

In Brief

A digest of news items about NPS RADAR, new drugs and changes to PBS listings.

Hydromorphone prolonged-release tablets (Jurnista) for chronic severe disabling pain

Hydromorphone prolonged release (Jurnista), a once-daily long-acting opioid, was listed on the Pharmaceutical Benefits Scheme (PBS) on 1 May 2009. It is available as a restricted benefit for chronic severe disabling cancer or non-cancer pain not responding to non-opioid analgesics. Other oral formulations of hydromorphone available on the PBS are immediate-release tablets and oral liquid (both with the brand name Dilaudid).

A maximum quantity of 10 hydromorphone prolonged-release tablets can be supplied under the PBS, with an authority required for supply of increased maximum quantities and/or repeats.

The Pharmaceutical Benefits Advisory Committee (PBAC) recommended listing on the basis of cost minimisation compared with oxycodone controlled-release tablets (that is, no less effective and at a similar price).¹

Hydromorphone prolonged-release tablets are an option for chronic severe pain not responding to non-opioid analgesics. In the absence of adequate, published head-to-head trials there is no evidence that hydromorphone is more effective than equivalent doses of other modified-release opioids with established clinical experience.

The risk of toxicity is high

Hydromorphone is a strong opioid that is approximately 5 times more potent than morphine.² The once-daily tablets are available in 8 mg, 16 mg, 32 mg and 64 mg strengths. The 32 mg and 64 mg tablets equate to about 160 mg and 320 mg oral morphine respectively and so would be suitable only for patients who are highly opioid tolerant. Prescribers are reminded of the risks of toxicity with inappropriate use or accidental overdose.

Opioid-naïve patients should start treatment with an immediate-release preparation, titrating upwards until an adequate level of analgesia is achieved, before converting to the appropriate total daily dose of hydromorphone prolonged-release tablets.³

If switching to hydromorphone from another opioid, switch to between one-third and one-half of the equianalgesic total daily dose of hydromorphone prolonged-release tablets to allow for incomplete cross-tolerance.^{3,4}

Provide patients and carers with clear instructions on how to take hydromorphone prolonged-release tablets

Advise patients and carers that hydromorphone prolonged-release tablets²:

- should only be taken **once daily**, at or around the same time each day
- must be swallowed whole; do not crush or chew hydromorphone prolonged-release tablets, as this can cause absorption of a large dose over a short time
- may cause adverse effects, including constipation, nausea, vomiting, sedation, somnolence, dizziness, headache, sweating, mood swings, dry mouth and pruritus
- can increase the risk of adverse effects, including sedation and potentially fatal respiratory depression if taken incorrectly or more often than prescribed
- have a non-dissolvable outer coating that may be visible in the patient's stool.

Avoid concomitant use with other CNS depressants, including alcohol

As with any slow-release opioid, concomitant use of hydromorphone prolonged-release tablets with other central nervous system depressants (e.g. other opioids, sedatives or alcohol) can increase the risk of adverse effects, including sedation, hypotension, respiratory depression and coma.^{2,3}

Intentional misuse may cause serious toxicity

Hydromorphone is a potential drug of abuse. The excipients in hydromorphone prolonged-release tablets may cause fatal complications when crushed and injected. In animals intravenous administration caused anaemia, damage to myocardial and renal tubular cells and death.²

Ensure a genuine medical need for hydromorphone. If in doubt, consider seeking management advice from a drug and alcohol specialist advisory service. Referring the patient to a drug and alcohol service (see www.ancd.org.au/links/aod-information/) is usually appropriate.

Be aware of common drug-seeking behaviours related to hydromorphone prolonged-release tablets, such as requests for injectable opioids or opioids in more than one form (injectable and oral), or being asked for hydromorphone by name.⁵

If you suspect that a patient is obtaining multiple PBS prescriptions for hydromorphone ('doctor-shopping') consider contacting Medicare Australia's Prescription Shopping Information Service for more information.^{3,6}

References

1. Australian Government Department of Health and Ageing. Positive Recommendations made by the PBAC — November 2008. <http://www.health.gov.au/internet/main/publishing.nsf/Content/pbacrec-nov08-positive> (accessed 6 April 2009).
2. JANSSEN-CILAG Pty Ltd. Jurnista prolonged-release tablets product information. 23 July 2008.
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4. Australian Medicines Handbook 2009.
5. NSW Therapeutic Assessment Group Inc. Prescribing guidelines for primary care clinicians: Rational use of opioids in chronic or recurrent non-malignant pain. 2002. <http://www.ciap.health.nsw.gov.au/nswtag/guidelines.html> (accessed 6 April 2009).
6. Australian Government Medicare Australia. Prescription Shopping Program. <http://www.medicareaustralia.gov.au/provider/pbs/prescription-shopping/index.jsp> (accessed 6 April 2009).

