

DIDANOSINE

RECOMMENDED CHANGES TO THE PRODUCT INFORMATION

The following changes to the product information of medicinal products containing the active substance didanosine are recommended (addition in bold and deletion stricken):

Summary of product characteristics

In section 4.3

Co-administration with stavudine due to the potential for serious and/or life-threatening events notably lactic acidosis, liver function abnormalities, pancreatitis and peripheral neuropathy (see section 4.4 and 4.5)

In section 4.4

Not recommended combinations

Pancreatitis (fatal and nonfatal) and peripheral neuropathy (severe in some cases) have been reported in HIV infected patients receiving didanosine in association with hydroxyurea and stavudine (see section 4.3).

In section 4.5

Stavudine/ didanosine

~~*No dose adjustment is necessary for either medicinal product.*~~

This combination is contraindicated given that both drugs exhibits high risk of mitochondrial toxicity (see section 4.3 and 4.4)

Package leaflet

[Add sections as relevant, ensuring that the above proposed changes to the SmPC are adequately reflected, in lay terms, in the package leaflet]