# Prescriber Update

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## Contents



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# Spotlight on cystic fibrosis transmembrane conductance regulator (CFTR) modulators

## Key messages

- Cystic fibrosis transmembrane conductance regulator (CFTR) modulators are indicated for the treatment of cystic fibrosis. They work by restoring the function of the faulty CFTR protein to improve lung function.
- CFTR modulators have been associated with liver injury. Transaminases and total bilirubin must be monitored in all people taking CFTR modulators.
- Other safety concerns include mood disturbances, cataracts/lens opacities and medicine interactions.

This article gives an overview of CFTR modulator medicines, including key safety considerations. Table 1 provides a list of approved CFTR modulators.

**Table 1: CFTR modulators approved in New Zealand**

| Brand name | Active substance(s) |
|---|---|
| Trikafta | elexacaftor + tezacaftor +ivacaftor |
| Alyftrek | vanzacaftor + tezacaftor + deutivacaftor |
| Kalydeco | ivacaftor |
| Orkambi | lumacaftor + ivacaftor |
| Symdeko | tezacaftor + ivacaftor |

Source: Medsafe Product/Application Search. URL: www.medsafe.govt.nz/DbSearch/ (accessed 29 July 2026).

## How do CFTR modulators work?[1]

Cystic fibrosis is caused by mutations affecting the CFTR protein, a chloride and bicarbonate ion channel located on epithelial cells. Disrupted ion transport at epithelial surfaces leads to thickened mucus in the lungs and other organs. This means that people with cystic fibrosis experience recurrent respiratory tract infections and decline in lung function, among many other complications.

CFTR modulators work by targeting the faulty CFTR protein to improve lung function. There are two types of CFTR medicines: potentiators and correctors.

Potentiators (eg, ivacaftor, deutivacaftor) improve the function of CFTR protein present at the cell membrane by increasing the probability that the ion channel is open. Correctors (eg, tezacaftor, lumacaftor, elexacaftor, vanzacaftor) increase the number of CFTR proteins on the cell surface by facilitating folding and trafficking of the CFTR protein.

Potentiators and correctors are often used in combination to treat cystic fibrosis, depending on the type of CFTR variant the person has.

## Safety considerations[2–6]

This section describes some significant safety considerations associated with CFTR modulators. Refer to the medicine data sheets for full prescribing information.

- Search for a data sheet

### Use in hepatic impairment

Because CFTR modulators undergo hepatic metabolism, they are not recommended for use in patients with severe hepatic impairment, and dose reductions are recommended for patients with moderate hepatic impairment.

### Elevated transaminases and liver injury

Elevated liver transaminases are common in people with cystic fibrosis and have been observed in people taking CFTR modulators. In some cases, total bilirubin can also be elevated.

Cases of liver failure requiring transplantation have been reported in patients taking elexacaftor + tezacaftor + ivacaftor (Trikafta). These events were seen during the first 6 months of treatment in patients with and without pre-existing advanced liver disease.

Monitor transaminases and total bilirubin throughout CFTR modulator treatment. Interrupt treatment if significant elevations occur or there are clinical signs of liver injury. Following resolution, review the benefits and risks of resuming treatment. Refer to the individual medicine data sheets for further details on liver monitoring.

### Mood disturbances

Effects on mood and behaviour such as anxiety, low mood, sleep disturbance and forgetfulness have occasionally been reported in people treated with CFTR modulators. In some young children (aged 2-5 years), these effects may present as behaviour changes.

A causal relationship has not been established with CFTR modulator treatment, and some patients have been reported to recover with continued treatment. Advise patients and caregivers to monitor for new or worsening symptoms and seek medical advice if they occur.

### Cataracts

There have been cases of non-congenital lens opacities without impact on vision in paediatric patients treated with ivacaftor-containing regimens. Cataracts were seen in juvenile rat studies with ivacaftor.

Baseline and follow-up ophthalmological examinations are recommended in paediatric patients starting CFTR modulator treatment.

### Medicine interactions

Several CFTR modulators are CYP3A substrates, including elexacaftor, tezacaftor, ivacaftor, vanzacaftor and deutivacaftor.

- **CYP3A inducers** (eg, rifampicin, phenobarbital, carbamazepine, phenytoin) may reduce systemic exposure and decrease the efficacy of these CFTR modulators. Avoid concomitant use of these CFTR modulators with strong CYP3A inducers.
- **CYP3A inhibitors** (eg, clarithromycin, fluconazole, itraconazole, posaconazole, erythromycin, verapamil) may increase exposure to these CFTR modulators. Reduce the dose of the CFTR modulator if used with moderate or strong CYP3A inhibitors.

Lumacaftor is a strong inducer of CYP3A and may decrease systemic exposure of medicines that are substrates of CYP3A, such as hormonal contraceptives.

Refer to the medicine data sheets for further information on medicine interactions.

