

## URGENT PRODUCT CORRECTION

GSK Australia, in consultation with the Therapeutic Goods Administration (TGA), has issued a **product correction** notice for several strengths of its Flixotide and Pavtide Accuhalers, following the identification of a manufacturing problem that may impact a very small number of Accuhaler devices.

### The affected batches are:

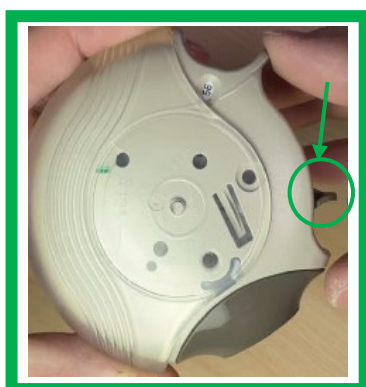
Product	AUST R	Batch Number	Expiry Date
FLIXOTIDE JUNIOR ACCUHALER (fluticasone propionate) 100 mcg, 60 doses	58439	PA8S	Sep-2027
FLIXOTIDE ACCUHALER (fluticasone propionate) 250 mcg, 60 doses	58438	HM6D PA8V	Jun-2028 Sep-2028
FLIXOTIDE ACCUHALER (fluticasone propionate) 500 mcg, 60 doses	58437	DT5H	Mar-2028
PAVTIDE ACCUHALER 100/50 (fluticasone propionate/salmeterol (as xinafoate)) 100/50 mcg, 60 doses	208200	SJ5R	Oct-2027
PAVTIDE ACCUHALER 250/50 (fluticasone propionate/salmeterol (as xinafoate)) 250/50 mcg, 60 doses	208201	SD3C	Oct-2027

### What is the problem?

These Accuhalers each contain a dry powder respiratory product for 60 doses. Each dose is delivered via a patient-activated lever (see Figure 1). The Accuhaler has been designed to automatically reset for the next dose when the patient rotates the Accuhaler clockwise following use (see Figure 2).



**Figure 1:**  
Accuhaler before use.



**Figure 2:**  
Accuhaler opened with lever in **correct** starting position.  
This is an **unaffected product**.



**Figure 3:**  
Accuhaler opened with lever in **incorrect** starting position.  
This is an **impacted product**.

GSK identified that a small number of Accuhalers may not automatically reload following the clockwise rotation (see Figure 3). The Accuhaler will function normally for several doses (anywhere between 20-59 doses) and may then stop working. We have worked quickly to alert authorities, customers and health care professionals to minimise consumer impact.

If the dose is not manually reset, this may lead to a short-term flare-up of asthma symptoms.

### **What should I do?**

In the unlikely event you have an impacted device (where the lever is in the incorrect starting position) do not stop using your Accuhaler. You can manually reset the starting position by pushing the lever down towards the mouthpiece. Following this, push the lever up, away from the mouthpiece to 'load' the dose (as per normal instructions). This will cause the dose counter to change, indicating the Accuhaler has been reset correctly.

If this problem occurs, you will need to reset the lever for each dose. After manually resetting the lever, a full dose will be delivered as normal. You should verify the dose counter advances. If this does not occur, the dose has not been delivered.

If you have an Accuhaler from any of the batches listed above and are having any difficulties administering a dose, please contact your doctor or pharmacist for support.

GSK has conducted a thorough investigation and has taken appropriate action to ensure further products are not affected.

Please contact GSK by phone on 1800 033 109 if you have any queries.

We regret any consumer inconvenience and remain committed to supplying high-quality medicines to patients.