

New drugs

Some of the views expressed in the following notes on newly approved products should be regarded as tentative, as there may have been little experience in Australia of their safety or efficacy. However, the Editorial Committee believes that comments made in good faith at an early stage may still be of value. As a result of fuller experience, initial comments may need to be modified. The Committee is prepared to do this. Before new drugs are prescribed, the Committee believes it is important that full information is obtained either from the manufacturer's approved product information, a drug information centre or some other appropriate source.

Bimatoprost

Lumigan (Allergan Australia)

0.3 mg/mL in 3 mL, 5 mL and 10 mL bottles

Approved indication: glaucoma

Australian Medicines Handbook section 11.2.5

Prostaglandin $F_{2\alpha}$ agonists are effective drugs for reducing intra-ocular pressure. Bimatoprost has a similar structure and like the prostaglandin $F_{2\alpha}$ agonists it increases the outflow of aqueous humour (see 'New drugs for glaucoma' Aust Prescr 2002;25:142-6).

Patients instil one drop each evening. Intra-ocular pressure starts to fall after four hours and is lowest after 8–12 hours. The pressure falls by about 8 mmHg and the effect is sustained for at least 24 hours. Little bimatoprost is absorbed into the systemic circulation.

In a three-month comparative study once-daily bimatoprost reduced intra-ocular pressure by a mean of 9.16 mmHg. This was a significantly greater reduction than the 6.74 mmHg seen with twice-daily doses of timolol 0.5%.¹

Another study compared bimatoprost with latanoprost for three months. Both drugs reduced intra-ocular pressure, but 53% of the patients taking bimatoprost achieved a target pressure of 17 mmHg or less compared with 43% of the latanoprost group.²

Bimatoprost causes more adverse effects than timolol. There is a higher incidence of conjunctival hyperaemia, itchy eyes and growth of eyelashes. Bimatoprost also causes more hyperaemia than latanoprost. Some patients develop increased iris pigmentation. Approximately 7% of patients stopped taking bimatoprost in the clinical trials because of adverse events.

There have been no specific drug interaction studies of bimatoprost, but it can be used as adjunctive therapy in patients whose intra-ocular pressure is not controlled by topical beta blockers.

Bimatoprost is at least as effective as latanoprost, but may be less well tolerated. Longer-term studies are needed to see if the benefits of bimatoprost are sustained.

REFERENCES

1. Brandt JD, VanDenburgh AM, Chen K, Whitcup SM. Comparison of once- or twice-daily bimatoprost with twice-daily timolol in patients with elevated IOP. *Ophthalmology* 2001;108:1023-32.
2. Gandolfi S, Simmons ST, Sturm R, Chen K. Three-month comparison of bimatoprost and latanoprost in patients with glaucoma and ocular hypertension. *Adv Ther* 2001;18:110-21.

Tiotropium bromide

Spiriva (Boehringer Ingelheim)

capsules containing 22.5 microgram as powder for inhalation

Approved indication: chronic obstructive pulmonary disease

Australian Medicines Handbook section 19.1.2

Ipratropium is an anticholinergic bronchodilator which is inhaled three or four times a day. Tiotropium has a similar mechanism of action, but only needs to be inhaled once a day.

Compared to ipratropium, tiotropium dissociates more slowly from M_1 and M_3 muscarinic receptors. Its bronchodilator effect begins within 30 minutes but can last for more than 24 hours.

In a placebo-controlled trial, 279 patients with stable chronic obstructive pulmonary disease inhaled tiotropium powder every morning for 13 weeks. Respiratory function tests (see 'Basic tests of respiratory function' Aust Prescr 2000;23:10–2) showed significant increases in forced expired volume in one second (FEV_1), forced vital capacity (FVC) and peak expiratory flow rate. The FEV_1 and FVC increased within 30 minutes of the first dose. After one week of treatment, the FEV_1 and FVC 24 hours after a dose were 10–13% greater than before treatment. The patients needed to use significantly less salbutamol than the 191 patients in the placebo group.¹

Another study randomised 191 patients to use tiotropium powder once a day and 97 to use an ipratropium inhaler four times a day for 13 weeks. The increases in mean FEV_1 and FVC were significantly greater with tiotropium than with ipratropium. Trough values (one hour before the next dose) of FEV_1 and FVC were significantly larger with tiotropium than with ipratropium.²

The most common adverse effect of tiotropium is a dry mouth. This affects nearly 15% of patients.²

Tiotropium seems to be more potent than ipratropium, but the clinical advantage is unclear. The difference between the peak expiratory flow rates narrowed over the course of the comparative study.² At the end of the study the difference was approximately 10 L/minute which is not significant. Although patients taking tiotropium used significantly less salbutamol, the mean difference was less than one puff per day.²

REFERENCES

1. US Tiotropium Study Group. The spirometric efficacy of once-daily dosing with tiotropium in stable COPD. *Chest* 2000;118:1294-302.
2. Dutch Tiotropium Study Group. A randomised controlled comparison of tiotropium and ipratropium in the treatment of chronic obstructive pulmonary disease. *Thorax* 2000;55:289-94.

NEW COMBINATION

Peginterferon alfa-2b with ribavirin

Pegatron Combination Therapy (Schering Plough) composite packs containing vials of either 50, 80, 100, 120 or 150 microgram peginterferon alfa-2b powder for injection, and 200 mg ribavirin capsules (See 'New drugs: Peginterferon alfa-2b' Aust Prescr 2002;25:121-2)

NEW PROPRIETARY BRAND

Ciprofloxacin hydrochloride

Ciprofloxacin-BC (Biochemie)
250 mg, 500 mg and 750 mg tablets

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Editorial office

For general correspondence such as letters to the Editor, please contact the Editor.

Telephone: (02) 6282 6755

Facsimile: (02) 6282 6855

Postal: The Editor
Australian Prescriber
Suite 3, 2 Phipps Close
DEAKIN ACT 2600
AUSTRALIA

E-mail: info@australianprescriber.com

Web site: www.australianprescriber.com

Answers to self-test questions

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|----------|----------|----------|
| 1. True | 3. False | 5. True |
| 2. False | 4. False | 6. False |
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| 8. False | | |