

Ezetimibe (Ezetrol) for dyslipidaemia

Pharmaceutical Benefits Scheme (PBS) listing

Ezetimibe inhibits the intestinal absorption of cholesterol and related phytosterols.¹ It is listed as an authority item for:

- combination therapy with a 'statin' for people who have coronary heart disease or diabetes and whose cholesterol levels are inadequately controlled by a statin
- monotherapy for people who are unable to take statins due to contraindications or clinically important adverse effects
- people with homozygous sitosterolaemia or homozygous familial hypercholesterolaemia.

Reason for listing on the PBS

Economic analyses submitted in support of the PBS listing of ezetimibe were based on short-term changes in lipid parameters. The effect of ezetimibe on clinical outcomes is unknown.

Patients with coronary heart disease or diabetes whose cholesterol levels are inadequately controlled by a statin

Ezetimibe was recommended for listing as its cost-effectiveness was acceptable compared to a statin alone. The additional cost of adding ezetimibe to a statin was justified by the expected benefit in terms of coronary heart disease events prevented by lowering cholesterol.²

Patients who are unable to take statins

Ezetimibe was considered no worse than cholestyramine and was recommended for listing on the basis of similar efficacy and cost.

Patients with homozygous familial hypercholesterolaemia or homozygous sitosterolaemia

Ezetimibe was recommended for listing because the benefits of treatment outweigh the risks and costs of long-term use in these patients who are at high risk of coronary heart disease.³

Place in therapy

Statins remain the drugs of choice for low-density lipoprotein (LDL) cholesterol because they are effective and have recognised cardiovascular benefits.

Ezetimibe is an alternative to other non-statin drugs, such as bile acid resins (cholestyramine and colestipol), fibrates (gemfibrozil and fenofibrate) and nicotinic acid for:

- combination therapy for people with diabetes or coronary heart disease whose cholesterol is inadequately controlled by a statin. Check compliance with lifestyle changes and statin therapy before starting combination treatment.
- monotherapy for people unable to take a statin due to contraindications or clinically important statin-related adverse effects.

Ezetimibe can be used to treat the rare inherited disorders of homozygous familial hypercholesterolaemia and homozygous sitosterolaemia.

Safety issues

Ezetimibe is the first member of a new class of drugs and has been used in only a limited number of patients.

Dosing issues

The recommended dose of ezetimibe in adults and children 10 years and over is 10 mg once daily. Doses above 10 mg provide no additional benefit.

References

1. New drugs. Ezetimibe. Aust Prescr 2003;26:146-51.
2. Department of Health and Ageing. December 2003 PBAC outcomes – positive recommendations. www.health.gov.au/pbs/general/listing/pbacrec/dec03/positive.htm#ezetimibe [cited 2004 Sept 6]
3. Department of Health and Ageing. June 2003 PBAC outcomes – positive recommendations. www.health.gov.au/pbs/general/listing/pbacrec/jun03/positive.htm#ezeti [cited 2004 Sept 6]

See the full NPS RADAR review of ezetimibe at www.npsradar.org.au for a discussion of:

- the evidence for ezetimibe's efficacy and safety
- how to identify and manage statin-related adverse effects
- when to cease a statin because of adverse effects
- lipid-modifying options for people with insufficient response to a statin.

Also in the latest issue of RADAR:

Fenofibrate (Lipidil) for dyslipidaemia

Carvedilol (Dilatrend) titration pack for heart failure

Ethacrynic acid (Edecrin) tablets