Patient Alert Card Important Information about

Amiodarone Hydrochloride 100 mg Tablets: PL 17907/0369 Amiodarone Hydrochloride 200 mg Tablets: PL 17907/0394

This card contains important safety information that you should know about Amiodarone. Patients should be alerted to the fact that use of amiodarone can cause serious side effects that can occur any time after starting treatment and be life-threatening, including:

· lung damage

5 mm

- · worsening of heartbeat problems
- · liver damage
- · thyroid problems

Some medicines can interact with Amiodarone and cause side effects, and a list of these can be found in the Patient Information Leaflet supplied with their

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly to the Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Bristol via email to info@bristol-labs.co.uk or via phone on 0044 (0)1442 200922

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What you should do:

STOP taking Amiodarone immediately and seek medical help if you have:

- A severe allergic reaction. Signs may include: a rash, swallowing or breathing problems, swollen eyelids, face, lips, throat or tongue
- A severe blistering rash with or without peeling of your skin. You may also feel unwell and have a fever, chills and aching muscles

Contact your doctor or seek medical help immediately if you have any of the following:

- Yellowing of the skin or eyes (jaundice), feel tired or sick, loss of appetite,
- stomach pain or high temperature; these may be signs of liver problems
- Shortness of breath or difficulty breathing (which may get progressively worse), tightness in the chest, coughing which will not go away, wheezing, weight loss and fever; these may be signs of serious lung damage
- Heartbeat becomes even more uneven or erratic; this could be a sign that the medicine is not working well
- Weakness, weight loss or weight gain, heat or cold intolerance, hair thinning, sweating, changes in menstrual periods, swelling of the neck (goitre), nervousness, irritability, restlessness, or decreased concentration; these may be signs of thyroid problems.

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