Prescriber Update

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MINISTRY OF HEALTH
MANATŪ HAUORA

Gynaecomastia: A medicine-induced hormone imbalance

Key messages

- Gynaecomastia is a proliferation of breast tissue in males. It has been reported in association with a wide range of medicines.
- Onset can be delayed – gynaecomastia can develop weeks to years after starting treatment or adjusting the dose.
- Consider a medicine-related cause in male patients presenting with breast enlargement or other breast tissue changes.

Medsafe recently published a Monitoring Communication on atomoxetine and the possible risk of gynaecomastia.

The article provides an overview of gynaecomastia and the medicines that can cause it.

Understanding gynaecomastia

Gynaecomastia occurs due to a hormone imbalance in males that causes a benign proliferation of glandular breast tissue accompanied by localised fat deposition[1,2] Clinical features include firm or rubbery subareolar tissue, with breast enlargement or tenderness.[1,3]

The hormonal imbalance is caused by an increased oestrogen-to-androgen ratio.[3] Contributing factors may include:[2,3,4]

- physiological changes – puberty or ageing
- underlying medical conditions – hypogonadism, chronic liver disease, chronic kidney disease, hyperthyroidism, and testicular or adrenal disorder
- metabolic factors – obesity
- substance use – cannabis, alcohol, anabolic steroid
- taking certain medicines.

Medicine-induced gynaecomastia

Medicines account for approximately 10-25% of cases of gynaecomastia.[5,6] Onset may occur up to several years after initiating treatment.[5]

Medicines associated with gynaecomastia can cause hormonal imbalances by:

- reducing androgen action at breast tissue, through androgen receptor antagonism or inhibition of androgen synthesis[2,3,5]
- reducing testosterone production, resulting in relative oestrogen excess[1,4]
- increasing prolactin concentration, promoting glandular breast tissue proliferation[2,3]
- Increasing peripheral conversion of androgens to oestrogens, particularly in adipose tissue[3]

- direct oestrogenic effects or altered oestrogen metabolism, increasing oestrogen exposure at the breast.[1,2]

Many medicines are associated with gynaecomastia. Table 1 provides examples of medicines approved in New Zealand for which gynaecomastia, breast enlargement or related breast disorders are listed as adverse reactions in the respective data sheet.

Table 1: Example of medicines approved in New Zealand associated with gynaecomastia or related breast disorders (list not exhaustive), grouped by WHO Anatomical Therapeutic Chemical (ATC) first level

ATC group[a]	Examples of medicines[b]
Alimentary tract and metabolism	omeprazole, domperidone
Cardiovascular system	digoxin, spironolactone, amlodipine, verapamil, diltiazem, simvastatin, atorvastatin, rosuvastatin
Dermatologicals	isotretinoin
Genitourinary system and sex hormones	testosterone, cyproterone, finasteride
Anti-infectives for systemic use	darunavir, zidovudine, efavirenz
Anti-neoplastic and immunomodulating agents	methotrexate, flutamide, bicalutamide
Nervous system	risperidone, paliperidone, olanzapine, sertraline, fluoxetine, amitriptyline, methylphenidate

a. WHO Collaborating Centre for Drug Statistics Methodology. ATC/DDD Index 2026. URL: https://atcddd.fhi.no/atc_ddd_index/ (accessed 11 February 2026).

b. Medsafe Data Sheets and Consumer Medicine Information Search. URL: https://www.medsafe.govt.nz/DbSearch/infoSearch.asp (accessed 29 January 2026).

Prescribing considerations

Consider medicines as a potential cause if a male patient presents with gynaecomastia. Dose reduction or discontinuation of the suspect medicine may lead to improvement, particularly when gynaecomastia is identified early.[1-4] Persistence beyond 12 months may be less likely to resolve without intervention.[6]

Refer to local clinical guidelines for information on the assessment and management of gynaecomastia.[6]

New Zealand case reports

From 1 January 2016 to 31 December 2025, there were 24 case reports of gynaecomastia in men reported to the New Zealand Pharmacovigilance Database.