## New Zealand case reports

Between 1 January 2020 and 31 May 2026, the New Zealand Pharmacovigilance Database received 17 case reports associated with CFTR modulators. These included:

- 5 reports for liver-related adverse events with elexacaftor + tezacaftor + ivacaftor (Trikafta)
- 5 reports describing mood or behaviour changes, of which, 4 reports were associated with elexacaftor + tezacaftor + ivacaftor (Trikafta) and 1 was associated with ivacaftor (Kalydeco).

## References


1. Ong T and Ramsey BW. 2023. Cystic fibrosis: A review. *JAMA* 329(21): 1859-71. DOI: 10.1001/jama.2023.8120 (accessed 7 July 2026).
2. Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics. 2026. *Symdeko New Zealand Data Sheet* 4 May 2026. URL: www.medsafe.govt.nz/profs/Datasheet/s/symdekotab.pdf (accessed 7 July 2026).
3. Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics. 2026. *Orkambi New Zealand Data Sheet* 4 May 2026. URL: www.medsafe.govt.nz/profs/Datasheet/o/orkambitabgranules.pdf (accessed 7 July 2026).
4. Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics. 2026. *Kalydeco New Zealand Data Sheet* 4 May 2026. URL: www.medsafe.govt.nz/profs/Datasheet/k/Kalydecotab.pdf (accessed 7 July 2026).
5. Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics. 2026. *Trikafta New Zealand Data Sheet* 2 June 2026. URL: www.medsafe.govt.nz/profs/Datasheet/t/trikaftatab.pdf (accessed 7 July 2026).
6. Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics. 2026. *Alyftrek New Zealand Data Sheet* 4 May 2026. URL: www.medsafe.govt.nz/profs/Datasheet/a/Alyftrektab.pdf (accessed 7 July 2026).

# Rosuvastatin: Dose considerations

**Key messages**

- The usual starting dose of rosuvastatin for hypercholesterolemia is 5-10 mg regardless of prior history of statin use. If necessary, the dose can be increased after 4 weeks of treatment. The usual maximum dose is 20 mg per day.
- As with all statins, rosuvastatin can cause skeletal muscle toxicity, and the risk of rhabdomyolysis increases with higher rosuvastatin doses. Be aware of other risk factors for skeletal muscle toxicity with rosuvastatin and recommended dose modifications.
- Advise patients to promptly report unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.
- Only use the 40 mg dose in patients who have not responded to the 20 mg dose, ie, who still have severe hypercholesterolaemia and are at high cardiovascular risk. The 40 mg dose is contraindicated in some patients.

The New Zealand Pharmacovigilance Database recently received a report concerning a person of Asian ethnicity who was switched from another statin to rosuvastatin 40 mg per day and subsequently experienced acute kidney injury, muscle pain, increased creatinine phosphokinase (over 10,000 units/L) and hyperkalaemia. This case highlights the importance of using the correct rosuvastatin dose (taking into account individual patient risk factors).

## Rosuvastatin indications and potency

Rosuvastatin is a statin indicated in the management of hypercholesteremia and the prevention of major cardiovascular events. Statins inhibit a key enzyme in the synthesis of cholesterol, 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase.[1]

Rosuvastatin is the most potent of the statins available in New Zealand, meaning that it achieves its therapeutic effect at lower doses than pravastatin, simvastatin and atorvastatin.[2]

Due to its potency, the recommended rosuvastatin starting dose for treatment of hypercholesterolaemia is 5 mg or 10 mg once per day both in statin naïve patients and in those switched from another HMG-CoA reductase inhibitor. A dose adjustment can be made after 4 weeks of treatment as necessary. The usual maximum dose is 20 mg per day. For prevention of cardiovascular events, the dose is 20 mg per day.[1]

As with other statins, rosuvastatin is associated with skeletal muscle toxicity (myopathy and rhabdomyolysis), and the reported rate for rhabdomyolysis is higher at the highest rosuvastatin dose.[1] Advise patients to promptly report unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever.[1]

Regardless of the indication, use rosuvastatin with caution in patients with additional risk factors for skeletal muscle toxicity, as described below.

## Start rosuvastatin at a low dose in patients with risk factors[1]

Certain patients are more at risk of skeletal muscle toxicity because of increased systemic exposure to rosuvastatin. This includes patients of Asian origin, with severe renal or hepatic impairment, advanced age, concomitant use of medicines that increase rosuvastatin levels and patients with certain genetic polymorphisms, as shown in Table 1. Dose modifications are needed for these patients.

