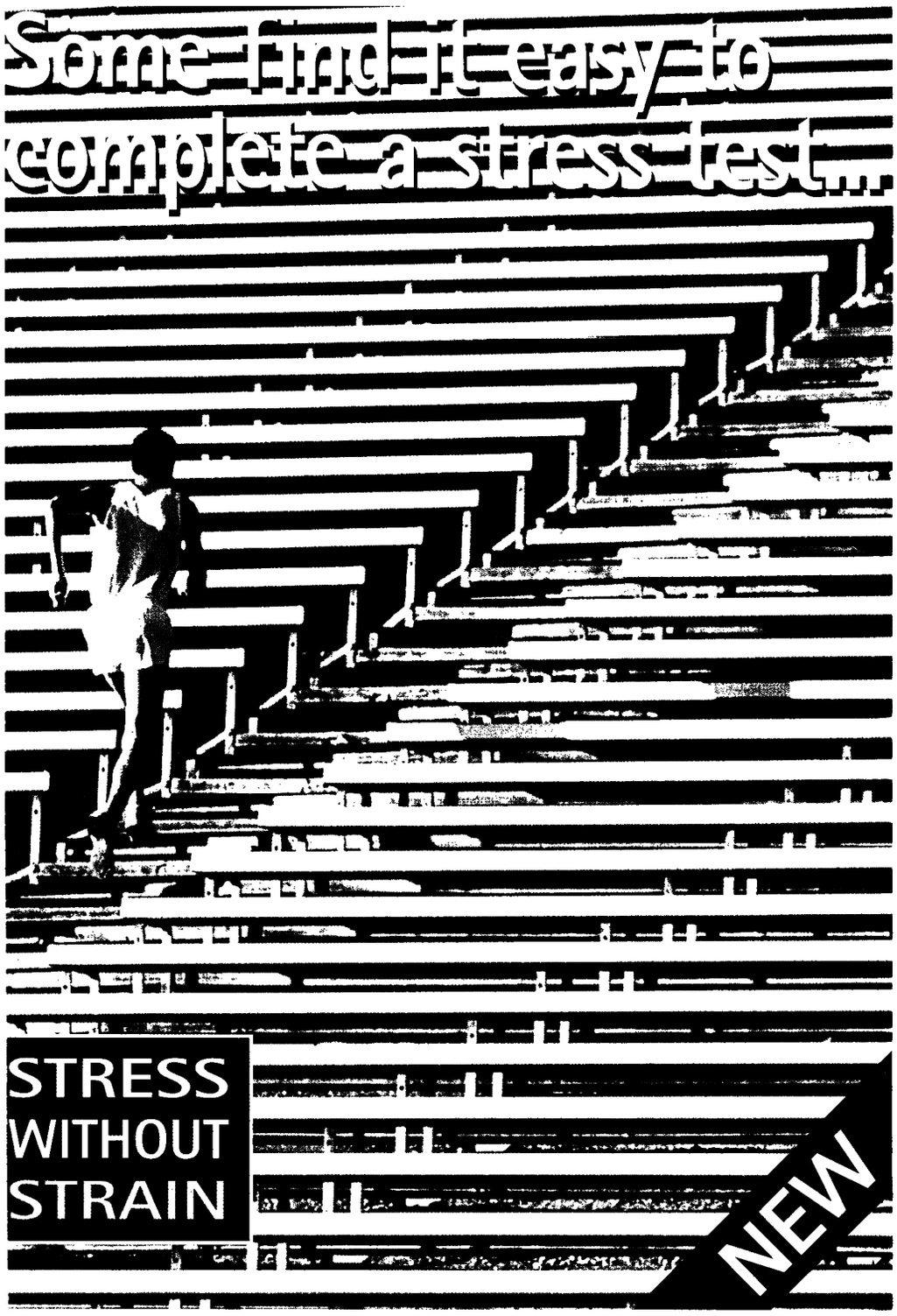
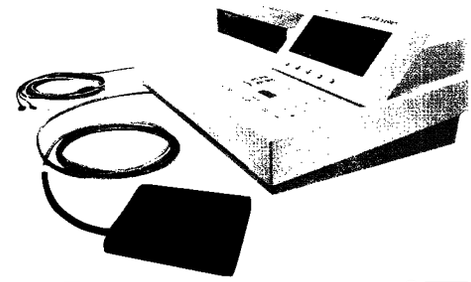


Over 21% of patients with suspected coronary artery disease are unable to complete an exercise stress test, making it difficult to obtain a diagnostic outcome without alternative investigation.[1, 2, 3]

The GenESA System combines the benefits of a potent new catecholamine stressing agent (arbutamine) with a computerised patient-responsive drug delivery and monitoring device.

- in inducing cardiac ischaemia. Sensitivity and specificity equivalent to conventional exercise stress test when used with ECG, Echo and Nuclear Perfusion Imaging.[4]
- - GenESA gives the physician precise control of heart rate increase to a diagnostic end-point.[5]
- - Integration of haemodynamic monitoring, automated drug titration and procedure recording and documentation.



