



SAQUINAVIR (SQV)

GENERAL INFORMATION

- Therapeutic class: Protease inhibitor (PI).
- WHO guidelines: Not currently included in WHO guidelines.
- Originator company and product brand name: Roche, Invirase.
- First approval by U.S. Food and Drug Administration (FDA): December 1995.²³
- WHO Model List of Essential Medicines (EML): Included in the 17th edition.²⁴
- World sales of originator product: There are no sales figures listed in the company's annual report.
- Patents: The basic patent was applied for by Roche in 1990²⁶⁷ and should have expired in countries not granting patent extensions. A patent related to oral dosage form was applied by Roche in 2004 and is due to expire in 2024.²⁶⁸

PRICE INFORMATION

Developing country prices in US\$ per patient per year, as quoted by companies.

The price in brackets corresponds to the price of one capsule / tablet. Products quality-assured by US FDA or WHO prequalification (as of May 2011) are in **bold**.

| | Daily dose | Roche | |
|----------------------------|------------|----------------------|----------------------|
| | | Category 1 countries | Category 2 countries |
| Who can access this price? | | See annex 2 | |
| SQV 200mg hard capsule | 10* | 1566 (0.429) | 3132 (0.858) |
| SQV 500mg tablet | 4* | 1435 (0.983) | 3130 (2.144) |

*The dose of SQV must be boosted with RTV 100mg twice a day.

SPOTLIGHT ON ACCESS ISSUES

In 2010, WHO recommendations for second-line therapy included two 'preferred' protease inhibitors (PI), to be taken in combination with two NRTIs. They are atazanavir (ATV) boosted with ritonavir (RTV) and lopinavir/ ritonavir (LPV/r). As saquinavir (SQV) was not identified as one of the priority products, its use in the developing world will be limited.⁷

SQV, like all PIs (with the exception of nelfinavir (NFV)), requires boosting with ritonavir (RTV). Abbott's heat-stable ritonavir received marketing approval in the U.S. and Europe in early 2010. Registering this new formulation in developing countries will be crucial in order to allow the use of other PIs than lopinavir.

A generic heat-stable RTV is now available and was WHO prequalified in late 2010.

SQV/r appears to be slightly less potent than other boosted PIs and in the original formulation has a high pill count (10 capsules).¹⁵⁹ In 2004, Roche marketed a 500mg tablet of SQV in the U.S. that reduced the pill count from 10 tablets to four. While this new formulation should improve adherence, it is only registered and marketed in selected developing countries.

As with other protease inhibitors, the high price of SQV continues to be a barrier. Solid competition and economies of scale among producers are minimal, as its use is fairly limited.

Patents

The basic patent was rejected in Brazil where this medicine is locally produced. It was however granted in many other countries including China, South Africa and OAPI countries.

Patents related to the oral dosage form are pending in Brazil and China and have been granted in South Africa.

In India, three patents^{269, 270, 271} on improved compositions and SQV mesylate have been granted, blocking generic production till 2024.

Paediatrics

SQV has not been approved for use in children in the US.

No paediatric is formulation available.