicines for ADHD
- Australasian ADHD Professionals Association (AADPA) guideline

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Systemic retinoids and diffuse idiopathic skeletal hyperostosis (DISH)

Key messages

- Diffuse idiopathic skeletal hyperostosis (DISH) is a non-inflammatory, systemic condition characterised by abnormal bone formation, primarily in the spine.
- Most patients with DISH are asymptomatic until the condition progresses and causes musculoskeletal problems, such as pain, morning stiffness and reduced range of motion.
- Cases of DISH have been reported following use of systemic retinoids, usually after prolonged use and/or at high doses.

The New Zealand Pharmacovigilance database recently received a case report of diffuse idiopathic skeletal hyperostosis (DISH) in a person taking isotretinoin (NZ-Medsafe-159059). This article provides an overview of the condition and medicines associated with it.

Diffuse idiopathic skeletal hyperostosis

DISH is a non-inflammatory, systemic condition characterised by the calcification and ossification of ligaments and entheses (the regions where tendons and ligaments attach to bone). It primarily affects the spine, although the pelvis, knee, heels and shoulders may also be affected.[1]

Most patients with DISH are asymptomatic and the condition is generally an incidental find on imaging. However, in advanced disease, new bone formation can cause patients to experience musculoskeletal symptoms such as pain, morning stiffness and reduced range of motion.[1] Rarely, compression of the oesophagus and spinal cord can cause dysphagia and motor and sensory disturbances, respectively.[2]

DISH is more common in men and its prevalence increases with age.[3]

The cause of DISH remains unclear. Genetic, metabolic, mechanical and environmental factors may be associated with its development.[3]

Systemic retinoid exposure and DISH

Cases of DISH have been reported with the use of systemic retinoids, such as isotretinoin and acitretin, usually after long-term use and/or at high doses.[4-8] Retinoids may cause stem cell proliferation and differentiation, leading to osteoblast formation and ossification.[4]

Abnormal bone formation (hyperostosis) may be detectable on imaging as soon as 6 months after starting retinoid treatment. More extensive hyperostosis can appear 3 to 5 years after continuous long-term therapy. However, patients with hyperostosis usually remain asymptomatic, unless the condition becomes advanced.[5]

Disease progression does not appear to continue after stopping retinoid therapy. Management of DISH is generally symptomatic.[9]

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Quarterly summary of recent safety communications

The table below is a summary of recent safety communications for healthcare professionals and consumers. Click on a specific topic to go to the communication.

Date	Communication	Topic
22/08/2025	Dear Healthcare Professional Letter	Topiramate-Actavis: New restrictions to prevent exposure during pregnancy (PDF, 7 pages, 848 KB)
14/08/2025	Dear Healthcare Professional Letter	Vancomycin (as hydrochloride) – approval for European batch to mitigate short-term gap in supply (PDF, 1 page, 114 KB)
12/08/2025	Dear Healthcare Professional Letter	Lenalidomide Viatris (lenalidomide) capsules – alternative registered foils (PDF, 2 pages, 306 KB)
04/08/2025	Dear Healthcare Professional Letter	Ocrevus (ocrelizumab): liver injury (without findings of viral hepatitis) (PDF, 3 pages, 219 KB)
31/07/2025	Monitoring	Update - Anti-CD20 monoclonal antibodies (rituximab, ocrelizumab, obinutuzumab, ofatumumab) and the possible risk of pyoderma gangrenosum
22/07/2025	Alert	Warning: advertisements claiming Medsafe approval or bearing the Medsafe logo are scams
21/07/2025	Dear Healthcare Professional Letter	CellCept (myophenolate mofetil): New important identified risk: anaphylactic reaction (PDF, 3 pages, 135 KB)
14/07/2025	Dear Healthcare Professional Letter	Lenalidomide Viatris capsules (lenalidomide): labelling exemption for alternative registered foils (PDF, 2 pages, 543 KB)
30/06/2025	Consumer information leaflet	Reporting side effects of medicines and vaccines (PDF, 1 page, 166 KB)
24/06/2025	Consultation outcome	Outcome of the consultation on the proposal to change the regulatory and funding restrictions for stimulant treatments for ADHD
13/06/2025	Dear Healthcare Professional Letter	Risperdal (risperidone): Accidental overdoses in children and adolescents treated with risperidone 1mg/ml oral solution following administration errors (PDF, 8 pages, 308 KB)
30/05/2025	Alert	Stop using Euky Bear Warm Steam Vaporiser – model number EBSV2013
30/05/2025	Dear Healthcare Professional Letter	Ventolin (salbutamol (as sulfate) aerosol inhaler) - reinforcing information regarding number of prescribed doses available (PDF, 2 pages, 200 KB)
22/05/2025	Dear Healthcare Professional Letter	Estradiol Transdermal Patches (Mylan) granted full consent; US packs will continue to be supplied in the short-term (PDF, 3 pages, 352 KB)
22/05/2025	Dear Healthcare Professional Letter	Zyprexa IM (olanzapine) 10mg powder for injection: Temporary supply of overseas product (PDF, 2 pages, 226 KB)

