

## Warning on tipranavir

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Access to the new protease inhibitor tipranavir (Aptivus) has been substantially expanded in Australia, but there are new questions about the drug's [effectiveness](#) [1](Of a drug or treatment). The maximum ability of a drug or treatment to produce a result regardless of dosage. A drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed. In the standard procedure, Phase II clinical trials gauge efficacy, and Phase III trials confirm it. and warnings about serious side effects.

Boehringer Ingelheim, the manufacturer of the drug, announced in June that tipranavir has been registered by the Australian Therapeutic Goods Administration ([TGA](#) [2][Therapeutic Goods Administration] The federal government body that approves drugs and treatments before they can be prescribed.), clearing the way for an application for listing on the [Pharmaceutical Benefits Scheme](#) [3][Pharmaceutical Benefits Scheme] The federal government program which subsidises medication costs in Australia. Anti-HIV drugs are part of a special part of the PBS called Section 100 (S100) which is used for expensive, highly specialised drugs. (PBS).

But the TGA approval coincides with an international warning issued by Boehringer over cases of intracranial haemorrhage (bleeding within the skull) associated with tipranavir. In a June 30 letter to US physicians, the company said it had identified 14 cases of intracranial haemorrhage in people taking tipranavir, eight of which had proven fatal. The warning letter recommends that the drug be used with caution in people who may be at risk of increased bleeding, or who are also taking anticoagulant (blood-thinning) drugs.

Most of the people who developed the condition had been on tipranavir for more than a year, and many had other risk factors which the company said may have contributed to the development of intracranial haemorrhage. The numbers of affected patients are relatively small in relation to the 6840 people the company said were on treatment, however bleeding within the skull represents a serious medical emergency if it occurs.

Boehringer noted that, while tipranavir was seen to cause changes in blood clotting in test-tube and animal studies, no events of this type were recorded in clinical trials in humans.

The news follows the announcement, a few weeks earlier, that Boehringer had halted an international trial of tipranavir in treatment-naive people, after it became clear that tipranavir was inferior to the comparison drug, Kaletra. Tipranavir has been shown to be an effective choice in people who have taken other protease inhibitors, and this was the basis of its approval by the TGA, but the cancellation of the treatment-naive trial puts a cloud over the drug's suitability for people who do not have [resistance](#) [4]HIV which has mutated and is less susceptible to the effects of one or more anti-HIV drugs is said to be resistant. to other PIs.

While it awaits consideration for listing on the PBS, Boehringer Ingelheim in Australia has announced an expanded Special Access Scheme ([SAS](#) [5]Before a drug has been approved, manufacturers often provide the drug free of charge to people who cannot participate in a clinical trial and who meet certain criteria under a Special Access Scheme (SAS). ) for tipranavir. Access to tipranavir is now open to people with demonstrated PI resistance and detectable [viral load](#) [6]A measurement of the quantity of HIV RNA in the blood. Viral load blood test results are expressed as the number of copies (of HIV) per milliliter of blood plasma., regardless of CD4 count (the SAS had previously set an upper CD4 count limit of 100).

People taking tipranavir who are concerned about side effects, or who are also taking drugs to prevent blood clotting (anticoagulants), should continue taking the drug until they have consulted their doctor.

- [tipranavir](#)

### Links:

[1] <http://www.napwa.org.au/glossary/term/486>

[2] <http://www.napwa.org.au/glossary/term/113>

[3] <http://www.napwa.org.au/glossary/term/121>

[4] <http://www.napwa.org.au/glossary/term/109>

[5] <http://www.napwa.org.au/glossary/term/112>

[6] <http://www.napwa.org.au/glossary/term/416>