**Table 1: Risk factors for skeletal muscle toxicity and recommended rosuvastatin dose modifications[a]**

| Risk factor | Rosuvastatin dose modifications |
|---|---|
| **Asian ethnicity** (having either Filipino, Chinese, Japanese, Korean, Vietnamese or Asian-Indian origin) | Start with 5 mg per day.<br>Use caution with doses up to 20 mg per day.<br>Do not use the 40 mg dose. |
| **Severe renal impairment** (creatinine clearance < 30 mL/min)[b] | Start with 5 mg per day.<br>Do not exceed 10 mg per day. |
| **Severe hepatic impairment**[b] | Start with 5 mg per day.<br>Use caution with doses above 10 mg per day. |
| **Advanced age** (older than 70 years)[b] | Start with 5 mg per day. |
| **Concomitant medicines** which inhibit the transporter proteins that rosuvastatin depends on (eg, OATP1B1 and BCRP), such as ciclosporin, ticagrelor and certain protease inhibitors | Start with 5 mg per day with concomitant medicines that increase rosuvastatin AUC by 2-fold or higher.<br>Refer to the data sheet for further guidance. |
| **Genetic polymorphisms** such as SLCO1B1 (OATP1B1) c.521CC or ABCG2 (BCRP) c.421AA genotype | No starting dose recommended in the data sheet. However, do not exceed 20 mg per day. |

Source: A. Menarini New Zealand Pty Ltd. 2026. *Crestor New Zealand Data Sheet* 4 May 2026. URL: www.medsafe.govt.nz/profs/datasheet/c/Crestortab.pdf (accessed 29 June 2026).

Notes:

a. List is not comprehensive – refer to the rosuvastatin data sheet for further information.

b. The Crestor data sheet was recently updated with a recommendation to initiate rosuvastatin with a dose of 5 mg per day in patients with severe renal or hepatic impairment (this was previously 10 mg per day). The starting dose recommendation of 5 mg per day in elderly patients (over 70 years of age) is new.

## When is it appropriate to use high dose rosuvastatin?

Only use the 40 mg per day dose in patients that still have severe hypercholesterolaemia and high cardiovascular risk despite treatment with 20 mg per day. Specialist supervision is recommended if a 40 mg daily dose is being considered.[1]

In addition to the patients with risk factors listed in Table 1, **do not use** the 40 mg dose in patients:[1]

- with a previous history of muscular toxicity with another HMG-CoA reductase inhibitor or fibrate
- with a personal or family history of hereditary muscular disorders
- who abuse alcohol
- with hypothyroidism
- who are being treated with fibrates.

## References


1. A. Menarini New Zealand Pty Ltd. 2026. *Crestor New Zealand Data Sheet* 4 May 2026. URL: www.medsafe.govt.nz/profs/datasheet/c/Crestortab.pdf (accessed 29 June 2026).
2. bpac$^{nz}$. 2022. *Rosuvastatin: Another Option to Lower Cardiovascular Disease Risk* February 2022. URL: https://bpac.org.nz/2022/rosuvastatin.aspx (accessed 29 June 2026).


# 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 |
|---|---|---|
| 24/08/2026 | Consultation outcome | Outcome of the consultation on changes to clozapine blood monitoring and prescribing requirements |
| 03/08/2026 | Advisory | Nitrous oxide advisory (August 2026 update) |
| 28/07/2026 | Monitoring | Update - Atomoxetine and the possible risk of gynaecomastia |
| 25/06/2026 | Alert | Product Alert of Dexcom US G7 Sensors: Lots 1725204004 and 1725069002 |
| 16/06/2026 | Alert | Recall of The Good Vitamin Co Kids Good Multi gummies (Kids Good Multi): Batches GV011015, GV011017V and GV011018V |
| 02/06/2026 | Dear Healthcare Professional Letter | Sumagran (sumatriptan succinate) 100 mg film coated tablets – NZ-Specific Cartons with "Dutch" Foils |
| 02/06/2026 | Dear Healthcare Professional Letter | Benzetacil (benzathine benzylpenicillin): Shortage of Bicillin L-A and alternative supply of Benzetacil (PDF, 3 pages, 260 KB) |

Note that sponsors write Dear Healthcare Professional Letters and distribute them to relevant healthcare professionals. Medsafe publishes copies of these letters on the Medsafe website.

# Prednisone-induced thyrotoxic periodic paralysis

**Key messages**

- In patients with hyperthyroidism, sudden intracellular shifts of potassium can cause thyrotoxic periodic paralysis (TPP).
- Prednisone can induce hypokalaemia. Therefore, suspect TPP in hyperthyroid patients treated with prednisone who present with signs or symptoms of muscle weakness.

The prednisone data sheet was recently updated to include a warning on thyrotoxic periodic paralysis (TPP).[1] This article describes TPP and how prednisone contributes to the condition.