Recent approvals: new active ingredients or new indications

New active ingredients

Table 1 shows recent approval of medicines with new active ingredients gazetted during the period 25 April 2025 to 24 July 2025.

Table 1: Recent approvals of medicines with new active ingredients

Medicine	New active ingredient	Dose form: • strength(s)	Therapeutic area
Trodelvy	Sacituzumab	Powder for infusion: • 180mg	Breast cancer

New indications

Table 2 shows approved medicines with new indications for additional therapeutic areas gazetted during the period 25 April 2025 to 24 July 2025.

Table 2: Approved medicines with new indications for additional therapeutic areas

Medicine (active ingredient)	Dose form: • strength(s)	New therapeutic area
Abilify Maintena* (aripiprazole)	Injection with diluent: • 300mg • 400mg	Bipolar I disorder
Enhertu (trastuzumab deruxtecan)	Powder for infusion: • 100mg	Gastric cancer
Imfinzi (durvalumab)	Concentrate for infusion: • 120mg/2.4mL • 500mg/10mL	Endometrial cancer
Lynparza (olaparib)	Film coated tablet: • 100mg • 150mg	Endometrial cancer
Rinvoq (upadacitinib)	Modified release tablet: • 15mg • 30mg • 45mg	Giant cell arteritis
Ryeqo (relugolix + estradiol + norethisterone)	Film coated tablet: • 40mg + 1mg + 0.5mg	Endometriosis

* New packaging will be available towards the end of the year.

More information

See the Medsafe website for:

- more information about these medicines
- data sheets of currently marketed medicines
- Gazette notices for approved medicine applications.

Medicine-induced Pisa syndrome

Key messages

- Pisa syndrome refers to an abnormal posture characterised by involuntary leaning to one side when upright. The person may have difficulty walking and standing up straight.
- Anticholinesterase inhibitors and antipsychotics are the most frequently reported medicines associated with Pisa syndrome.
- Medicine-induced Pisa syndrome may appear months to years after starting the medicine. It usually resolves after stopping the suspected medicine or lowering the dose.

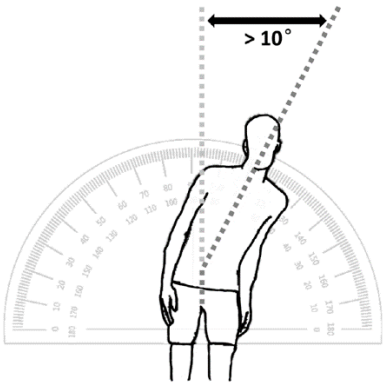
Medsafe recently reviewed the risk of Pisa syndrome with donepezil (an anticholinesterase inhibitor) and concluded that there is sufficient evidence to support an association. We have requested sponsors to update their donepezil data sheets with this adverse effect. As of 1 August 2025, the New Zealand Pharmacovigilance database has not received any reports of Pisa syndrome.

What is Pisa syndrome (pleurosthotonus)?

