



Pfizer Australia Pty Ltd
ABN: 50 008 422 348
38 - 42 Wharf Road
West Ryde NSW 2114
Australia

5 December 2016

Dear Chief Pharmacist,

URGENT RECALL FOR PRODUCT CORRECTION

Re: DILANTIN (phenytoin sodium) 30 mg capsule bottle - AUST R 14306
(Pfizer product code: PF_03070003)
DILANTIN (phenytoin sodium) 100 mg capsule bottle - AUST R 14305
(Pfizer product code: PF_03070010)
DILANTIN (phenytoin) INFATABS 50 mg tablet bottle - AUST R 14308
(Pfizer product code: PF_03070205)

Cap with Child Resistant Closure mechanism potentially not engaged/secured on some bottles

In consultation with the Therapeutic Goods Administration (TGA), Pfizer Australia would like to inform you of the following important safety information for Dilantin capsules and tablets:

The Child Resistant Closure of the Dilantin capsule and tablet bottles listed above may not be engaged/secured. We request that you confirm that the Child Resistant Closure is engaged/secured and hand tighten the cap, as needed, before dispensing to patients.

Any bottle where the Child Resistant Closure cannot be engaged/secured after hand tightening the cap should NOT be dispensed.

Pfizer requests that you attempt to communicate to patients who may have been dispensed Dilantin by sending them the attached Patient Communication Letter (attachment 1) to inform them of the importance of securing the Child Resistance Closure.

In the event that patients cannot engage/secure the Child Resistant Closure, they should return the bottle to their pharmacy.

A list of the affected Dilantin lots in distribution in Australia is attached (attachment 2). The list includes the date each affected lot was first released in Australia.

Please return any affected bottles to the wholesalers you purchased from for credit.

If purchased directly from Pfizer please contact us on 1800 629 921.

We also wish to inform you, that any **DILANTIN (phenytoin sodium) 30 mg capsule bottle, DILANTIN (phenytoin sodium) 100 mg capsule bottle** or **DILANTIN (phenytoin) INFATABS 50 mg tablet bottle** released on or after **28 November 2016**, are not affected by the above recall for correction.

Dilantin capsules and tablets should always be kept in a location that is inaccessible to children in order to limit the risk of accidental ingestion.

If a child accidentally ingests Dilantin tablets or capsules, contact the Poisons Information Centre on 13 11 26.

Call for reporting Adverse Events:

Suspected adverse drug reactions (ADRs) should be reported to Pfizer Medical Information on 1800 675 229, or by email medicalaffairs.anz@pfizer.com. When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates.

Pfizer apologises for the inconvenience caused to pharmacists and your patients and appreciates your cooperation in this matter.

If you require any additional information or wish to discuss this further, please contact Pfizer Medical Information on 1800 675 229.

Yours sincerely,



Dr. Charanjeet Singh, MB.BS
Medical Advisor
Pfizer Australia / New Zealand
www.pfizer.com.au

Attachment 1 – Pfizer Patient Communication Letter

Attachment 2 – Pfizer Dilantin Affected Batches



Pfizer Australia Pty Ltd
ABN: 50 008 422 348
38 - 42 Wharf Road
West Ryde NSW 2114
Australia

Urgent Recall for Product Correction

5 December 2016

Dear Sir/Madam,

It has come to our attention that the child resistant feature on the cap of some Pfizer Dilantin bottles may not be secured, creating a potential risk that the cap could be opened by a child.

You are receiving this communication from your pharmacist because you have been dispensed Pfizer Dilantin tablets or capsules. Please check your bottle to ensure that the cap is fully tightened and that the child resistant feature is secured. If the cap is secured you do not need to do anything further. If you are unable to secure the child resistant cap even after further tightening (cap comes off without application of downward pressure) or if you are unsure, please return the product to the pharmacy.

In any case, even if the child lock engages it is advised that the bottle be kept out of sight and reach of children.

If a child accidentally ingests Dilantin tablets or capsules, contact the Poisons Information Centre on 13 11 26.

We apologise for this inconvenience and appreciate your cooperation in this matter.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Dr. Charanjeet Singh".

Dr. Charanjeet Singh, MB.BS
Medical Advisor
Pfizer Australia / New Zealand
www.pfizer.com.au