## What is TPP?

TPP is a complication of hyperthyroidism characterised by recurrent attacks of muscle weakness and hypokalaemia due to a sudden intracellular shift of potassium. Serious clinical consequences (eg, ventricular arrhythmia, respiratory failure) may result if TPP is left undiagnosed and untreated.[3]

TPP predominantly affects males of Asian descent, but is increasingly recognised in Western countries.[2,3] A New Zealand study found higher rates of TPP in patients of Polynesian descent compared with those of European descent.[4]

## Pathophysiology

TPP is likely caused by increased sodium-potassium-adenosine triphosphatase (Na/K-ATPase) pump activity, which leads to potassium shifting mostly into the muscles and depleting circulating levels.[2,3] Hyperpolarisation of muscle membranes leads to reduced muscle excitability, causing paralysis.[2] The increase in Na/K-ATPase activity is driven by an increase in thyroid hormones and resulting beta-adrenergic response.[2,3]

Attacks usually occur a few hours after ingesting a high carbohydrate meal or strenuous exercise. These precipitating factors stimulate Na/K-ATPase pump activity and increase potassium uptake by muscle from the circulation.[2,3]

## Prednisone can precipitate TPP

Prednisone may induce hypokalaemia that can precipitate TPP. Therefore, patients with hyperthyroidism who require treatment with prednisone are at risk of experiencing TPP.[1]

## Management

If TPP is suspected, monitor blood potassium and correct hypokalaemia.[1] Ensure adequate control of hyperthyroidism to prevent recurrence.[2,3] Because there is an enhanced beta-adrenergic response in thyrotoxicosis, non-selective beta-blockers (eg, propranolol) may be used as adjunctive management.[2,3,5,6]

## References

1. Clinect NZ Pty Limited. *Prednisone (Clinect) New Zealand Data Sheet* 23 February 2026. URL: www.medsafe.govt.nz/profs/Datasheet/a/Apoprednisonetab.pdf (accessed 15 July 2026).
2. Kung AWC. 2006. Clinical review: Thyrotoxic periodic paralysis: A diagnostic challenge. *The Journal of Clinical Endocrinology & Metabolism* 91(7): 2490-95. DOI: 10.1210/jc.2006-0356 (accessed 15 July 2026).
3. Lin SH. 2005. Thyrotoxic periodic paralysis. *Mayo Clinic Proceedings* 80(1): 99-105. DOI: 10.1016/S0025-6196(11)62965-0 (accessed 15 July 2026).
4. Elston MS, Orr-Walker BJ, Dissanayake AM, et al. 2007. Thyrotoxic, hypokalaemic periodic paralysis: Polynesians, an ethnic group at risk. *Internal Medicine Journal* 37(5): 303-07. DOI: 10.1111/j.1445-5994.2007.01313.x (accessed 15 July 2026).
5. Teva Pharma (New Zealand) Limited. *Drofate New Zealand Data Sheet* 26 March 2024. URL: www.medsafe.govt.nz/profs/Datasheet/d/drofatetab.pdf (accessed 15 July 2026).
6. Ipca Pharma (NZ) Pty Limited. *Ipca-Propranolol New Zealand Data Sheet* 1 June 2023. URL: www.medsafe.govt.nz/profs/Datasheet/I/IpcaPropranololtab.pdf (accessed 15 July 2026).


# MARC's remarks: June 2026 meeting

The Medicines Adverse Reactions Committee (MARC) convened for their 206th meeting on 11 June 2026.

The Committee discussed the safety of **colecalciferol** 50,000 IU capsules in pregnancy. They noted that all overseas product information for similar products either contraindicate use in pregnancy, or state that use is not recommended and a lower-dose formulation should be used. The Committee acknowledged there may be a clinical need for the use of high doses of vitamin D in pregnancy in specific circumstances but considered that such cases should be managed on an individual basis with specialist advice where appropriate. No changes to the safety information in the data sheet were recommended.

The Committee discussed paternal exposure to low-dose **methotrexate**. Because the contraceptive advice for methotrexate is consistent with regulatory guidance on genotoxic medicines, the Committee agreed that the current recommendation contraception in men during treatment and for three months after cessation should be retained in the data sheet. However, the data sheet should be updated to reflect the current evidence that preliminary studies have not demonstrated an increased risk of congenital malformations or adverse pregnancy outcomes with paternal exposure to low-dose methotrexate, but a small risk cannot be excluded.

The Committee discussed sexual dysfunction following discontinuation of **serotonin reuptake inhibitors** (SSRI/SNRI). The Committee was not in favour of adding the term 'post-SSRI sexual dysfunction' to data sheets. However, they considered that there would be benefit in reviewing the specific symptoms of sexual dysfunction that have been reported, including whether they continue following discontinuation of treatment. The Committee recommended that Medsafe present a review of specific symptoms of sexual dysfunction with serotonin reuptake inhibitors at a future meeting.