- Age was reported in 21 cases with a median of 62 years (range 18 to 76 years).
- The most frequently reported medicines were atorvastatin (3 reports), finasteride (3), omeprazole (3), isotretinoin (2), risperidone (2) and rosuvastatin (2).
- Time to onset was reported in 14 cases and ranged from immediate onset to 10 years after starting treatment.

Monitoring communication

Medsafe is reviewing the risk of gynaecomastia with atomoxetine. The New Zealand Pharmacovigilance Database recently received a report of a 36-year-old male patient who developed bilateral gynaecomastia following a dose increase of atomoxetine. Gynaecomastia is not listed in the atomoxetine data sheets.

Medsafe encourages reporting of gynaecomastia with atomoxetine. Anyone can submit a report.

References

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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
09/02/2026	Dear Healthcare Professional Letter	Alecensa (alectinib) new adverse reaction of severe hypertriglyceridaemia (PDF, 2 pages, 145 KB)
02/02/2026	Dear Healthcare Professional Letter	Zypine ODT (Olanzapine) 10 mg Orodispersible Tablets – Alternative Registered Foils (PDF, 2 pages, 410 KB)
26/01/2026	Monitoring	Glucagon-like peptide-1 receptor agonists (dulaglutide, liraglutide, semaglutide, tirzepatide) and acute persistent visual loss
16/01/2026	Dear Healthcare Professional Letter	Columvi (glofitamab): New important identified risk of haemophagocytic lymphohistiocytosis (PDF, 3 pages, 145 KB)
15/12/2025	Monitoring	Atomoxetine and the possible risk of gynaecomastia
28/11/2025	Alert	Recall of FreeStyle Libre 3 Plus CGM sensors (some batches only)
20/11/2025	Dear Healthcare Professional Letter	Codeine Phosphate Tablets (Noumed) 15 mg, 30 mg and 60 mg – Overlabelling of cartons and blister packs due to stock shortages / out of stock (PDF, 2 pages, 594 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.

MARC's remarks: December 2025 meeting

The Medicines Adverse Reaction Committee (MARC) convened for their 204th meeting on 4 December 2025.

The Committee discussed the risk of psychiatric disorders with **cystic fibrosis transmembrane conductance regulator (CFTR) modulators**. CFTR modulators include ivacaftor (Kalydeco) and ivacaftor/tezacaftor/elexacaftor (Trikafta). The Committee agreed that while a causal relationship has not been established, the data sheets for CFTR modulators should be updated to state that psychiatric disorders have been reported and that patients should be monitored for these symptoms.

The Committee discussed **antipsychotic**-induced hyperprolactinemia and the risk of breast cancer. The Committee considered that there was biological plausibility for an association, but the epidemiological evidence was unconvincing. The current data sheet information was considered appropriate, and no regulatory action was recommended.

The Committee reviewed the risk of drug reaction with eosinophilia and systemic symptoms (DRESS) with **calcium channel blockers**. The Committee considered the evidence for an association to be limited and concluded that no regulatory action is needed.

Medsafe presented a summary of New Zealand adverse reaction reports for **pregabalin**. The Committee noted that usage of pregabalin is increasing in New Zealand and commented that misuse and abuse of pregabalin is a significant problem internationally.

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

Document clinical trial participation in the patient's medical record

Key messages

- Document clinical trial participation (including contact details for the investigator/research team) in the patient's medical record.
- This ensures that other health care providers who are involved in the patient's care:
  - are aware of the patient's participation in the trial
  - have access to information that may be relevant to the patient's medical care.

Medsafe recently updated the clinical trial guidelines for industry.[1,2] In the guideline we encourage documenting clinical trial participation in the patient's medical record.

Documenting the patient's participation ensures that other health care providers are aware of the patient's involvement in a clinical trial. It will also provide information that may be relevant for the patient's medical care. This may be particularly important in situations where trial participants are unable to inform health providers about the trial (eg, in the case of emergency admission to hospital).

