



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## **Gentamicin Injection BP 80 mg in 2 mL Steriluer**

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### **Recall - potential for allergic reactions due to higher than expected amounts of histamine**

**6 October 2017**

Consumers and health professionals are advised that Pfizer Australia, in consultation with the TGA, is recalling 10 batches of Gentamicin Injection BP 80 mg in 2 mL Steriluer ampoules in packs of 10 and 50.

Gentamicin Injection belongs to a group of medicines known as aminoglycoside antibiotics, which work by preventing bacteria from growing and by killing them. Gentamicin Injection is most commonly used to treat serious and potentially life-threatening infections in many different parts of the body, such as chest infections, urinary tract infections and infected wounds or burns. It can be used in adults and children.

It has been identified that the affected batches of Gentamicin Injection (listed below) may contain higher than expected amounts of histamine.

Histamine injected intravenously or intramuscularly can potentially lead to signs and symptoms of hypersensitivity reactions, including severe allergic reaction (anaphylaxis). The risk of this occurring is increased for patients who are children and patients with severe kidney impairment.

The batch numbers and expiry dates are:

- A115 exp 30 November 2017
- A115A exp 30 November 2017
- A115B exp 30 November 2017
- A129 exp 31 December 2017
- A297 exp 31 May 2018
- A316 exp 31 August 2018
- A318 exp 31 May 2018
- A342 exp 31 July 2018

- A394 exp 31 October 2018
- A448 exp 31 December 2018.

Gentamicin Injection is primarily used in hospitals, but it can be dispensed from community pharmacies for use in settings such as nursing homes or local clinics. It is possible that some affected products could have been dispensed to patients for use outside of a clinical setting, such as at home.

Any such patients are advised to return the affected products to their pharmacy for a refund and to speak to their health professional as soon as possible to discuss replacement.

### **Information for consumers**

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If you or someone you provide care for is using Gentamicin Injection outside of a clinical setting, such as at home, check to see if your medicine is from an affected batch.

If it is, return the affected product to your pharmacy for a refund and speak to your health professional as soon as possible to discuss replacement.

Signs and symptoms of severe allergic reactions can include one or more of the following:

- generalised rash
- hives or welts (a red, itchy, lumpy rash, like mosquito bites)
- a tingling feeling in or around the mouth
- stomach pain, vomiting and/or diarrhoea
- facial swelling
- difficulty with breathing and/or noisy breathing
- swelling of the tongue
- swelling and/or tightness in throat
- difficulty talking and/or hoarse voice
- loss of consciousness and/or collapse.

If you have any questions or concerns about this issue, talk to your health professional.

### **Information for health professionals**

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Pfizer Australia has written to health professionals who supply Gentamicin Injection to provide them further information about this issue, including details of the recall procedure.

If you have any unused Gentamicin Injection, check your stock and quarantine any products from the affected batches.

If you have any questions or concerns about this issue, contact Pfizer Australia on 1800 999 543.

## **Reporting problems**

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Consumers and health professionals are encouraged to [report problems with medicines or vaccines \(/reporting-problems\)](#). Your report will contribute to the TGA's monitoring of these products.

The TGA cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a health professional if you are concerned about a possible adverse event associated with a medicine or vaccine.

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**Category:** Alert/Advisory, Medicines safety

**Tags:** recalls, antibiotics

**URL:** [https://www.tga.gov.au/node/765885 \(/https://www.tga.gov.au/alert/gentamicin-injection-bp-80-mg-2-ml-steriluer\)](https://www.tga.gov.au/node/765885 (/https://www.tga.gov.au/alert/gentamicin-injection-bp-80-mg-2-ml-steriluer))

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