Oxybutynin patch (Oxytrol) PBS listed as an alternative for overactive bladder

Oxybutynin transdermal patches (Oxytrol) were PBS listed as a restricted benefit on 1 August 2009. Each patch is applied twice weekly and releases approximately 3.9 mg of oxybutynin per 24 hours.¹

The PBAC recommended the listing of oxybutynin patches on the basis of acceptable cost-effectiveness compared with placebo.² The listing is restricted to patients with detrusor overactivity who cannot tolerate or swallow oral oxybutynin.² There is no evidence to suggest that transdermal oxybutynin has an efficacy advantage over oral oxybutynin.³

Oxybutynin patches may cause less anticholinergic side effects, but skin reactions are common and may be intolerable for some people

Anticholinergic side effects such as dry mouth and constipation are less likely with transdermal oxybutynin than with the oral formulation.³ Application-site reactions occur in at least 10% of patients, and include redness, rash, itching, macule or vesicle formation.^{1,3,4} Such reactions are usually transient and mild in severity, but were the most common reason for stopping the patches in trials.^{1,3}

Information for patients about proper use and disposal of patches

Instruct patients to apply one patch twice a week (every 3-4 days).¹ To help minimise skin reactions, a new application site should be used for each new patch, avoiding the same site for at least 7 days after patch removal.¹

Advise patients to discard used patches safely by disposal in household refuse that is out of reach of children, pets or others.¹ Folding a patch in half so that the adhesive layers evenly stick together can also help to prevent accidental application.

References

1. Hospira Australia Pty Ltd. Oxytrol product information. 9 May 2008.
2. Australian Government Department of Health and Ageing. March 2009 PBAC Outcomes — Positive Recommendations. [http://www.health.gov.au/internet/main/publishing.nsf/Content/EE62734C748A1C12CA25759E0014357F/\\$File/PBACOutcomesMarch2009-Positiverecommendations.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/EE62734C748A1C12CA25759E0014357F/$File/PBACOutcomesMarch2009-Positiverecommendations.pdf) (accessed 25 May 2009).
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Praziquantel (Biltricide) tablets PBS listed for schistosomiasis

Praziquantel tablets (600mg) have been listed as an authority-required (streamlined) benefit on the PBS as of 1 August 2009. In the light of government initiatives to address the health care needs of refugees, the PBAC recommended listing for the treatment of schistosomiasis (bilharzia) on the basis of acceptable cost-effectiveness.¹

Schistosomiasis is caused by parasitic worms inhabiting the gastrointestinal or renal tract

Larvae released into fresh water by infested snails penetrate the skin of people coming into contact with the contaminated water. Even brief exposure can lead to infestation. After entering the body, the adult worms live in blood vessels and the females release eggs. Some eggs are passed out of the body in the urine or faeces but others become trapped in body tissues, causing an immune reaction.² Adult worms can live for decades in the body.^{2,3}

Schistosomiasis is often asymptomatic

Schistosomiasis is often asymptomatic. A pruritic rash may develop soon after the larvae penetrate the skin.

In the following months an individual may develop Katayama fever (sudden fever, fatigue, myalgia, malaise, cough, weight loss, eosinophilia, abdominal pain, diarrhoea and haematuria).^{2,4} Katayama fever is more common in travellers; it is rare among those living in endemic areas.²

Chronic untreated schistosomiasis progressively damages the bladder, ureters and intestines as well as causing enlargement of the liver and spleen. It may eventually lead to kidney failure or bladder cancer.^{2,3,5}

Schistosomiasis is endemic in Africa and parts of south-east Asia

Schistosomiasis occurs throughout tropical and subtropical regions (Table 1) but the greatest burden of illness is in Africa.³ Up to 41% of recently arrived African refugees have positive serology for schistosomiasis.³

