



Pacific
Pharmaceuticals Ltd

PO Box 11183 Ellerslie
76 Leonard Rd, Mt Wellington
Auckland, New Zealand
Telephone 0-9-579 2792
Facsimile 0-9-579 7072

Medicine Recall of Felo ER Tablets 2.5mg, 5mg and 10mg

Q: Why are Felo ER tablets being recalled?

A: Medsafe, a division of the Ministry of Health, has recommended that the distributor Pacific Pharmaceuticals Ltd recall Felo ER as new data reviewed by Medsafe has raised questions about whether Felo ER is as effective in lowering blood pressure and preventing angina attacks as other brands of felodipine. This recall does not apply to other types of medicines used to treat high blood pressure and angina, or other brands of felodipine (the active ingredient of Felo ER).

Medsafe's recommendation is based on new evidence demonstrating that the European studies used to prove Felo ER is as effective as the other brand of felodipine available in New Zealand are of such quality that they cannot now be trusted. To answer these concerns Swiss-based Siegfried Ltd (the manufacturer) have ordered new studies to be conducted.

Q: What should I do if I am on this medicine?

A: If you are currently taking Felo ER you should:

- Continue taking your medicines, including Felo ER, until you can see your doctor. In the short term the risks of being completely off treatment for your hypertension and angina are higher than continuing on Felo ER.
- Make an appointment to see your doctor as soon as is practical and before your current pack of Felo ER runs out.

Q: Should I see my Doctor about this?

A: Yes, you need to see your doctor to allow him (or her) to assess your treatment plan and provide you with a new prescription. During this consultation your doctor will transfer you to another treatment that is right for you. This may mean that your doctor either changes the type of medicine you take for your blood pressure or angina, or if you are placed on an alternative brand of felodipine, alters the dose that you take.

Q: Is another brand of felodipine available?

A: Medsafe advises that an alternative brand of felodipine called Plendil ER is available if you and your doctor decide that it is best for you to continue taking felodipine.

Q: Will I have to pay anything?

A: Pacific Pharmaceuticals Ltd will pay the cost of one GP visit to allow you to get a new prescription, provided you visit your doctor within the next 30 days. You will be asked to fill out a patient disclosure form when you visit your doctor, to enable your doctor to claim the consultation fee.

You will, however, have to pay the costs of getting the medicine from the pharmacy. Depending on whether you have a community services card, or not, this will cost either \$3 or \$15.

Q: If I cannot reach my doctor, or want further information, who can I talk to about this?

A: Pacific Pharmaceuticals Ltd have set up a free phone number. You should ring 0800 18 18 16 for additional information.

Q: What should I do with my unused tablets?

A: When you take your replacement prescription to the pharmacist, please return all your unused Felo ER tablets.

**Prepared by: Pacific Pharmaceuticals Ltd, Private Bag 11914, Ellerslie,
Auckland in consultation with Medsafe, Ministry of Health.
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