CARBOMEDICS – Important Safety Information

INDICATIONS
EUROPE: The Carbomedics Prosthetic Heart Valve is intended for use as a replacement valve in patients with diseased, damaged, or malfunctioning aortic or mitral heart valve. The Carbomedics Prosthetic Heart Valve Aortic/Mitral models, respectively, are indicated for use in patients suffering from aortic/mitral valvular heart disease, that is a condition involving obstruction of the aortic/mitral heart valve or stenosis; leakage of the aortic/mitral valve, known as regurgitation, incompetence, or insufficiency; and combinations of the two or patients with a previously implanted aortic/mitral valve prosthesis that is no longer functioning adequately and requires replacement.
US, CANADA: The Carbomedics Prosthetic Heart Valves are indicated as a replacement for human cardiac valves that are malfunctioning as a result of acquired or congenital disease, or as a replacement of a previously implanted prosthesis.

KEY CONTRAINDICATIONS
There are no absolute contraindications to the use of the Carbomedics Prosthetic Heart Valve. The mechanical heart valves are contraindicated or difficult to apply in patients unable to tolerate long term anticoagulation therapy or for whom this type of therapy is difficult to carry out.

KEY WARNINGS
For single use only. Safety and effectiveness of the Carbomedics valve has not been demonstrated for valve replacement in the pulmonic and tricuspid positions. Handle the valve only with accessories provided by the manufacturer specifically for the Carbomedics valve. Only use sizers provided by the manufacturer specifically for the Carbomedics valve.

TOP POTENTIAL SIDE EFFECTS
The risks or potential adverse events associated with cardiac valve replacement with a prosthetic mechanical heart valve include: cardiac arrhythmias, death, endocarditis, hemolysis, anti-coagulation related hemorrhage, leaflet entrapment by tissue ingrowth or impingement on anatomic structures, intravalvular and/or paravalvular leak, prosthesis thrombosis, thromboembolism, structural valve deterioration.

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For professional use. Please contact us through our website to receive instructions for use containing full prescribing information, including indications, contraindications, warnings, precautions and adverse events. Not approved in all geographies. Consult your labeling.