Table 1: Areas of endemic schistosomiasis^{6,7}

Region	Endemic areas	Schistosome species
Africa	Throughout Africa: highest risk in southern and sub-Saharan Africa	<i>S. haematobium</i> <i>S. mansoni</i> <i>S. intercalatum</i>
Asia	Cambodia, Laos, Philippines, Southern China	<i>S. japonicum</i> <i>S. mekongi</i>
Middle East	Egypt, Iran, Iraq, Oman, Saudi Arabia, Yemen	<i>S. haematobium</i> <i>S. mansoni</i>
South America & Caribbean	Brazil, Dominican Republic, Suriname, Venezuela	<i>S. mansoni</i>

Diagnosis of schistosomiasis

The diagnostic 'gold standard' for schistosomiasis is the examination of the faeces or urine for eggs. However, this may require multiple samples and on its own may not detect a light-to-moderate worm burden. For this reason, diagnosis often relies on serology.³

Positive serology does not distinguish between current and past infection. However, most new arrivals to Australia with positive serology are probably infected, as the worms can survive for decades and individuals in endemic areas are repeatedly infected.³

For travellers returning from endemic regions, a positive antibody response will only be detected more than 6 weeks after initial infection.⁸

In people with equivocal serology the specimen should be re-tested using a different serological method.³ If the result remains equivocal, treat the individual as if it was positive.

Treat with 2 doses of praziquantel 4 hours apart

Current Australian guidelines recommend 2 doses of praziquantel 4 hours apart in people with positive serology. For people infected anywhere except south-east Asia, each dose should be praziquantel 20 mg/kg.^{3,9} This dosage regimen has been shown in systematic reviews to be effective and well tolerated.³ For people infected in south-east Asia, each dose should be praziquantel 30 mg/kg.³

Each dose should be taken after food. The tablets can be broken into four pieces to ensure accurate dosing but should not be chewed because of their bitter taste.^{10,11}

The praziquantel product information recommends an alternative dosage regimen of 3 doses of praziquantel, 20 mg/kg, 4 hours apart.¹¹ This dosage regimen is the same irrespective of country of infection.

Praziquantel is available as 600 mg tablets, with a maximum of 8 tablets. This will be sufficient for most individuals. However, if prescribing for a person infected in south-east Asia who weighs ≥ 80 kg, you will need to request an increase in the maximum quantity.*

Praziquantel is only active against adult worms.^{2,8} In recently infected people, who are likely to have immature worms, a second round of treatment with praziquantel several weeks later may be necessary.⁸

Check for eggs in all people with positive serology

In addition to treatment with praziquantel, all people with positive (or equivocal) serology should be examined for eggs to identify those with a high worm burden.³

If eggs are present in the faeces, check for indicators of end-organ damage[†] and refer to a specialist if necessary. Repeat the faecal examination in 3 months and prescribe another dose of praziquantel if eggs are still present.³

* If using the 3-dose regimen specified by the product information, any individual who weighs ≥ 80 kg will require an increase to the maximum quantity.

† History of chronic liver disease, gastrointestinal haemorrhage, hepatomegaly, splenomegaly, ascites, positive hepatitis B or C serology, thrombocytopenia, low albumin or raised liver enzyme concentration.

Perform a urinalysis to check for blood and, if positive, request urine microscopy to check for eggs. If eggs are present in the urine check for a history of recurrent urinary tract infections, evidence of genital lesions or hydronephrosis, and perform a renal ultrasound. Refer to a urologist if necessary. Repeat the urine examination in 3 months and prescribe another dose of praziquantel if eggs are still present.³

If there are no eggs but the individual has eosinophilia, perform a full blood count after 3 months and investigate further if eosinophilia is still present.³

Adverse effects are mainly caused by dying worms

Common adverse effects with praziquantel include dizziness, headache, malaise, drowsiness, nausea, vomiting, abdominal pain and diarrhoea.^{2,3,10} Many are thought to be caused by immune responses to the dying worms.^{3,10} Symptoms are usually mild and transient. However, there have been occasional reports of acute colic with bloody diarrhoea in heavy infections.^{2,12,13}

There is limited information on use of praziquantel in pregnant and lactating women.^{3,10} In endemic areas the WHO advises that the health advantages of treating pregnant women outweigh the risks to their health and to the health of their babies.¹⁴ Withhold treatment during the first trimester but offer it in the second or third trimester or during lactation, after discussing its risks and benefits with the patient.^{3,10}

The federal government provides assistance for refugee health assessments

Medicare Benefits Schedule (MBS) item numbers 714 and 716 reimburse general practitioners who perform refugee and humanitarian entrant health assessments within 12 months of the patient's arrival in Australia.