GenESA®▼

arbutamine 50 microgrammes/ml

▼ 20ml pre-filled syringe as a 50µg/ml sterile solution arbutamine for infusion. Intended for irect intravenous infusion ONLY with the GenESA System. The GenESA System combines the cardiac stress agent GenESA (arbutamine) with a closed-loop proprietary delivery device, the GenESA® evice. As an adjunct to electrocardiography (ECG), echocardiography or radionuclide myocardial perfusion imaging for the evaluation of patients with suspected coronary artery disease who annot exercise adequately. In patients who can exercise there is a less favourable risk-benefit profile for arbutamine compared with exercise, and in such patients, exercise should be considered the :ress method of choice. See Summary of Product Characteristics and Device User Manual for full details. GenESA® (arbutamine) must only be administered using the GenESA® evice, supervised by a physician experienced in cardiac stress testing. Emergency monitoring and therapeutic equipment and supplies together with skilled personnel, must be always available. ECG nd blood pressure should be monitored continuously. Initially, the GenESA® Device administers a small dose of arbutamine (0.1µg/kg/min for one minute) to the patient and measures the heart rate HR) response. The GenESA® Device individualises the dosing regimen of arbutamine according to the HR response of the patient. The maximum infusion rate delivered by the device is 0.8µg/kg/min; ıe maximum total dose delivered is 10µg/kg. ECG, HR, blood pressure and dosing information are displayed continously. The device has a series of "alerts" that warn of conditions which may require ttention, and "alarms" that stop drug delivery due to a potential safety hazard. The physician may interrupt manually the delivery of arbutamine at any time, terminate the infusion when a diagnostic ndpoint is reached or if clinically significant symptoms or arrhythmias occur. On termination, monitor the patient until HR and blood pressure reach acceptable levels and any ECG changes are resolved. Idiopathic hypertrophic subaortic stenosis. Haemodynamically significant left ventricular outflow obstruction or valvular disease. Predisposition to, or a history of arrhythmias, articularly recurrent sustained ventricular tachycardia. Congestive heart failure (NYHA Class III or IV). Significant cardiac conduction defects. Myocardial infarction within 30 days. Unstable angina. ncontrolled systemic hypertension. History of cerebrovascular haemorrhage. Aortic aneurysm. Hypersensitivity to arbutamine. Implanted cardiac pacemaker or automated cardioverter/defibrillator. see Summary of Product Characteristics. Supraventricular and ventricular arrhythmias may be precipitated; discontinue immediately and treat appropriately (not Class I and III antiarrhythmic gents). Not recommended in patients with a history of sustained arrhythmias. Arbutamine should not be administered to patients having a prolonged corrected QT interval at rest, or with known ypokalaemia or hypomagnesaemia. Monitor ECG carefully in the presence of an arrhythmia as the GenESA® Device may register an inaccurate heart rate. For patients with resting ECG abnormalities, CG should not be the diagnostic modality of choice. Arbutamine may cause rapid, reversible increases or paradoxical decreases in heart rate and blood pressure. Arbutamine in combination with anglion blockers or α-blockers may produce an exaggerated vasodilatory or hypotensive response. Do not restart arbutamine infusion following a "heart rate saturation" alarm. Arbutamine is not :commended in patients with dilated cardiomyopathy, cardiac transplant, narrow angle glaucoma, uncontrolled hyperthyroidism or those receiving antiarrhythmic agents, digoxin, anticholinergic drugs :g atropine) or tricyclic antidepressants. Caution in the elderly, those with impaired renal or hepatic function and patients receiving drugs affecting catecholamine metabolism. Possible reduction in :rum potassium (including hypokalaemia) and increase in corrected QT interval are greatest at the end of arbutamine infusion, but generally normalise within 60 and 30 minutes of discontinuation, :spectively. The sodium metabisulphite excipient may cause allergic reactions (including anaphylaxis or asthmatic episodes). Care should be taken to avoid the possibility of paravenous dosing. rbutamine should not be used during pregnancy. Beta-blockers may attenuate the response to arbutamine and should be withdrawn at least 48 hours before conducting a GenESA test. Atrial and ventricular tachyarrhythmias, occasional cases of severe cardiac ischaemia. Tremor, headache, flushing, hypotension, dizziness, paraesthesia, nausea, hot flushes, angina pectoris nd increased sweating. Rarely (incidence <2%): dry mouth, taste perversion, chest pain, fatigue, pain (non-specific), vasodilation and hypoaesthesia. Possible hypokalaemia, tachycardia or palpitation. see Summary of Product Characteristics. £69.50 POM 10476/0007

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ır ordering information contact Customer Services. For product information contact Medical Information Department.

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Data on File - Clinical Studies 0122, 0123 and 0127. 5. Data on File - Clinical Studies 0123 and 0127