



Pacific
Pharmaceuticals Ltd

Approved MS 8/11/02

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11th November 2002

To Pharmacies and Wholesalers

MEDICINE RECALL
Felo ER Tablets 2.5mg, 5 mg and 10 mg – All Batches

In consultation with Medsafe, Pacific Pharmaceuticals Ltd is recalling all batches of Felo ER tablets (2.5mg, 5mg and 10 mg) to patient level.

Problem:

The decision to institute a patient recall follows Medsafe's assessment of new information. It is now not currently possible to determine the quality, accuracy and validity of the testing methods used in the Swiss bioequivalence studies supplied to demonstrate the effectiveness of Felo ER. This product is manufactured in Europe for Swiss generic company Siegfried Ltd. Medsafe believes information provided by the German regulatory authority indicates that the quality systems utilised by the Swiss company that performed the bioequivalence studies for Felo ER, failed to control aspects of the studies used to demonstrate the effectiveness of Felo ER. These quality system failures occurred in clinically crucial areas and are of such a nature that the Felo ER bioequivalence studies cannot be regarded as accurate and must be discarded. Without these studies there is no compelling evidence for the effectiveness of Felo ER, and Medsafe can no longer be satisfied as to whether Felo ER offers the same degree of protection from the complications of hypertension and angina as other brands of felodipine.

Action:

- Please immediately quarantine all stock of Felo ER Tablets 2.5mg, 5 mg and 10 mg.
- Please complete and return the attached Acknowledgement Form in the Medi Media reply paid envelope. Return this form even if you do not have Felo ER Tablets in stock.
- Return all stock by courier to the following address:

"Recalled Stock"
Pacific Pharmaceuticals Ltd,
76 Leonard Road,
Mt Wellington,
Auckland.

Please call NZ Couriers at 0800 800 841 and quote Pacific Pharmaceuticals Ltd number 2275730.

Please include a completed Acknowledgement Form with any returned stock.

- Pacific Pharmaceuticals Ltd will credit all wholesalers and pharmacies for returned stock.
- Pharmacists to please destroy all Felo ER returned to you by your customers.

Advice for Patients

To minimise the risk to patients who are currently taking Felo ER, the key patient messages are:

1. Patients should not suddenly stop taking their Felo ER medication, as prolonged periods off all treatment represents a higher health risk to patients than continuing on Felo ER.
2. Advise customers who present prescriptions for Felo ER or requests for repeats that they should visit their GP for a new prescription. Patients should see their GP as soon as is practical and certainly before their current pack of Felo ER runs out. Medsafe advises that there are acceptable levels of alternative medicines available (including a replacement brand of felodipine).
3. Pacific Pharmaceuticals Ltd will reimburse GPs for the first patient visit relating to this recall of Felo ER, within 30 days from the date of this letter.
4. PHARMAC confirms that Plendil ER will be fully subsidised as of 11th November, 2002.
5. Please use the enclosed Questions and Answers sheet to discuss the issue with customers or as handouts for them. Pacific Pharmaceuticals Ltd has set up a patient hotline on freephone: 0800 18 18 16 for any enquiries.

Background Information

GPs and Specialists have been advised that care is necessary where a patient has had their dose of Felo ER changed to control their hypertension or angina and a decision is made to transfer the patient to the replacement brand of felodipine.

Pacific Pharmaceuticals Ltd will be advertising this recall in major newspapers on 14th November 2002.

Yours sincerely,



Jenny Roodt
Recall Co-ordinator
Pacific Pharmaceutical Ltd

ACKNOWLEDGEMENT FORM FOR MEDICINE RECALL

FELO ER TABLETS (2.5mg, 5mg and 10 mg)

ALL BATCHES

- 1. Please complete this acknowledgment form** as soon as possible and return it in the prepaid MediMedia (NZ) Limited addressed envelope, **even if no stocks of Felo ER Tablets are held.**

- 2. Please Return All Stock For Credit To Pacific Pharmaceuticals Ltd,**
*76 Leonard Road,
Mt Wellington,
Auckland.*

Call NZ Couriers 0800 800 841 and quote Pacific Pharmaceuticals Ltd number 2275730

- 3. Number of cartons of this product that will be returned:**

Felo ER Tablets 2.5mg _____

Felo ER Tablets 5mg _____

Felo ER Tablets 10mg _____

I confirm that the above details are correct.

Name: _____ Signature: _____

Position: _____ Date: _____

Customer name, address and contact details:

REMEMBER: PLEASE RETURN THIS FORM IN THE PREPAID ADDRESSED ENVELOPE PROVIDED AND ENCLOSE A COPY WITH THE RETURNED STOCK