Advice for investigators

Investigators should:

- record relevant information about clinical trial participation in the patient's medical record (or request for it to be added via appropriate channels), including:
  - a clinical trial identifier
  - contact details for the investigator/research team (including out-of-hours)
- inform the patient's usual health care provider of their participation in a clinical trial, if appropriate.

Advice for health care providers

Health care providers should:

- check that relevant information about clinical trial participation is recorded in the patient's medical record
- contact the investigator/research team if more information about the study is needed to provide appropriate medical care to the patient
- alert the investigator/research team to hospital admissions or other potential adverse events, if appropriate.

Other points for consideration

- Any information sharing should be part of the informed consent process (note that the patient has the right to decline the sharing of their information).
- Ideally, information about trial participation should be recorded in the electronic medical record so that it is more readily accessible.
- The medical record should be updated when the patient's participation in the trial is complete.

More information

- National Ethics Advisory Committee: Informed consent in clinical trials

References

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2. Medsafe. 2026. *Guideline on the Regulation of Therapeutic Products in New Zealand: Clinical Trials – Regulatory Approval and Good Clinical Practice Requirements* (Edition 3.0). URL: www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Clinical-Trials-Regulatory-Approval-and-GCP-Requirements.pdf (accessed 3 February 2026).

Update: Fournier's gangrene can occur in patients treated with empagliflozin who do not have type 2 diabetes mellitus

Key messages

- Fournier's gangrene (necrotising fasciitis) is a rapidly progressive infection affecting the soft tissue and fascia of the perineal, perianal or genital areas.
- Fournier's gangrene has been known to occur in patients treated with empagliflozin for type 2 diabetes mellitus and is now known to occur with the use of empagliflozin in patients who do not have type 2 diabetes mellitus.

We have received two case reports of Fournier's gangrene in patients taking empagliflozin for heart failure. These cases highlight that Fournier's gangrene not only occurs in patients taking empagliflozin for type 2 diabetes but can occur in patients taking empagliflozin for any indication.[1,2] The data sheets for empagliflozin-containing products were recently updated to reflect this.

Jardiance (empagliflozin) and Jardiamet (empagliflozin + metformin) are both indicated for use in type 2 diabetes mellitus.[1,2] Jardiance is also indicated for use in heart failure and chronic kidney disease in patients with or without type 2 diabetes mellitus.[1]

Fournier's gangrene is a rapidly progressive necrotising fasciitis of the external genitalia, perineum and perianal region. It is more common in males than females.[3]

Promptly evaluate patients treated with empagliflozin for any indication who present with pain or tenderness, erythema (redness), swelling in the genital or perineal area, fever or malaise for Fournier's gangrene.[1,2]

Discontinue empagliflozin treatment immediately if Fournier's gangrene is suspected and promptly treat the patient, including broad-spectrum antibiotics and surgical debridement if necessary.[1,2]

New Zealand case reports

As of 31 December 2025, there were 44 case reports of Fournier's gangrene/necrotising fasciitis associated with empagliflozin. Age was reported in 32 cases with a median of 57.5 years (range: 35 to 81 years). All cases were serious, including 3 cases with a fatal outcome.

See Table 1 for a summary of these 44 cases.

Table 1: Summary of the 44 Fournier's gangrene/necrotising fasciitis cases reported in association with empagliflozin in the New Zealand Pharmacovigilance Database, 1 January 2021 to 31 December 2025

Subgroup	Number of cases
Medicine	
Empagliflozin	38
Empagliflozin + metformin	6
Indication	
Type 2 diabetes mellitus	30
Heart failure	2
Unknown/not reported	12
Gender	
Male	27
Female	14
Unknown/not reported	3
Ethnicity	
Māori	10
European or Other	8
Pacific Peoples	6
Asian	2
Unknown/not reported	18

Source: New Zealand Pharmacovigilance Database, accessed 19 February 2026.