Pisa syndrome (also known as pleurosthotonus) is a rare neurological condition characterised by more than 10 degrees of constant lateral flexion of the spine when the patient is upright (Figure 1). This abnormal posture resembles the Leaning Tower of Pisa, which gives the syndrome its name. Patients may have difficulty with walking or standing up straight. Some patients may be unaware they are leaning.[1]

There are a variety of causes for Pisa syndrome, and many other conditions can have similar presentations.[1] However, Pisa syndrome is most strongly associated with older age, females, neurodegenerative diseases and polypharmacy with antipsychotics and anticholinesterase inhibitors (especially with prolonged use or high doses).[1,2]

Figure 1: Pisa syndrome – characterised by more than 10 degrees of constant lateral flexion of the spine when upright



Source:

Rissardo JM, Vora NM, Danaf N, et al. 2024. Pisa syndrome secondary to drugs: A scope review. *Geriatrics* 9(4): 100. DOI: https://doi.org/10.3390/geriatrics9040100 (accessed 27 June 2025).

Medicine-induced Pisa syndrome

A recent review of medicine-induced Pisa syndrome cases reported in the literature found that anticholinesterase inhibitors and antipsychotics were the most frequently reported medicines associated with Pisa syndrome (Table 1).[2]

The mechanism behind Pisa syndrome is unknown but may be due to an imbalance between dopaminergic and cholinergic neurotransmitters leading to postural control dysfunction.[1,2] Medicines associated with Pisa syndrome affect these neurotransmitters.

Table 1: Medicines reported in the literature to be associated with Pisa syndrome (list not exhaustive)

Medicine class	Medicines
Anticholinesterase inhibitors	Donepezil Rivastigmine Galantamine
Typical antipsychotics	Haloperidol Chlorpromazine Droperidol
Atypical antipsychotics	Quetiapine Risperidone Olanzapine Aripiprazole Clozapine Paliperidone Ziprasidone
Antidepressants	Amitriptyline Clomipramine Nortriptyline Mirtazapine Sertraline
Antiparkinsonian medicines	Levodopa Pramipexole Ropinirole
Mood stabilisers	Lithium
Anti-seizure medicines	Valproate

Adapted from: Rissardo JM, Vora NM, Danaf N, et al. 2024. Pisa syndrome secondary to drugs: A scope review. *Geriatrics* 9(4): 100. DOI: https://doi.org/10.3390/geriatrics9040100 (accessed 27 June 2025).

Management

Though rare, Pisa syndrome is a recognisable and often reversible condition.[2] However, the time between starting the medicine and the onset of symptoms is unpredictable, and it may occur weeks to months later.[1]

Consider medicines as a possible cause of new-onset postural abnormalities consistent with Pisa syndrome. Symptoms usually resolve after stopping the medicine or reducing the dose.[1]

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Gathering knowledge from adverse reaction reports: September 2025

Adverse drug reaction (ADR) reporting is an important component of medicine safety monitoring. Case reports can highlight significant safety issues with medicines and how they are used.

The table below presents a selection of recent informative cases reported to the New Zealand Pharmacovigilance Database.

Case details[a,b]	Reaction description and data sheet information[b,c]
Report ID: 161822 **Age:** Elderly **Gender:** Male **Medicine(s):** Hyoscine **Reaction(s):** Hallucinations, paranoia, delusion, psychosis	Soon after applying the Scopolamine patch, the patient experienced hallucinations, paranoia, psychosis and delusions.
	The Scopolamine Transdermal System data sheet warns that the elderly may be at increased risk of adverse reactions due to scopolamine's anticholinergic effects. This includes neuropsychiatric effects such as confusion and/or visual hallucinations. Use with caution in the elderly. Remove the patch immediately if these occur.
Report ID: 161925 **Age:** 83 years **Gender:** Female **Medicine(s):** Furosemide **Reaction(s):** Bullous pemphigoid	The patient developed biopsy-confirmed bullous pemphigoid after starting furosemide.
	The IPCA-Frusemide data sheet states that allergic reactions may occur, including bullous lesions and pemphigoid.
Report ID: 162075 **Age:** 65 years **Gender:** Female **Medicine(s):** Shingles vaccine **Reaction(s):** Guillain Barré syndrome	The patient developed Guillain Barré syndrome after receiving the shingles vaccine.
	The Shingrix data sheet warns that there is an increased risk of Guillain-Barré syndrome (GBS) following vaccination. GBS is listed as a very rare ADR.