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

# Gathering knowledge from adverse reaction reports: September 2026

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:** 166470<br>**Age:** 67 years<br>**Gender:** Male<br>**Medicine(s):** Felodipine<br>**Reaction(s):** Gingival hypertrophy | The patient experienced gum hyperplasia while taking felodipine. |
| | The Felo ER data sheet lists gingival hyperplasia and gingivitis as ADRs. The gingival enlargement can be avoided or reversed by careful dental hygiene. |
| **Report ID:** 166844<br>**Age:** 78 years<br>**Gender:** Male<br>**Medicine(s):** Osimertinib<br>**Reaction(s):** Congestive cardiac failure, pulmonary oedema, congestive cardiomyopathy, ejection fraction decreased | During treatment with osimertinib, the patient developed pulmonary oedema due to congestive heart failure. They were found to have a dilated cardiomyopathy with severe left ventricular failure. |
| | The Tagrisso data sheet describes cardiac adverse events, including congestive heart failure, ejection fraction decreased and pulmonary oedema, that are consistent with cardiac failure or cardiomyopathy. |
| **Report ID:** 167163<br>**Age:** 76 years<br>**Gender:** Female<br>**Medicine(s):** Zoledronic acid<br>**Reaction(s):** Atrial fibrillation, heart rate increased, pruritus, malaise, pyrexia, pain, chills | Immediately after receiving zoledronic acid infusion, the patient developed itchy skin. The next day, they became generally unwell with fever, chills and body aches plus an increased heart rate. They were subsequently diagnosed with atrial fibrillation. |
| | Atrial fibrillation is listed as an uncommon ADR in the Zoledronic acid Viatris data sheet.<br>Acute phase reactions (post-dose or flu-like symptoms) are also described and usually resolve within a few days. See also the March 2026 *Prescriber Update* article: Zoledronic acid: May be less tolerable for elderly patients |
| **Report ID:** 167284<br>**Age:** 63 years<br>**Gender:** Female<br>**Medicine(s):** Sertraline<br>**Reaction(s):** Microscopic colitis | Approximately four months after starting sertraline, the patient developed lymphocytic colitis (a subtype of microscopic colitis). |
| | Microscopic colitis is listed as a postmarketing ADR in the Setrona data sheet. See also the December 2022 *Prescriber Update* article: Microscopic colitis - could it be caused by a medicine? |

*Continues*

| Case details[a,b] | Reaction description and data sheet information[b,c] |
|---|---|
| **Report ID:** 167417<br>**Age:** 39 years<br>**Gender:** Female<br>**Medicine(s):** Semaglutide<br>**Reaction(s**): Cholecystitis | Several months after starting semaglutide, the patient developed cholecystitis. |
| | The Wegovy data sheet states that cholelithiasis was reported in 1.6% and led to cholecystitis in 0.6% of patients treated with semaglutide. |
| **Report ID:** 167685<br>**Age:** 45 years<br>**Gender:** Female<br>**Medicine(s):** Estradiol, progesterone<br>**Reaction(s):** Pulmonary embolism, deep vein thrombosis | The patient developed a pulmonary embolism and deep vein thrombosis while taking estradiol and progesterone. She had a history of deep vein thrombosis. |
| | Estradot and Utrogestan are contraindicated in women with previous or current venous thromboembolism (ie, deep vein thrombosis, pulmonary embolism). |

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).

For help with searching, see the How to Search SMARS page.

# Ocular adverse effects of stimulant medicines for ADHD

**Key messages**

- Ocular adverse effects, including increased intraocular pressure (IOP), glaucoma, and dry eye, have been reported with use of stimulant medicines for attention deficit hyperactivity disorder (ADHD).
- Patients with a history of increased IOP or glaucoma, or who are at risk for acute angle-closure glaucoma require careful assessment before starting treatment and ongoing monitoring during treatment.
- Advise patients to promptly report visual disturbances or other changes in vision.

The stimulant medicines used to treat attention deficit hyperactivity disorder (ADHD) are methylphenidate, lisdexamfetamine and dexamfetamine.[1–4] This article highlights the ocular adverse effects associated with these medicines.

## Ocular adverse effects

Increased intraocular pressure (IOP), glaucoma, dry eye and other ocular adverse effects have been reported with use of stimulant medicines for ADHD.[1–4]

Glaucoma refers to a group of eye conditions characterised by progressive optic nerve damage, usually associated with increased IOP and is one of the leading causes of irreversible blindness.[5] There have been international reports of increased IOP and glaucoma with methylphenidate treatment.[1,2]

Acute angle-closure (AAC) glaucoma has also been reported with methylphenidate.[1] AAC glaucoma results from a rapid increase in IOP due to an obstruction blocking the regular outflow of vitreous humour from the eye.[6] It is a medical emergency and presents as a sudden onset of severe unilateral eye pain or a headache associated with blurred vision, rainbow-colored halos around bright lights, nausea and vomiting.[6] Patients with significant hyperopia (farsightedness) are at risk of AAC glaucoma.[1,2]

Dry eye has been reported with methylphenidate and lisdexamfetamine.[2,3] Symptoms of dry eye may include ocular irritation, foreign body sensation, redness, blurred vision and discomfort.[7]

Other ocular adverse reactions reported with methylphenidate, lisdexamfetamine and dexamfetamine include diplopia (double vision), difficulties with accommodation, blurred vision and mydriasis (excessively dilated pupils).[1–4]

Refer to the recommendations provided in the relevant data sheets for patients with a history of increased IOP or glaucoma, or those at risk for acute angle-closure glaucoma.