Further information

For prescribers:

- Spotlight on empagliflozin (*Prescriber Update* December 2020)
- Empagliflozin: advise patients on the risk of ketoacidosis and Fournier's gangrene (*Prescriber Update* September 2021)
- Reminder: Flozins and the risks of diabetic ketoacidosis and Fournier's gangrene (*Prescriber Update* December 2022)

For patients:

- Watch out for Fournier's gangrene (infection) when taking SGLT-2 inhibitors like empagliflozin (Medsafe consumer information leaflet November 2022)
- Empagliflozin (also called Jardiance) and Jardiamet (also called empagliflozin + metformin) (Healthify medicine information)

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2. Boehringer Ingelheim (N.Z.) Limited. *Jardiamet New Zealand Data Sheet* 29 January 2025. URL: www.medsafe.govt.nz/profs/Datasheet/j/jardiamettab.pdf (accessed 7 January 2026).
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Zoledronic acid: May be less tolerable for elderly patients

Key messages

- Elderly patients receiving zoledronic acid infusions are at higher risk of adverse reactions and may experience more severe adverse reactions or find them more disabling than younger people.
- In particular, acute phase reactions are noted as a cause of concern in reports to the New Zealand Pharmacovigilance Database.
- Consider the following prior to the zoledronic infusion.
  - Inform the patient that acute phase reactions are common and usually resolve in a few days. However, patients should seek medical attention if symptoms are serious or prolonged.
  - Ensure the patient is adequately hydrated and measure their serum creatinine. Maintain adequate hydration following the infusion.
  - Treat pre-existing hypocalcaemia with adequate intake of calcium and vitamin D.

Background

Zoledronic acid is a bisphosphonate given as an intravenous infusion to treat various bone diseases such osteoporosis, Paget's disease[1], tumour-induced hypercalcaemia and to prevent skeletal-related events in advanced malignancy involving the bone.[2]

Elderly patients receiving zoledronic acid infusions are at higher risk of adverse effects , including acute phase reactions, renal adverse events and hypophosphataemia and hypocalcaemia. Reasons for this include age-related decline in renal function, complex co-morbidities and polypharmacy.[1,2]

Elderly patients may also experience more severe adverse reactions or find them more disabling than younger people, as noted in recent reports to the New Zealand Pharmacovigilance Database.

Acute phase reactions

Acute phase reactions (also known as post-dose symptoms) are a constellation of symptoms including fever, joint pain and swelling, myalgia, influenza-like illness and gastrointestinal symptoms (abdominal pain, vomiting and diarrhoea) that usually occur within the first three days after zoledronic administration.[1,2] Ocular inflammation, such as uveitis, can rarely occur.[1,3,4]

These reactions are possibly due to a transient and rapid release of pro-inflammatory cytokines from the activation of T-cells following administration of zoledronic acid.[5]

Prior to infusion, inform the patient that acute phase reactions commonly occur, particularly following the first infusion. Symptoms are usually mild to moderate and resolve within a few days of onset.[1,2] Advise patients to seek medical attention if the symptoms are serious or prolonged.

Administering paracetamol shortly after the zoledronic acid infusion may reduce symptoms.[1,6]

Promptly refer patients that develop symptoms of ocular inflammation (eg, eye redness, eye pain, light sensitivity, blurred vision) to an ophthalmologist for examination and treatment.[7]

Renal adverse events

Renal impairment can occur following administration of zoledronic acid, particularly if the patient has pre-existing renal impairment or additional risk factors, including age.[1]

To minimise the risk of renal impairment in elderly patients:

- ensure the patient is adequately hydrated[1] prior to and after the infusion (especially if acute phase reactions cause dehydration)
- use caution if the patient is also taking medicines that can impair renal function, such as nephrotoxic medicines and diuretics[1,8]
- measure the patient's serum creatinine prior to infusion and calculate their creatinine clearance.[1,8] Refer to the respective product data sheet for when zoledronic acid should not be given.