Continues

Case details[a,b]	Reaction description and data sheet information[b,c]
Report ID: 162083 **Age:** Elderly **Gender:** Male **Medicine(s):** Simvastatin, itraconazole **Reaction(s):** Myositis, drug interaction	Following the concurrent administration of simvastatin and itraconazole, the patient experienced myositis, indicating a drug interaction.
	As stated in the Simvastatin Viatris and Itrazole data sheets, concomitant administration of these medicines is contraindicated. Itraconazole is a potent inhibitor of CYP3A4 and reduces elimination of simvastatin. This leads to an increased risk of simvastatin-related ADRs, such as myopathy, rhabdomyolysis and liver enzyme abnormalities.
Report ID: 162944 **Age:** 19 years **Gender:** Male **Medicine(s):** Isotretinoin **Reaction(s):** Achilles tendon pain, enthesopathy, stiffness	Approximately two weeks after starting isotretinoin, the patient developed bilateral pain and stiffness at the insertion points of the Achilles tendon (enthesopathy).
	Section 4.8 of the Oratane data sheet has information about musculoskeletal and connective tissue disorders, including tendonitis.

Notes:

a. Only the medicines suspected to have caused the reaction are listed in the table.
b. The reactions listed in the 'Case details' column are coded according to the Medical Dictionary for Regulatory Activities (MedDRA), an internationally used set of standardised terms relating to medical conditions, medicines and medical devices. The reactions listed in the 'Reaction description' column are based on what was reported, and do not always match the MedDRA term exactly.
c. If the suspect medicine's brand name is not described in the ADR report, only the data sheet for the funded medicine is included in the table.

Information about reported suspected adverse reactions is available on the Medsafe website using the Suspected Medicines Adverse Reaction Search (SMARS).

By selecting the ingredient of a medicine or vaccine, you can find out:

- the number of reports and suspected adverse reactions for that ingredient. The suspected reactions are grouped by body system or organs (Summary report)
- single case reports, listing the medicines and/or vaccines involved that contain the ingredient and the suspected adverse reactions (Detail report).

Recent data sheet updates: important new safety information

Table 1 below provides a list of data sheets recently updated with important new safety information. Note that this is not a comprehensive list of all recently updated data sheets, nor does it describe all changes to a particular data sheet.

To find out if sponsors have made any changes to their data sheets, refer to:

- section 10 'Date of revision of the text' at the end of each data sheet. Search for a data sheet
- the New/updates to data sheets and CMIs page on the Medsafe website.

Table 1: Recently updated data sheets (by active ingredient): important new safety information

Click on the specific medicine to open the data sheet.