- Search for a data sheet

Advise patients to promptly report visual disturbances or other changes in vision.[8]

## New Zealand case reports

Between 1 January 2010 and 31 May 2026, the New Zealand Pharmacovigilance Database received 5 case reports of eye-related disorders with stimulant medicines.

- Blurred vision (111822, 114103, NZ-Medsafe-158750) and mydriasis (NZ-Medsafe-155052) were reported with methylphenidate.
- Blurred vision (149093) was reported with dexamfetamine.

## References


1. Novartis New Zealand Limited. 2026. *Ritalin* and *Ritalin LA New Zealand Data Sheet* 29 January 2026. URL: www.medsafe.govt.nz/profs/Datasheet/r/RitalintabSRtabLAtab.pdf (accessed 20 July 2026).
2. Janssen-Cilag (New Zealand) Ltd. 2026. *Concerta Tablet New Zealand Data Sheet* 27 January 2026. URL: www.medsafe.govt.nz/profs/Datasheet/c/Concertatab.pdf (accessed 20 July 2026).
3. Takeda New Zealand Limited. 2026. *Vyvanse Capsule New Zealand Data Sheet* 4 June 2026. URL: www.medsafe.govt.nz/profs/Datasheet/v/vyvansecap.pdf (accessed 20 July 2026).
4. Pharmacy Retailing (NZ) Limited. 2026. *Aspen Dexamfetamine Tablet New Zealand Data Sheet* 16 March 2026. URL: www.medsafe.govt.nz/profs/datasheet/a/AspenDexamfetaminetab.pdf (accessed 27 July 2026).
5. Jannini TB, Alisi L, Giovannetti F, et al. 2026. The effect of psychotropic medications on glaucoma risk and intraocular pressure: A Bayesian meta-analysis. *CNS Drugs* 40(3): 451–466. DOI: 10.1007/s40263-025-01249-6 (accessed 20 July 2026).
6. Khazaeni B, Zeppieri M, Khazaeni L. 2026. Acute angle-closure glaucoma. In: *StatPearls [Internet]* updated 10 January 2026. URL: www.ncbi.nlm.nih.gov/books/NBK430857/ (accessed 6 August 2026).
7. Health New Zealand Te Whatu Ora. 2026. *Dry eyes* 22 July 2026. URL: www.healthnz.govt.nz/health-topics/conditions-treatments/eyes/dry-eyes#symptoms-of-dry-eyes-6009 (accessed 27 July 2026).
8. Takeda New Zealand Limited. 2026. *Vyvanse Capsules New Zealand Consumer Medicine Information* June 2026. URL: www.medsafe.govt.nz/consumers/CMI/v/vyvanse.pdf (accessed 20 July 2026).

# 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 24 April 2026 to 23 July 2026.

**Table 1: Recent approvals of medicines with new active ingredients**

| Medicine | New active ingredient | Dose form: Strength(s) | Therapeutic area |
|---|---|---|---|
| Intuniv | Guanfacine | Modified release tablet: 1mg, 2mg, 3mg, 4mg | Attention deficit hyperactivity disorder (ADHD) |
| Beyfortus | Nirsevimab | Solution for injection: 50mg/0.5mL, 100mg/mL | Prevention of Respiratory Syncytial Virus (RSV) |

## New indications

Table 2 shows approved medicines with new indications for additional therapeutic areas gazetted during the period 24 April 2026 to 23 July 2026.

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

| Medicine (active ingredient) | Dose form: Strength(s) | New therapeutic area |
|---|---|---|
| Tremfya (guselkumab) | Concentrate for infusion: 200mg/20mL<br>Solution for injection (pre-filled pen): 100mg/mL, 200mg/2mL<br>Solution for injection (pre-filled syringe): 100mg/mL, 200mg/2mL | Ulcerative colitis; Crohn's disease |

## More information

See the Medsafe website for:

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

# Alpha-gal syndrome: An emerging cause of hypersensitivity reactions to medicines

**Key messages**

- Alpha-gal syndrome (AGS) is a tick-associated IgE-mediated allergy that may cause hypersensitivity reactions to some medicines.
- Consider AGS in patients with unexplained hypersensitivity reactions, particularly if they have a history of tick bites or a history of delayed allergic reactions following consumption of mammalian products.

The Stelara (ustekinumab) data sheet was recently updated to highlight reports of serious hypersensitivity reactions in patients with a history of alpha-gal syndrome (AGS).[1] This article provides information about this rare, but clinically significant, hypersensitivity.