Hypocalcaemia and hypophosphatemia

Elderly patients are at risk of developing low serum calcium and phosphate levels following zoledronic acid infusion.[1] Cardiac arrythmias and neurological events are a potential consequence of severe hypocalcaemia.[2]

Administration of zoledronic acid is contraindicated in patients with hypocalcaemia. Pre-existing hypocalcaemia must be treated by adequate intake of calcium and vitamin D before initiating therapy with zoledronic acid.[1,2]

New Zealand case reports

From 1 January 2016 to 31 December 2025, there were 428 cases reported to the New Zealand Pharmacovigilance Database where zoledronic acid was suspected to cause an adverse reaction. There were 355 reports in females, 69 in males and 4 where gender was not reported. Age was reported in 413 cases, with a median age of 70 years (range 15 to 94 years).

Cases reported in elderly patients

There were 290 cases reported in elderly patients aged 65 years and older, including 219 serious reports.

- **Acute phase reactions**: there were 220 reports describing acute phase reactions, including 159 serious reports. The most frequently reported reactions were arthralgia (53 reports), myalgia (40), influenza-like illness (36), headache (34) and pyrexia (29).
- **Renal adverse events**: there were 22 reports of renal adverse events, including 14 reports of acute renal failure and 6 reports of renal impairment.
- **Hypocalcaemia and hypophosphataemia**: there were 17 reports of hypocalcaemia and 9 reports of hypophosphataemia, including 3 cases where both hypocalcaemia and hypophosphataemia were reported.

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Gathering knowledge from adverse reaction reports: March 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: 163830 **Age:** 39 years **Gender:** Female **Medicine(s):** Codeine **Reaction(s):** Biliary spasm	The patient experienced a possible biliary duct spasm (swelling, itching, pain, yellow coloured eyes and abnormal liver function tests) after taking codeine.
	Biliary spasm is listed in the Codeine Phosphate data sheet.
Report ID: 164379 **Age:** 6 years **Gender:** Male **Medicine(s):** Midazolam **Reaction(s):** Agitated, aggression, violent behaviour	Following administration of midazolam, the child became aggressive, violent and agitated.
	The Midazolam Injection data sheet states that paradoxical reactions (including agitation, anger, rage reaction, aggressiveness and assault) have been reported, particularly among children and the elderly.
Report ID: 164390 **Age:** 21 years **Gender:** Not reported **Medicine(s):** Ibuprofen **Reaction(s):** Toxic epidermal necrolysis (TEN)	Two days after taking ibuprofen, the patient developed a widespread blanching maculopapular rash plus fever, sore eyes, photophobia, tachycardia, hypotension and airway sloughing. The patient was diagnosed with TEN.
	TEN is listed as a very rare ADR in the Ibuprofen SR BNM and Ibuprofen (Relieve) data sheets.
Report ID: 165878 **Age:** 15 years **Gender:** Female **Medicine(s):** Atomoxetine **Reaction(s):** Raynaud's phenomenon	The patient experienced Raynaud's phenomenon during treatment with atomoxetine.
	Raynaud's phenomenon is listed as a very rare ADR in the Apo-Atomoxetine data sheet.

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).

Medicines Amendment Act 2025: Information for prescribers

Key messages

- The Medicines Amendment Act 2025 amends the Medicines Act 1981 by:
  - introducing a verification pathway for medicines approval
  - updating prescribing settings to enable wider prescribing of unapproved medicines
  - enabling advertising of unapproved medicines at medical conferences
  - removing a restriction that prevented prescribers from holding a financial interest in a pharmacy
  - updating the membership of the Medicines Classification Committee.

The Medicines Amendment Act 2025 came into force on 19 November 2025. It amends the Medicines Act 1981 to improve access to medicines, change pharmacy ownership restrictions and update the Medicines Classification Committee membership.

