Media Release: Sydney, Australia. 20 November 2012

PHEBRA WELCOMES PBS LISTING OF NAPROXEN SUSPENSION

The Australian pharmaceutical company, Phebra, today welcomed the Federal Government's decision to approve Naproxen Suspension for reimbursement through the Pharmaceutical Benefits Scheme (PBS).

Naproxen Suspension is manufactured in Australia for patients who cannot take a solid dose form of a non-steroidal anti-inflammatory agent. Naproxen Suspension is available as 125mg/5mL strength, which is equivalent to 25 mg/mL strength, in a bottle containing 474mL.

Naproxen Suspension is indicated for the treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis; for the symptomatic treatment of primary dysmenorrhoea; for the relief of acute and/or chronic pain states in which there is an inflammatory component and as an analgesic in acute migraine attack.

Phebra's Chief Executive Officer, Dr Mal Eutick, said today: "We welcome the decision to make Naproxen Suspension available on the PBS, given its importance as an effective pain relief medication, particularly in younger patients."

Phebra was granted marketing approval for Naproxen Suspension by the Therapeutic Goods Administration (TGA) in September this year, replacing the previously available Naprosyn® oral suspension.

About Phebra

Phebra Pty Ltd is an Australian based speciality pharmaceutical company that develops and markets critical medicines in Australia, New Zealand, Asia, Canada and parts of Europe. For more information about Phebra please refer to the company website at www.phebra.com

At Phebra, we create critical medicines that save and improve lives.

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PBS Information: Restricted Benefit: Refer to PBS schedule for full information AND Authority required (STREAMLINED). Refer to PBS Schedule for full authority information

PLEASE REVIEW FULL PRODUCT INFORMATION BEFORE PRESCRIBING.

PRODUCT INFORMATION AVAILABLE AT WWW.PHEBRA.COM

Minimum Product Information. Naproxen Suspension (25 mg/mL). Indications: Treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis; primary dysmenorrhoea; relief of acute and/or chronic pain with an inflammatory component; acute migraine attack. **Contraindications**: Hypersensitivity to naproxen or naproxen sodium, aspirin or NSAIDs; NSAID related gastrointestinal ulcer, bleed, perforation (or history); peptic ulcer, haemorrhage (or history); chronic dyspepsia or history; severe heart failure; children < 2 yrs. **Precautions**: CV disease or risk factors; hypertension (monitor blood pressure); heart failure; fluid retention and oedema; GI discomfort, history of inflammatory bowel disease or patients with GI risk factors (e.g. elderly, debility, history of serious GI events, smoking, alcoholism); renal impairment, should not be given if creatinine clearance is < 30 mL/min; hypovolaemia; hepatic impairment; coagulation disorders; infection; sodium restricted diet. Use in Pregnancy: Category C, only administer if the benefit justifies the potential risk. Use in Lactation: not recommended. Use in Children: not recommended in children under 5 years of age. **Drug Interactions**: NSAIDs; warfarin; anticoagulants or antiplatelet agents; SSRI's; steroids; probenecid; methotrexate; beta-blockers; diuretics; lithium; sodium bicarbonate, zidovudine; ACE-inhibitors. **Adverse Effects**: Constipation, heartburn, abdominal pain, nausea, dyspepsia, diarrhoea, stomatitis, headache, dizziness, drowsiness, light headedness, vertigo, itching, skin eruption, ecchymoses, sweating, purpura, tinnitus, oedema, dyspnoea, palpitations, hearing disturbances, visual disturbances, thirst. May cause jaundice or fatal hepatitis, elevations of ALT or AST, severe skin reactions, oedema, bleeding, anaphylactic reactions. **Dosage and Administration:** Should be taken with food. Use lowest effective dose for shortest possible duration. Chronic pain (rheumatoid arthritis, osteoarthritis, ankylosing spondylitis): initially ≥ 500 mg/day in two divided doses; maintenance: 375-1000 mg/day in two divided doses; Acute pain states, dysmenorrhoea: initially 500 mg; then 250 mg every 6-8 hours as necessary; Acute migraine: 750 mg at first symptom; then 250-500 mg as necessary (≥ 1 hour after initial dose); Maximum 1250 mg/day. Juvenile RA (children > 5 yrs): 5 mg/kg twice daily. **Presentation**: Naproxen Suspension containing naproxen 25 mg in 1 mL is available as a pineapple-orange flavoured aqueous suspension in bottles of 474 mL.

Poisons Schedule: Schedule 4. Date of TGA Approval 25th September 2012.

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