Refugee health assessments should always be undertaken with an appropriate interpreter, preferably someone who is not known to the patient personally.³ The Telephone Interpreting Service (TIS) is available free of charge to general practitioners who provide a Medicare service to non-English speaking permanent residents or Australian citizens. Call the TIS Doctors' Priority Line (1300 131 450) to access this service.¹⁵

References

1. Pharmaceutical Benefits Advisory Committee. Positive Recommendations made by the PBAC — March 2009. Canberra: Australian Government Department of Health and Ageing, 2009. <http://www.health.gov.au/internet/main/publishing.nsf/Content/pbacrec-mar09-positive> (accessed 26 May 2009).
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3. Australasian Society for Infectious Diseases Refugee Health Guidelines Writing Group. Diagnosis, management and prevention of infections in recently arrived refugees. Sydney: Australasian Society for Infectious Diseases, 2009.
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Update on PBS listings for Aboriginal and Torres Strait Islander peoples

Since August 2006 a number of medicines have been listed on the PBS specifically for people who identify as Aboriginal or Torres Strait Islander. The PBAC recommended these authority-required listings to improve the capacity of the PBS to meet the particular healthcare needs of these people. Most are streamlined authority listings.

Box 1 lists the medicines currently subsidised on the PBS for treating common conditions in Aboriginal and Torres Strait Islander peoples.

To keep up to date with future listings, go to the health professionals' site at www.pbs.gov.au, click on 'PBS publications' and scroll to the 'PBS listings for Aboriginal and Torres Strait Islander people' fact sheet.

Box 1: Authority-required PBS listings* for Aboriginal and Torres Strait Islander peoples (as at 1 July 2009)

Treating condition	Subsidised medicine
Fungal or yeast infection	Bifonazole cream, 1% Clotrimazole cream, 1% Ketoconazole cream, 1%; shampoo, 2% Miconazole nitrate cream, powder, lotion, 2% Miconazole tincture, 2% Nystatin cream, 100 000 units per gram Terbinafine hydrochloride cream, 1%
Thiamine deficiency (prophylaxis)	Thiamine hydrochloride tablet, 100 mg
Whipworm infestation	Albendazole tablet, 200 mg
Chronic suppurative otitis media (age ≥ 1 month)	Ciprofloxacin ear drops, 0.3%
Dermatophyte infection when topical treatment has failed	Terbinafine hydrochloride tablet, 250 mg
Nicotine dependence as the sole PBS-subsidised therapy	Nicotine transdermal patch, releasing approximately 15 mg per 16 hours
Nasal colonisation with <i>Staphylococcus aureus</i>	Mupirocin nasal ointment, 2%

* Authority-required listings are streamlined except for ciprofloxacin ear drops and terbinafine hydrochloride tablets.

Sitagliptin with metformin (Janumet) fixed-dose combination tablets PBS listed for type 2 diabetes mellitus

Sitagliptin with metformin tablets (Janumet) in fixed-dose combinations of 50/500 mg, 50/850 mg and 50/1000 mg are available on the PBS as of 1 August 2009. The authority required (streamlined) listing is for the treatment of type 2 diabetes when:

- HbA_{1c} is > 7% despite use of metformin, and when a combination of metformin and a sulfonylurea is contraindicated or not tolerated, or
- people are stabilised on a PBS-subsidised regimen of oral medicines for diabetes that includes metformin and sitagliptin.

The fixed-dose combination tablets are **not** TGA approved or PBS subsidised for use as initial drug therapy, or in combination with a sulfonylurea or a thiazolidinedione (glitazone) as part of triple oral therapy.