Verification

The Medicines Amendment Act introduced a verification pathway so that medicines can be approved in New Zealand if two recognised overseas regulatory authorities have already approved the same product. For more information, refer to Medicines Amendment Act: Verification pathway on the Ministry of Health website. Further legislative changes to the Medicines Regulations 1984 and introduction of rules are underway to enable the pathway.

Wider prescribing of unapproved medicines

Previously under Section 29 of the Medicines Act, only medical practitioners were permitted to prescribe unapproved medicines.

The Medicines Amendment Act means:

- nurse practitioners and pharmacist prescribers can prescribe unapproved medicines (including cannabidiol [CBD]) for the treatment of a named patient under their care (section 29).
- any authorised prescriber can prescribe an unapproved medicine when it is funded by Pharmac as an alternative to an approved funded medicine that is in short supply, for the treatment of a named patient in their care (section 29A).

For more information, refer to:

- Use of unapproved medicines and use of approved medicines for an unapproved purpose
- Supplying unapproved medicines

Advertising at medical conferences

Section 20(2)(c) of the Medicines Act prevents advertising of unapproved medicines. The Medicines Amendment Act modifies the Medicines Act to provide an exemption for advertising unapproved medicines at medical conferences (section 34AA.)

A medical conference is any conference, including an associated trade show, where the intended audience are health practitioners regulated under the Health Practitioners Competence Assurance Act 2003.

The organiser of a medical conference must notify the Director-General of Health at least 30 working days before the opening of the conference.

For more information, including the notification form, refer to:

- Exemption for advertising unapproved medicines at medical conferences

Prescribers holding an interest in a pharmacy

Section 42C of the Medicines Act prevented authorised prescribers and delegated prescribers from holding an interest in pharmacies unless approved by Medsafe. Section 14 of the Medicines Amendment Act has repealed this section.

While a small number of pharmacies (such as hospital pharmacies) operate under different ownership provisions, most pharmacies must still be majority owned by pharmacist(s) that are able to exert effective control (sections 55D and 55E of the Medicines Act).

For guidance on the Effective Control Principles for pharmacy ownership, refer to:

- Effective Control Principles

Medicines Classification Committee

Previously, the Medicines Act specified that the Medicines Classification Committee must consist of 2 persons nominated by the NZ Medical Association, 2 persons nominated by the Pharmaceutical Society of NZ and 2 officers from the Ministry of Health.

The Medicines Amendment Act modifies section 9 of the Medicines Act to allow wider representation on the Committee:

- the Minister must appoint at least 7 members to the Committee, but the composition is not specified
- the Minister must be satisfied that the person is be suitably qualified to be a member.

GPs and pharmacists will continue to be the core expertise on the Committee, but the changes enable consumers and nurses (for example) to contribute.

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 October 2025 to 22 January 2026.

Table 1: Recent approvals of medicines with new active ingredients

Medicine	New active ingredient	Dose form: strength(s)	Therapeutic area
Comirnaty LP.8.1	SARS-CoV-2 spike protein (mRNA) LP.8.1	Concentrate or suspension for injection Multidose vial: 3mcg/0.3mL dose, 10mcg/0.3mL dose, 30mcg/0.3mL dose Single dose vial: 10mcg/0.3mL dose Prefilled syringe: 30mcg/0.3mL dose	COVID-19 disease
Itovebi	Inavolisib	Film coated tablet: 3mg, 9mg	Breast cancer
Mounjaro	Tirzepatide	Solution for injection Pre-filled pen: 2.5mg/0.5mL, 5mg/0.5mL, 7.5 mg/0.5mL, 10mg/0.5mL, 12.5mg/0.5mL, 15mg/0.5mL Vial: 2.5mg/0.5mL, 5mg/0.5mL, 7.5 mg/0.5mL, 10mg/0.5mL, 12.5mg/0.5mL, 15mg/0.5mL KwikPen: 4.17mg/mL, 8.33mg/mL, 12.5mg/mL, 16.67mg/mL, 20.83mg/mL, 25mg/mL	Type 2 diabetes mellitus; Chronic weight management
Welireg	Belzutifan	Film coated tablet: 40mg	von Hippel-Lindau disease-associated tumours; Advanced renal cell carcinoma

New indications

Table 2 shows approved medicines with new indications for additional therapeutic areas gazetted during the period 24 October 2025 to 22 January 2026.