Attachment : Dilantin Inventory (100mg , 50mg and 30mg) - Australia

Market	Product	Lot #	Manufacturing Date	First Batch Released Date	Expiry Date	Shelf life	Quantity released
Australia	Dilantin Capsule 100mg	161424471	5/09/2016	20/09/2016	5/03/2018	18	6350
Australia	Dilantin Capsule 100mg	161424461	29/08/2016	20/09/2016	28/02/2018	18	6100
Australia	Dilantin Capsule 100mg	161424431	16/08/2016	31/08/2016	16/02/2018	18	6350
Australia	Dilantin Capsule 100mg	161424401	11/08/2016	25/08/2016	11/02/2018	18	5970
Australia	Dilantin Capsule 100mg	161424371	13/07/2016	9/08/2016	13/01/2018	18	4320
Australia	Dilantin Capsule 100mg	161424341	11/07/2016	1/08/2016	11/01/2018	18	4320
Australia	Dilantin Capsule 100mg	161424331	2/07/2016	22/07/2016	2/01/2018	18	6310
Australia	Dilantin Capsule 100mg	161424241	31/03/2016	17/05/2016	30/09/2017	18	6250
Australia	Dilantin Capsule 100mg	161424201	09/03/2016	4/04/2016	9/09/2017	18	8257
Australia	Dilantin Capsule 100mg	161424191	7/03/2016	5/04/2016	7/09/2017	18	9324
Australia	Dilantin Capsule 100mg	161424151	24/02/2016	15/03/2016	24/08/2017	18	4320
Australia	Dilantin Capsule 100mg	161424141	18/02/2016	14/03/2016	18/08/2017	18	6310
Australia	Dilantin Capsule 100mg	161424101	25/01/2016	17/02/2016	25/07/2017	18	6080
Australia	Dilantin Capsule 100mg	161424071	7/01/2016	29/01/2016	7/07/2017	18	6110
Australia	Dilantin Capsule 100mg	161424011	7/12/2015	18/12/2015	7/06/2017	18	6300
Australia	Dilantin Capsule 100mg	151424581	30/09/2015	21/12/2015	30/03/2017	18	4320
Australia	Dilantin Capsule 100mg	15142453R1	31/08/2015	27/10/2015	28/02/2017	18	6220
Australia	Dilantin Capsule 100mg	151424521	27/08/2015	22/09/2015	27/02/2017	18	6280
Australia	Dilantin Capsule 100mg	15142451R1	25/08/2015	28/09/2015	25/02/2017	18	6220
Australia	Dilantin Capsule 100mg	15142445R1	4/08/2015	16/09/2015	4/02/2017	18	6200

Market	Product	Lot #	Manufacturing Date	First Batch Released Date	Expiry Date	Shelf life	Quantity released
Australia	Dilantin Capsule 100mg	15142443R1	27/07/2015	15/09/2015	27/01/2017	18	5890
Australia	Dilantin Capsule 100mg	15142446R1	4/08/2015	10/09/2015	4/02/2017	18	6190
Australia	Dilantin Capsule 100mg	151424351	15/06/2015	14/07/2015	15/12/2016	18	6357
Australia	Dilantin Capsule 100mg	151424401	7/07/2015	4/08/2015	7/01/2017	18	4320
Australia	Dilantin Capsule 100mg	151424381	25/06/2015	22/07/2015	25/12/2016	18	4320
Australia	Dilantin Capsule 100mg	15142428R1	1/06/2015	3/07/2015	1/12/2016	18	6398
Australia	Dilantin Capsule 100mg	151424083	4/02/2015	27/02/2015	4/02/2017	24	6275
Australia	Dilantin Capsule 100mg	151424051	14/01/2015	16/02/2015	14/01/2018	36	4320
Australia	Dilantin Capsule 100mg	141424362	2/12/2014	23/12/2014	2/12/2017	36	6360
Australia	Dilantin Capsule 100mg	141424203	21/05/2014	25/08/2014	21/05/2017	36	14040
Australia	Dilantin Capsule 100mg	141424082	26/02/2014	12/06/2014	26/02/2017	36	12960
Australia	Dilantin Capsule 100mg	141424051	31/01/2014	11/04/2014	31/01/2017	36	12960
Australia	Dilantin Capsule 100mg	141424031	13/01/2014	16/04/2014	13/01/2017	36	12523
Australia	Dilantin Capsule 100mg	131424601	12/11/2013	18/02/2014	12/11/2016	36	12960
Australia	Dilantin Capsules 30mg	161424292	30/04/2016	7/06/2016	30/04/2019	36	6730
Australia	Dilantin Capsules 30mg	161424262	4/04/2016	12/05/2016	4/04/2019	36	4320
Australia	Dilantin Capsules 30mg	151424664	30/11/2015	13/01/2016	30/11/2018	36	3580
Australia	Dilantin Capsules 30mg	151424373	22/06/2015	13/10/2015	22/06/2018	36	3740
Australia	Dilantin Capsules 30mg	151424273	18/05/2015	22/07/2015	18/05/2018	36	2663
Australia	Dilantin Capsules 30mg	151424261	18/05/2015	2/06/2015	18/05/2018	36	4012

Market	Product	Lot #	Manufacturing Date	First Batch Released Date	Expiry Date	Shelf life	Quantity released
Australia	Dilantin Capsules 30mg	151424121	12/02/2015	13/04/2015	12/02/2018	36	3917
Australia	Dilantin Capsules 30mg	141424403	12/11/2014	20/01/2015	12/11/2017	36	824
Australia	Dilantin Capsules 30mg	141424281	22/09/2014	3/11/2014	22/09/2017	36	4860
Australia	Dilantin Capsules 30mg	141424271	19/09/2014	3/10/2014	19/09/2017	36	4040
Australia	Dilantin Infatabs 50mg	161424421	7/07/2016	26/07/2016	7/07/2019	36	2270
Australia	Dilantin Infatabs 50mg	161424041	3/12/2015	12/01/2016	3/12/2018	36	1770
Australia	Dilantin Infatabs 50mg	151424321	3/07/2015	27/08/2015	3/07/2018	36	2260
Australia	Dilantin Infatabs 50mg	151424211	20/04/2015	20/04/2015	20/04/2018	36	1933
Australia	Dilantin Infatabs 50mg	141424381	21/10/2014	15/12/2014	21/10/2017	36	2220