The authority-required listing for sitagliptin (Januvia) has been revised and is now streamlined to be consistent with the listing for Janumet.¹

Starting or switching to the fixed-dose combination tablets

Sitagliptin with metformin fixed-dose combination tablets should be taken twice daily with meals.² If necessary, increase the dose gradually so as to minimise gastrointestinal side effects with metformin.²

Individualise the starting or switching dose according to the patient's current regimen, level of glycaemic control and tolerability, while maintaining a daily dose of sitagliptin of 100 mg/day.²

The initial dose for patients who are inadequately controlled on metformin is sitagliptin 50 mg twice daily plus the previous dose of metformin.²

For patients who are already taking sitagliptin and metformin, a fixed-dose combination tablet may be prescribed at the dose of each medicine that was used separately.²

Advise patients who are switching to the combination tablets to return their separate medicines to a pharmacy for disposal.

Consider prescribing metformin and sitagliptin as separate medicines for some patients

Sitagliptin with metformin fixed-dose combination tablets provide metformin at a total daily dose of 1000 mg, 1700 mg or 2000 mg. However, some patients may be taking other doses of metformin, such as 1500 mg or 3000 mg daily.

For patients who are less flexible to changes in their current metformin regimen — for example, because of tolerability — it may be preferable to start or continue with sitagliptin and metformin as separate medicines. In doing so, side effects with either drug can also be identified and assessed more easily.

For more information on starting dual oral therapy with sitagliptin, see the *NPS RADAR* review on Sitagliptin (Januvia) for type 2 diabetes mellitus.

References

1. Australian Government Department of Health and Ageing. March 2009 PBAC Outcomes — Positive Recommendations. [http://www.health.gov.au/internet/main/publishing.nsf/Content/EE62734C748A1C12CA25759E0014357F/\\$File/PBACOutcomesMarch2009-Positiverecommendations.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/EE62734C748A1C12CA25759E0014357F/$File/PBACOutcomesMarch2009-Positiverecommendations.pdf) (accessed 25 May 2009).
2. Merck Sharp & Dohme (Aust.) Pty Ltd. Janumet product information. 20 April 2009.

Risedronate (Actonel Once-a-month) and summary of anti-resorptive drug listings

A new once-monthly tablet formulation containing risedronate sodium 150 mg (Actonel Once-a-month) was listed on the PBS on 1 July 2009. The authority-required (streamlined) listing is for treatment as the sole PBS-subsidised anti-resorptive agent for osteoporosis in people¹:

- with a fracture due to minimal trauma
- aged 70 years or older with a bone mineral density (BMD) T-score ≤ -3.0
- on long-term high-dose corticosteroid therapy (at least 7.5 mg/day of prednisolone or equivalent for ≥ 3 months) with a BMD T-score ≤ -1.5 .

These restrictions are in line with other currently listed risedronate products (Actonel, Actonel Once-a-week, Actonel Combi, Actonel Combi D).

Update on PBS-listed anti-resorptive drugs and their restrictions

Since 2006 several new medicines, formulations and indications for anti-resorptive drugs have been listed on the PBS. Table 1 lists the anti-resorptive drugs currently subsidised for osteoporosis.

For more information about prescribing anti-resorptive drugs, go to the NPS Health Professional webpage at www.nps.org.au/health_professionals and search for 'osteoporosis'.

References

1. Australian Government Department of Health and Ageing. March 2009 PBAC Outcomes — Positive Recommendations. [http://www.health.gov.au/internet/main/publishing.nsf/Content/EE62734C748A1C12CA25759E0014357F/\\$File/PBACOutcomesMarch2009-Positiverecommendations.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/EE62734C748A1C12CA25759E0014357F/$File/PBACOutcomesMarch2009-Positiverecommendations.pdf) (accessed 25 May 2009).

Table 1: PBS listings of anti-resorptive drugs for osteoporosis (as at 1 July 2009)

Anti-resorptive drug	PBS listing restriction		
	Established osteoporosis with fracture due to minimal trauma	70 years of age or older with BMD T-score ≤ -3.0	Long-term high-dose corticosteroid therapy with BMD T-score ≤ -1.5
Alendronate sodium (<i>Adronat, Alendrobell, Alendro Once Weekly, Fosamax Once Weekly, Fosamax Plus, Ossmax</i>)	✓	✓	✗
Disodium etidronate with calcium carbonate (<i>Didrocal</i>)	✓	✗	✗
Raloxifene hydrochloride (<i>Evista</i>)	✓*	✗	✗
Risedronate sodium (<i>Actonel, Actonel Once-a-month, Actonel Once-a-week, Actonel Combi, Actonel Combi D</i>)	✓	✓	✓
Strontium ranelate (<i>Protos</i>)	✓*	✓*	✗
Zoledronic acid (<i>Aclasta</i>)	✓†	✓*	✗

* Postmenopausal women only.

