



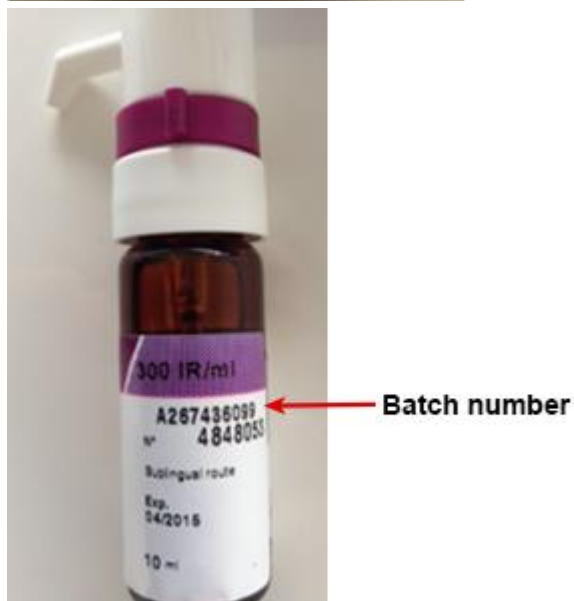
Australian Government
Department of Health
Therapeutic Goods Administration

Staloral and Phostal

Recall - potential incorrect labelling

23 December 2015

Consumers and health professionals are advised that Stallergenes Australia, in consultation with the TGA, is recalling certain batches of Staloral and Phostal.



Staloral is a range of sublingual solutions and Phostal is a suspension for injection. Both medicines are used for allergen immunotherapy. Staloral is for a range of allergens and the affected batch of Phostal is used specifically for European dust mite (*D.Pteronyssinus*).

This recall follows a directive from the French health authority, Agence Nationale de Sécurité du Médicament (ANSM), to temporarily suspend manufacturing and distribution of pharmaceutical products and active ingredients for use in pharmaceutical products from the Stallergenes production plant in Antony (France), commencing 2 December 2015. Subsequently, the TGA have cancelled the manufacturing clearance for this site.

This decision was made after identification by ANSM that the implementation of a new IT system on 13 August 2015 could lead to these medicines having incorrect labelling that could result in incorrect dosing. It also caused operational disruptions and supply shortages. Any medicines manufactured before 13 August 2015 are not affected and can be used.

If the dosage for these medicines is incorrect, there is a potential for inadequate treatment, excessive dosage and/or allergic reaction.

As of 16 December 2015, there have been no reports of adverse events in Australia or outside of France associated with this issue.

The affected name/description and lot numbers are:

Staloral:

Product code	Product name/description	Batch no. start	Batch no. end
A400007246	D.PTERONYSSINUS	A315133501	A325450501
A400007248	DPTE/DFAR.50/50	A315249501	A325289601
A400007249	D.PTERONYSSINUS	A315165801	A325382401
A400007250	DPTE/DFAR.50/50	A315480401	A325293301
A400007252	DPTE/DFAR.50/50	A316120801	
A400007253	DPTE/DFAR.50/50	A315134901	A325437001
A400007256	5 GRASSES MIX	A315141701	A325366501
A400007257	5 GRASSES MIX	A315200501	A325325801
A400007259	D.PTERONYSSINUS	A315141801	A325357101
A400007260	DPTE/DFAR.50/50	A315138401	A325399601
A400007262	DPTE/DFAR.50/50	A315190301	A325300901
A400007263	5 GRASSES MIX	A315466901	A325440801
A400007264	5 GRASSES MIX	A315849301	A325724401
A400007265	12 GRASSES MIX	A315229101	A325713901
A400007266	12 GRASSES MIX	A316230401	A324831401

Product code	Product name/description	Batch no. start	Batch no. end
A400007267	D.PTERONYSSINUS	A315184501	A325291901
A400007271	5 GRASSES MIX	A315248101	A325646501
A400007273	DPTE/DFAR.50/50	A318947501	A323020801
A400007275	D.PTERONYSSINUS	A316480601	A324822401
A400007280	DPTE/DFAR.50/50	A322045101	
A400007281	CUPRESSACEAE	A317548601	A317548801
A400007287	D.PTERONYSSINUS	A317343401	A317343501
A400007939	DPTE/DFAR.50/50	A316179601	A323749001
A400008215	3 GRASSES MIX	A316999601	
A400008216	5 GRASSES MIX	A319237901	
A400008383	BIRCH	A317948001	
A400008686	3 GRASSES MIX	A320570001	
A400008728	3 GRASSES MIX	A325357201	
A400009060	D.PTERONYSSINUS	A321881001	
A400009114	D.PTERONYSSINUS	A324066401	
A400009115	5 GRASSES MIX	A323998001	
A400009459	3 GRASSES MIX	A323478901	A324040701

Phostal:

- Product name/description - *D.Pteronyssinus*
- Lot numbers - 2000277946 and 2000577822

Information for consumers

Health professionals who have prescribed/delivered Staloral or Phostal from one of the affected batches will contact those patients and provide further information about this issue. In some cases, Stallergenes Australia will contact patients directly.

If you or someone you care for is taking Staloral or Phostal from an affected batch (see product codes and lot numbers in the section above), stop using it and return it to the doctor or pharmacy where you obtained it as soon as possible. Refunds will be provided for all returned medicine from the affected batches.

If you have any questions or concerns about this issue, speak to your health professional. Alternatively, you can call Stallergenes Australia on 1800 635 306.

Information for health professionals

Stallergenes Australia has contacted health professionals who have prescribed/delivered Staloral or Phostal from the affected batches providing further information about this issue, including details regarding the recall process.

If you have prescribed Staloral or Phostal from one of the affected batches, contact those patients and advise them of this issue. Instruct them to stop taking the medicine and to return any unused product to you or to the pharmacy where they obtained it as soon as possible.

If you have any questions or concerns about this issue, contact Stallergenes Australia on 1800 500 499 (prescriber-only number).

Reporting problems

Consumers and health professionals are encouraged to [report problems with medicines or vaccines](https://www.tga.gov.au/reporting-problems) ([/www.tga.gov.au/reporting-problems](https://www.tga.gov.au/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.

Category: Alert/Advisory, Medicines safety

Tags: recalls, immunological medicines

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