Safety Alert



Avanafil – Risk of Visual defects including central serous chorioretinopathy (CSCR)

EDA performs label update to include the following:

Special warnings and precautions for use

Visual problems

Visual defects, including Central Serous Chorioretinopathy (CSCR), and cases of non-arteritic anterior ischaemic optic neuropathy (NAION) have been reported in connection with the intake of PDE5 inhibitors. The patient should be advised that in case of sudden visual effects he should stop taking Spedra and consult a physician immediately.

Background:

Therapeutic Indication

Treatment of erectile dysfunction in adult males.

Central Serous Chorioretinopathy (CSCR)

Central serous chorioretinopathy (CSCR) is the fourth most common retinopathy after age-related macular degeneration, diabetic retinopathy, and branch retinal vein occlusion. CSCR typically occurs in males in their 20s to 50s who exhibit acute or subacute central vision loss or distortion. Other common complaints include micropsia, metamorphopsia, hyperopic (most common) or myopic shift, central scotoma, and reduced contrast sensitivity and color saturation.

<u>References:</u> TGA <u>(Click here)</u>