Active ingredient(s): • Medicine(s)	Data sheet updates	
	Section*	Summary of new safety information
Acalabrutinib • Calquence	4.2	Dose adjustments: management of adverse reactions in patients receiving Calquence in combination with bendamustine and rituximab for patients with previously untreated mantle cell lymphoma (MCL)
	4.8	Safety data in patients with previously untreated MCL
Adrenaline • EpiPen • EpiPen Jr	4.4	Biphasic anaphylaxis – recurrence of symptoms following initial resolution
Alprostadil • Prostin VR	4.4	Contains ethanol as an excipient, which may cause central nervous system depressant effects, such as somnolence, and may alter the effects of other medicines
Amitriptyline • Arrow-Amitriptyline	4.4, 4.8	Severe cutaneous adverse reactions (SCARs) including drug reaction with eosinophilia and systemic symptoms (DRESS)
Apixaban • Eliquis	4.8	Cutaneous vasculitis
Diltiazem • Cardizem CD	4.8	Lupus-like syndrome
Durvalumab • Imfinzi	4.4	In combination with olaparib: warnings for pure red cell aplasia and autoimmune haemolytic anaemia
Elexacaftor + tezacaftor + ivacaftor • Trikafta	4.2, 4.5	No dose adjustment required with concomitant use of ciprofloxacin
	4.4, 4.8	Liver failure leading to transplantation in patients with and without pre-existing advanced liver disease; Updated monitoring recommendations for serum transaminases and total bilirubin; Added clinical signs of liver injury
Empagliflozin • Jardiance	4.4	Ketoacidosis and glycosuria may last longer than expected after stopping Jardiance; Necrotising fasciitis reported in patients treated with empagliflozin for all indications
	4.8	Phimosis reported with genital infection
Gadolinium-based contrast agents • Gadovist • Primovist	4.6	Pregnancy: information from the literature regarding exposure during pregnancy and fetal outcomes
Lamotrigine • Lamictal	4.4	Skin rash: Human leukocyte antigen (HLA)-B*1502 allele associated with risk of developing Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN)
	4.8	Photosensitivity reaction

Continues

Active ingredient(s): • Medicine(s)	Data sheet updates Section*	 Summary of new safety information
Lenvatinib • Lenvima	4.4, 4.8	Tumour lysis syndrome
Losartan + hydrochlorothiazide • Arrow-Losartan potassium & Hydrochlorothiazide	4.4, 4.8	Intestinal angioedema
Lidocaine + prilocaine • Numit	4.2	Increased risk of serious adverse reactions (eg, methaemoglobinaemia) if recommended dose or duration of treatment exceeded especially in children aged below 3 months.
Mesalazine • Asacol	4.4, 4.8	Idiopathic intracranial hypertension (pseudotumor cerebri)
Metronidazole • Flagyl, Flagyl-S	4.4, 4.8	Drug reaction with eosinophilia and systemic symptoms (DRESS)
Olaparib • Lynparza	4.4, 4.8	Drug-induced liver injury (DILI)
Paracetamol + codeine + doxylamine succinate • Mersyndol	4.4, 4.5	Concomitant use with gabapentinoids is not recommended due to the risk of additive CNS depressant effects (eg, respiratory depression, hypotension, sedation, coma, death)
Propofol • Diprivan	4.5	Interactions with alfentanil, dexmedetomidine, sevoflurane, midazolam
Rifampicin + isoniazid • Rifinah	4.6	Fertility: Rifampicin has a genotoxic potential in animals, which is a risk factor for impairment of human fertility
Salbutamol • Ventolin	4.4, 6.6	The inhaler does not have a dose counter. It contains enough salbutamol for 200 actuations (puffs) only. After 200 actuations, the inhaler can continue to spray but without the prescribed dose of salbutamol. Consider keeping a record of the number of doses administered and/or a back-up inhaler
Sunitinib • Sunitinib Pfizer • Sutent	4.4, 48	Hyperammonaemic encephalopathy
Tobramycin • Tobra-Day	4.4	Severe cutaneous adverse reactions (SCARs)
Tramadol • Tramal	4.5	Concomitant use with anticholinergics may result in increased anticholinergic adverse effects
	4.9	Death can occur following overdose
Upadacitinib • Rinvoq	4.4	Medication residue in stool
Varicella zoster (shingles) vaccine • Shingrix	4.4, 4.8	Guillain-Barré syndrome
	4.5	Shingrix may be given concomitantly with respiratory syncytial virus (RSV) vaccine (recombinant, adjuvanted)
Zuclopenthixol • Clopixol	4.4, 4.8	Dysphagia can occur secondary to extrapyramidal symptoms, sialorrhea, sedation and neuroleptic malignant syndrome

* Data sheet sections listed in the table are: 4.2: Dose and method of administration; 4.4: Special warnings and precautions for use; 4.5: Interaction with other medicines and other forms of interaction; 4.6: Fertility, pregnancy and lactation; 4.8: Undesirable effects; 4.9: Overdose; 6.6 Special precautions for disposal

Medsafe

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