## Alpha-gal syndrome (AGS)[2–4]

AGS (also called red meat allergy or mammalian meat allergy) is an IgE-mediated allergy to alpha-gal (galactose-α-1,3-galactose). Alpha-gal is a carbohydrate found in the tissues of most non-primate mammals, and in the gut and saliva of ticks. Sensitisation occurs following bites from certain tick species, although the tick species associated with AGS varies geographically.

Once sensitised, a person with AGS may experience hypersensitivity reactions when they consume mammalian products (ie, red meat such as beef, pork or lamb, and other products such as gelatin or milk). Other products containing mammalian-derived alpha-gal (eg, certain biological medicines, vaccines and pharmaceutical excipients) may also cause hypersensitivity reactions in these people. Unlike most food allergies, reactions associated with AGS are typically delayed, occurring 2 to 6 hours after exposure.

Clinical manifestations of AGS range from urticaria, angioedema and gastrointestinal symptoms, to severe anaphylaxis. Diagnosis is based on clinical history and detection of serum alpha-gal-specific IgE antibodies.

## AGS and biological medicines

Some biological medicines, including monoclonal antibodies, may contain alpha-gal epitopes.[2] In patients with AGS, exposure to these medicines may trigger a hypersensitivity reaction.[2]

Internationally, hypersensitivity reactions have been reported in patients with AGS who received cetuximab, infliximab or natalizumab.[2] In New Zealand, the Erbitux (cetuximab) and Stelara (ustekinumab) data sheets contain information about AGS and the risk of hypersensitivity reactions.[1,5] The Remicade (infliximab) and Simponi (golimumab) data sheets are being updated.

Consider AGS as a possible explanation for immediate or delayed hypersensitivity reactions associated with medicines, particularly in patients with:[2,3]

- a history of tick bites
- a history of delayed allergic reactions following consumption of mammalian products (eg, beef, pork, lamb, gelatin or milk).

Manage suspected anaphylaxis according to local guidelines; treatment discontinuation may be necessary.

## References


1. Janssen-Cilag (New Zealand) Ltd. 2026. *Stelara New Zealand Data Sheet* 2 April 2026. URL: www.medsafe.govt.nz/profs/datasheet/s/stelarainj.pdf (accessed 3 August 2026).
2. Macdougall JD, Thomas KO and Iweala OI. 2022. The meat of the matter: Understanding and managing alpha-gal syndrome. *ImmunoTargets and Therapy* 11: 37–54. DOI: 10.2147/ITT.S276872. URL: www.tandfonline.com/doi/pdf/10.2147/ITT.S276872 (accessed 14 July 2026).
3. Lesmana, E, Rao S, Keehn, et al. 2025. Clinical presentation and outcomes of alpha-gal syndrome. *Clinical Gastroenterology and Hepatology* 23(1): 68–78. URL: www.cghjournal.org/article/S1542-3565(24)00672-4/pdf (accessed 15 July 2026).
4. Australasian Society of Clinical Immunology and Allergy (ASCIA). 2024. *Mammalian Meat and Tick Allergy: Frequently Asked Questions.* URL: www.allergy.org.au/patients/food-allergy/mammalian-meat-tick-faq (accessed 15 July 2026).
5. Healthcare Logistics. 2026. *Erbitux New Zealand Data Sheet* 22 January 2026. URL: www.medsafe.govt.nz/profs/Datasheet/e/Erbituxinf.pdf (accessed 3 August 2026).

## 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) / Class<br>Medicine(s) | Data sheet updates<br>Section[a] | Summary of new safety information |
|---|---|---|
| Atorvastatin<br>Lorstat | 4.8 | Depression |
| Atovaquone + proguanil<br>Malarone | 4.8 | Psychiatric disorders including abnormal dreams, depression, anxiety, panic attacks, crying, nightmares, psychotic disorders |
| Captopril<br>DP-Captopril | 4.4 | Hypersensitivity/Angioedema: May occur particularly during the first week of treatment with ACE inhibitors but can also develop after months or years of treatment. Immediately discontinue treatment and give emergency therapy. |
| | 4.4, 4.8 | Insulin Autoimmune Syndrome (IAS):[b] Cases of IAS have been reported, including severe hypoglycaemic events. If suspected, discontinue use and treat appropriately. |
| Ciclosporin<br>Neoral, Sandimmun | 4.4, 4.5 | Interactions: Avoid concomitant use of St John's wort (Hypericum perforatum) as it may decrease ciclosporin blood levels and potentially impact the clinical efficacy of ciclosporin. |
| Clobazam<br>Frisium | 4.4, 4.8 | Drug reaction with eosinophilia and systemic symptoms syndrome (DRESS) |
| CFTR modulators[c]<br>Alyftrek, Kalydeco, Orkambi, Symdeko, Trikafta | 4.4 | Mood disturbances: Effects on mood and behaviour, such as anxiety, low mood, sleep disturbance and forgetfulness have occasionally been reported. |
| Dexamethasone<br>Dexmethsone | 4.8 | Panniculitis |
| Doxycycline<br>Doxine | 4.4 | Severe skin reactions: Exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and DRESS have been reported with doxycycline treatment. If severe skin reactions occur, discontinue treatment immediately and treat appropriately. |
| Fingolimod<br>Gilenya | 4.4 | Infections/Progressive Multifocal Leukoencephalopathy (PML): Immune reconstitution inflammatory syndrome (IRIS) has been reported after discontinuation of Gilenya in patients who developed PML on treatment. Monitor for signs of IRIS following Gilenya cessation. |
| Fludarabine<br>Fludarabine Ebewe | 4.6 | Effects on fertility: Male patients must use effective methods of contraception and be advised to not father a child while receiving fludarabine, and at least for 3 months following completion of treatment. |

