NEW DRUGS

New drugs

Some of the views expressed in the following notes on newly approved products should be regarded as tentative, as there may be limited published data and little experience in Australia of their safety or efficacy. However, the Editorial Executive 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 from the manufacturer's approved product information, a drug information centre or some other appropriate source.

Boceprevir

Approved indication: hepatitis C
Victrelis (Merck Sharp & Dohme)
200 mg capsules
Australian Medicines Handbook section 5.4.3

The standard treatment for patients with chronic hepatitis C is a combination of peginterferon alfa and ribavirin. However, susceptibility to treatment varies depending on the viral genotype. Only 40–50% of patients with genotype 1 achieve a sustained virological response. In Australia, 55% of patients are infected with genotype 1.[1] Boceprevir is a protease inhibitor that can be added to standard therapy for these patients. It blocks viral replication by binding to the NS3 (non-structural 3) protease.

In phase III trials, boceprevir (800 mg three times a day orally) added to peginterferon alfa and ribavirin (after a four-week lead-in period) significantly improved the sustained virological response in patients with chronic hepatitis C genotype 1 (Table 1). One trial enrolled patients who had not responded or had relapsed after previous therapy[2] and the other enrolled previously untreated patients.[3] Interferon responsiveness predicts a sustained response to boceprevir. This was an inclusion criteria in the trial of previously treated patients.[2]

The most common adverse events with boceprevir were fatigue, anaemia, nausea, headache and dysgeusia. Almost half of the patients given boceprevir developed anaemia compared to about a third of patients given peginterferon alfa and ribavirin alone. Most of these patients were treated with erythropoietin.[2,3] In the trial of previously treated patients, more patients required a blood transfusion for their anaemia with boceprevir than with standard treatment (9% vs 0%).[2] Neutropenia also increased when boceprevir was added to standard treatment.

Complete blood counts should be done before starting treatment with boceprevir and regularly after that. Treatment may need to be modified if haemoglobin or neutrophils fall.

This drug should be taken with food as it increases bioavailability. Boceprevir is a strong inhibitor of cytochrome P450 3A4/5 so there is a potential for many drug interactions. The concomitant use of midazolam, triazolam, amiodarone, cisapride, alfuzosin, sildenafil or tadalafil for pulmonary arterial hypertension, and ergot derivatives is contraindicated. In addition, rifampicin, carbamazepine, phenobarbitone and phenytoin use is not recommended. Boceprevir may increase plasma concentrations and therefore the adverse effects of simvastatin.

Boceprevir is contraindicated in patients with decompensated liver function (Child-Pugh score >6), and in pregnant women because of risks to the fetus. This drug should not be given to patients with rare galactose intolerance disorders such as Lapp lactase deficiency or glucose-galactose malabsorption.

Adding boceprevir to standard hepatitis C treatment is a promising option for patients with genotype 1 disease. However, not all patients will have a sustained response. Regular blood monitoring is important as anaemia is a common adverse effect. The safety and efficacy of boceprevir has not been tested in people co-infected with HIV or hepatitis B.

T T manufacturer provided additional useful information

REFERENCES

1. Batey R. Managing hepatitis C in the community. Aust Prescr 2006;29:36-9.
2. Bacon BR, Gordon SC, Lawitz E, Marcellin P, Vierling JM, Zeuzem S, et al. Boceprevir for previously treated chronic HCV genotype 1 infection. N Engl J Med 2011;364:1207-17.
3. Poordad F, McCone J, Bacon BR, Bruno S, Manns MP, Sulkowski MS, et al. Boceprevir for untreated chronic HCV genotype 1 infection. N Engl J Med 2011;364:1195-206.

Table 1 **Sustained virologic responses in patients with chronic hepatitis C genotype 1** [2,3]

Treatment for 44 weeks	Sustained virologic response *	
	Previously treated patients	Previously untreated patients
Placebo plus peginterferon/ribavirin	21% (17/80)	38% (137/363)
Boceprevir plus peginterferon/ribavirin	66% (107/161)	66% (242/366)

* undetectable viral RNA for six months after treatment

The T-score (T) is explained in 'New drugs: T-score for transparency', Aust Prescr 2011;34:26–7.

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ANSWERS TO SELF-TEST QUESTIONS

1	False	2	False
3	False	4	True
5	False	6	True
7	False	8	True
9	False	10	True

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