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

Medicine (active ingredient)	Dose form: strength(s)	New therapeutic area
Mekinist (trametinib)	Film coated tablet: 0.5mg, 2mg Powder for oral solution: 0.05mg/mL	Paediatric glioma[a]
Tafinlar (dabrafenib)	Capsule: 50mg, 75mg Dispersible tablet: 10mg	Paediatric glioma[b]

a. Trametinib in combination with dabrafenib.

b. Dabrafenib in combination with trametinib.

More information

See the Medsafe website for:

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

GLP-1 receptor agonists and altered skin sensations: A touchy subject

Key messages

- GLP-1 receptor agonists can cause altered skin sensations.
  - Semaglutide is associated with dysaesthesia, paraesthesia, hyperaesthesia, burning sensation, allodynia and sensitive skin.
  - Tirzepatide is associated with dysaesthesia.
- Consider GLP-1 receptor agonists as a possible cause in patients presenting with altered skin sensations.

The New Zealand Pharmacovigilance Database has received several reports of altered skin sensations, particularly allodynia, in association with semaglutide.

Semaglutide and tirzepatide can cause altered skin sensations

The term dysaesthesia describes abnormal and unpleasant skin sensations, such as burning, tingling, numbness or cold sensation. Allodynia is a type of dysaesthesia, where the person experiences a painful sensation in response to a stimulus that does not normally cause pain, for example, light touch from clothes.[1,2]

In semaglutide clinical trials, altered skin sensations such as dysaesthesia, paraesthesia, hyperaesthesia, burning sensation, allodynia and sensitive skin were reported in 2.1% of patients treated with Wegovy (semaglutide) and 1.2% of patients treated with placebo. Most patients recovered while on continued treatment.[3]

Dysaesthesia is also associated with Mounjaro (tirzepatide), a GLP-1 and glucose-dependent insulinotropic polypeptide (GIP) receptor agonist.[4]

Consider GLP-1 receptor agonists as a possible cause in patients presenting with altered skin sensations.

New Zealand case reports

As of 31 January 2026, there were 9 cases of altered skin sensations reported to the New Zealand Pharmacovigilance Database in association with semaglutide. The reported reactions were allodynia (6 reports), burning skin sensation, hypersensitive skin and skin pain (1 report each).