*Continues*

| Active ingredient(s) / Class<br>Medicine(s) | Data sheet updates<br>Section[a] | Summary of new safety information |
|---|---|---|
| Fludrocortisone<br>Florinef | 4.8 | Panniculitis |
| Glofitamab<br>Columvi | 4.4, 4.8 | Serious infections: PML, including fatal cases, has occurred in patients treated with Columvi. Monitor patients for new or worsening neurological toxicities. |
| Inclisiran<br>Leqvio | 4.8 | Hypersensitivity including anaphylactic reaction, angioedema, rash, urticaria, pruritus |
| Metformin-containing products<br>Metformin Viatris<br>Jardiamet | 4.4 | Patients with known or suspected mitochondrial diseases: Metformin is not recommended for use in these patients, such as those with Mitochondrial encephalopathy with lactic acidosis and stroke-like episodes (MELAS) syndrome and Maternal inherited diabetes and deafness (MIDD) |
| Primidone<br>Primidone (Clinect) | 4.4 | Vitamin D: Primidone may affect vitamin D metabolism. Monitor bone density in patients on long-term treatment and consider vitamin D supplementation.<br>Severe skin reactions: SJS and TEN have been reported. The risk is highest during the first few weeks of primidone treatment. Advise patients of the signs and monitor closely. |
| | 4.6 | Contraception: Women of childbearing potential should use effective contraception during treatment with primidone and for 2 months after stopping treatment. |
| Quetiapine<br>Quetapel | 4.4 | New warnings for Venous thromboembolism, Orthostatic hypotension, Serotonin syndrome with concomitant use of other serotonergic agents, Body temperature regulation, Interference with laboratory tests |
| RSV pre-fusion F protein<br>Arexvy | 4.5 | May be given concomitantly with pneumococcal vaccine or COVID-19 mRNA vaccine |
| Rifampicin + isoniazid<br>Rifinah | 4.3, 4.5 | Contraindicated when given concurrently with daclatasvir, sofosbuvir, telaprevir, lurasidone |
| Semaglutide<br>Wegovy | 4.4, 4.8 | Patients with gastroparesis: Patients with gastroparesis may experience more serious or severe gastrointestinal adverse events. Use with caution in these patients. |
| Sumatriptan<br>Clustran | 4.6, 4.8 | Breast pain |
| | 4.8 | Cerebellar infarction |
| Tretinoin<br>Vesanoid | 4.5 | Interaction with antifungal agents such as posaconazole, voriconazole, ketoconazole and itraconazole |
| Tirzepatide<br>Mounjaro | 4.8 | Non-arteritic ischaemic optic neuropathy (NAION) |
| Tranexamic acid<br>Cyklokapron | 4.8 | Renal cortical necrosis (eg, after severe blood loss, such as after post-partum haemorrhage) |
| Voriconazole<br>Vfend | 4.5 | Co-administration of voriconazole with mavacamten may increase mavacamten plasma concentration and increase the risk of heart failure |
| Zuclopenthixol<br>Clopixol | 4.4 | Neuroleptic malignant syndrome (NMS): Rhabdomyolysis may occur as a rare complication of NMS |

Key: CFTR = Cystic fibrosis transmembrane conductance regulator; RSV = Recombinant respiratory syncytial virus

a. Data sheet sections listed in the table are: 4.3: Contraindications; 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.

b. See the June 2026 edition of *Prescriber Update* for more information about Insulin autoimmune syndrome.

c. See the Spotlight on CFTR modulators article on page 38 of this edition of *Prescriber Update*.

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**In memoriam**
Medsafe acknowledges the passing of Janelle Ashton in August 2026, and we extend our sympathies to her family and friends. Before her retirement, Janelle was the Information Systems Manager at the New Zealand Pharmacovigilance Centre and played a vital role in the collecting and processing of suspected adverse reactions reported to the Centre for Adverse Reactions Monitoring.

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***Prescriber Update*** is written for prescribers, and as such, some of the language may not be familiar to consumers. Medsafe advises consumers to speak to their healthcare professional if they have concerns or questions about any of the information in this publication or the medicines they are taking.

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