† Use in men only subsidised if they have had a hip fracture due to minimal trauma.

Clopidogrel (Iscover, Plavix) PBS listing extended to cardiac stent insertion

From 1 August 2009 clopidogrel can be prescribed in combination with aspirin as an authority (streamlined) PBS benefit after coronary artery stent insertion.¹ Previously a PBS subsidy was available for the treatment of acute coronary syndrome (ACS), and for prevention of recurrence of ischaemic stroke, transient cerebral ischaemic events, myocardial infarction or unstable angina. The extended PBS listing allows patients who require a stent to have equitable access to clopidogrel therapy.

The PBAC noted that there is evidence that prescribing clopidogrel, in combination with aspirin, is best clinical practice to prevent blood clots reforming after cardiac stent insertion.¹

Clopidogrel was PBS listed for ACS on 1 February 2009. For further information refer to the March 2009 *NPS RADAR* In Brief Item: Clopidogrel PBS listing extended to include acute coronary syndrome (ACS) in combination with aspirin.

References

1. Australian Government Department of Health and Ageing. Public summary document for clopidogrel hydrogen sulfate, tablet 75 mg (base), Iscover, Plavix March 2009. Department of Health and Ageing - Clopidogrel hydrogen sulfate, tablet, 75 mg (base), Iscover®, Plavix®, March 2009 (accessed 14 July 2009).

Lanthanum (Fosrenol) tablets for adults with chronic kidney disease who are on dialysis

Lanthanum (Fosrenol) was listed on the PBS on 1 May 2009. The authority listing allows prescribing for the treatment of hyperphosphataemia in adults with chronic kidney disease who are on dialysis*, but **not** in combination with sevelamer.¹ Until this listing, lanthanum had been available only on private prescription.

Lanthanum is a rare earth element that reduces serum phosphate concentration by binding phosphate in the gut.^{2,3} Calcium-based phosphate binders are first line for the treatment of hyperphosphataemia (unless serum calcium concentration is > 2.4 mmol/L),⁴ Lanthanum may

be an alternative for people taking calcium carbonate (Caltrate, Cal-Sup), for whom hypercalcaemia is a problem.^{2,4} Other available phosphate binders include aluminium hydroxide (Alu-tab), which is not PBS listed, and sevelamer (Renagel), which has the same PBS authority listing as lanthanum.⁵

Monitor serum phosphate concentrations every 2-3 weeks (adjust lanthanum dose as needed) until stable, then at regular intervals.^{2,3} Although only a very small amount is absorbed, it is distributed into bone.³ Lanthanum often causes gastrointestinal adverse effects (e.g. nausea). As with any new drug, the full toxicity profile and long-term effects of lanthanum are unknown.

A 6-month unblinded randomised trial (n = 777) showed similar efficacy for lanthanum and calcium carbonate in reducing serum phosphate concentrations.⁶ This was maintained for those who remained in the extension trial: 46 people for 2.5 years⁷ and 22 people for 6 years.⁸ Another randomised unblinded trial (2 years, n = 1359) showed similar efficacy for lanthanum and other phosphate binders (including calcium [carbonate and acetate] and sevelamer).⁹

References

1. Pharmaceutical Benefits Advisory Committee. Positive recommendations made by the Pharmaceutical Benefits Advisory Committee (PBAC) in November 2008 relating to the listing of drugs on the Pharmaceutical Benefits Scheme (PBS). Canberra: Australian Government Department of Health and Ageing, 2008. <http://www.carers.health.gov.au/internet/main/publishing.nsf/Content/pbacrec-nov08-positive> (accessed 24 December 2008).
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8. Hutchison AJ, et al. *Nephron Clin Pract* 2008;110:c15-23.
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* Hyperphosphataemia in an adult with chronic kidney disease who is on dialysis and whose serum phosphate level is not controlled with other products and when:
(a) serum phosphate concentration is > 1.6 mmol/L, or
(b) the serum calcium (mmol/L) × phosphate (mmol/L) product is > 4.0 mmol²/L²