References

1. International Association for the Study of Pain. 2011. *IASP terminology* URL: www.iasp-pain.org/resources/terminology/ (accessed 14 January 2026).
2. Eileen McManus, Elaine Luther, Amanda Oakley, et al. 2020. *Cutaneous dysaesthesia* February 2020. URL: https://dermnetnz.org/topics/cutaneous-dysaesthesia (accessed 20 January 2026).
3. Novo Nordisk Pharmaceuticals Ltd. 2025. *Wegovy New Zealand Data Sheet* 21 August 2025. URL: www.medsafe.govt.nz/profs/Datasheet/w/wegovyinjection.pdf (accessed 16 January 2026).
4. Eli Lilly and Company (NZ) Limited. 2025. *Mounjaro New Zealand data sheet* 22 December 2025. URL: www.medsafe.govt.nz/profs/Datasheet/m/MounjaroInj.pdf (accessed 20 January 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): Medicine(s)	Data sheet updates	
	Section[a]	Summary of new safety information
Alfentanil Alfentanil (Medsurge)	4.4	Opioid class effects: Sleep-related breathing disorders; Adrenal insufficiency; Endocrine effects; Hepatobiliary disorders; Gastrointestinal toxicity
	4.8	Opioid class effects: Central sleep apnoea syndrome; Pancreatitis; Spasm of sphincter of Oddi; Adrenal insufficiency and Androgen deficiency
	4.9	Toxic leukoencephalopathy has been observed with opioid overdose.
Amoxicillin + clavulanic acid Augmentin	4.4, 4.8	Haemophagocytic lymphohistiocytosis (HLH)/Macrophage activation syndrome (MAS)
Azathioprine Azamun	4.4	Posterior reversible encephalopathy syndrome (PRES)
	4.8	PRES; Pellagra; Tremor; Sialadenitis
Bacillus Calmette-Guérin (BCG) OncoTICE	4.8	HLH
Dabrafenib Tafinlar	4.8	When used in combination with trametinib: Tattoo-associated skin reaction
Dexamethasone DBL Dexamethasone Sodium Phosphate	4.4. 4.5	Musculoskeletal disorders: Acute myopathy has been reported with high doses, in patients with neuromuscular transmission disorders or with concomitant use of anticholinergics, such as neuromuscular blocking agents (eg, pancuronium bromide).
Dulaglutide Trulicity	4.4	Psychiatric disorders: Suicidal behaviour and ideation have been reported with GLP-1 receptor agonists.
Enalapril Acetec	4.4	Neutropenia/agranulocytosis
	4.8	Psoriasis/psoriasis aggravated
Flucloxacillin Flucil	4.8	Aseptic meningitis; Hyperkinesia
Gadobutrol Gadovist 1.0	4.4	Acute respiratory distress syndrome (ARDS)
Hydroxychloroquine Plaquenil	4.4	Haemolytic anaemia associated with glucose-6-phosphate dehydrogenase (G6PD) deficiency
Ibrutinib Imbruvica	4.8	Uveitis

Continues

Active ingredient(s): Medicine(s)	Data sheet updates	
	Section[a]	Summary of new safety information
Isotretinoin Oratane	4.4	Sexual disorders have been reported in patients treated with isotretinoin. In some cases, symptoms have persisted after discontinuation. Psychiatric disorders (updated): Reports of persistent symptoms after discontinuation; Assess mental health before treatment; Discontinue treatment if symptoms of depression develop or worsen.
	4.8	Anhedonia; Gynaecomastia
Leflunomide Arava	4.4	Skin reactions: HLH, including MAS
	4.8	Pulmonary nodule
Medroxyprogesterone acetate[b] Depo-Provera Provera[c]	4.4	Meningioma (updated): Monitor patients for signs and symptoms; If used for a non-oncological indication and meningioma develops, discontinue use; If used for an oncological indication and meningioma develops, carefully consider the ongoing need for treatment.
Meropenem Meropenem-AFT	4.4, 4.8	Drug-induced liver injury
	4.8	Hypokalaemia
Mesalazine Pentasa	4.4, 4.8	Idiopathic intracranial hypertension (pseudotumor cerebri)
	4.4	Discontinue use immediately if renal function deteriorates.
Tamoxifen Tamoxifen Sandoz	4.4	Premenopausal women (updated): May reduce bone mineral density – provide advice about measures to maintain bone health.
Testosterone Reandron 1000 Sustanon	4.4, 4.8	Pulmonary oil microembolism
	4.5	Interaction with insulin and other anti-diabetic medicines, including sodium-glucose co-transporter 2 (SGLT-2) inhibitors
Trametinib Mekinist	4.8	When used in combination with dabrafenib: Tattoo-associated skin reaction
Warfarin Marevan	4.8	Tracheal or tracheobronchial calcification
Zopiclone Imovane Zopiclone Actavis	4.4, 4.9	Haemolysis/haemolytic anaemia have been reported in cases of overdose

a. Data sheet sections listed in the table are: 4.4: Special warnings and precautions for use; 4.5: Interaction with other medicines and other forms of interaction; 4.8: Undesirable effects; 4.9: Overdose.

b. See also the March 2025 article: Medroxyprogesterone acetate and meningioma.

c. For Provera, the meningioma warning applies to ≥100mg dose tablets.

Medsafe

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