The name of your medicine is Digoxin 250 micrograms/ml Solution for Injection. It will be referred to as Digoxin Injection for ease of use hereafter.

In this leaflet:
1. What Digoxin Injection is and what it is used for
2. Before you are given Digoxin Injection
3. How Digoxin Injection is given
4. Possible side effects
5. How to store Digoxin Injection
6. Further information

WHAT DIGOXIN INJECTION IS AND WHAT IT IS USED FOR

Digoxin belongs to a group of medicines called cardiac glycosides. It works by increasing the strength of the heart muscle and slowing the rate of contraction of the heart, i.e. the pulse rate.

Digoxin is used to treat:
• Chronic heart failure. Heart failure is a condition in which the heart fails to pump the blood round the body adequately. This may cause tiredness, breathlessness and ankle swelling
• Some types of irregular heart beat including those caused by an overdose of digoxin and heart block, and enlargement of the heart muscle. Your doctor will be able to advise you.

You should have periodic tests to assess kidney function and blood electrolyte levels.

A large number of drugs can interact with Digoxin Injection which can significantly alter their effects.

Taking other medicines:
Tell your doctor before you are given this medicine if you are or think you may be pregnant or are planning to become pregnant, or are breast-feeding. As with all drugs, this medicine should only be given in pregnancy and when breast feeding if the doctor thinks it is absolutely necessary.

Tell your doctor before you are given this medicine if you are already taking one of these medicines, including medicines obtained without a prescription.

Tell your doctor before you are given this medicine if you are allergic to digoxin or to any other ingredients (see section 6 of this leaflet)

Tell your doctor before you are given this medicine if you are or think you may be pregnant or are planning to become pregnant, or are breast-feeding. As with all drugs, this medicine should only be given in pregnancy and when breast feeding if the doctor thinks it is absolutely necessary.
Driving and using machines
Digoxin may cause some patients to have changes in their sight which could interfere with the ability to drive or to operate machines. If this happens, do not drive or operate machinery and ask your doctor for advice.

Important information about some of the ingredients of Digoxin Injection
This medicinal product contains less than 1mmol sodium (23mg) per 4ml, i.e. is essentially 'sodium-free'. This medicinal product also contains small amounts of ethanol (alcohol), less than 100mg per 4ml.

3. HOW DIGOXIN INJECTION IS GIVEN

A dose of digoxin will be dissolved into a solution and slowly injected into a vein over 10 - 20 minutes. This is known as an infusion or drip. The dose should be divided so that one half is given as the first dose and the remainder is given in divided doses every 4 to 8 hours.

Adults: The dose will be calculated by your doctor according to your age and weight.

Infants and children up to age 10 years: The dose will be calculated by the doctor according to weight and age.

If you are elderly, or if you have kidney problems, or if you have received a cardiac glycoside within the past two weeks, your dose will be reduced. Your doctor may want to take blood samples to ensure that your blood levels of digoxin are in the required range.

Use in the elderly:
The tendency to impaired renal function and low lean body mass in the elderly influences the action of digoxin such that high serum digoxin levels and associated toxicity can occur quite readily, unless doses of digoxin lower than those in non-elderly patients are used. Serum digoxin levels should be checked regularly and lowering of the potassium levels should be avoided.

Dose recommendations in renal disorder or with a diuretic therapy:
The dosing recommendations should be reconsidered if patients are elderly or there are other reasons for the renal clearance of digoxin being reduced. A reduction in both initial and maintenance dose should be considered.

In patients receiving diuretics (water tablets) and medicines to reduce high blood pressure (ACE inhibitors) or diuretics alone, the withdrawal of digoxin has been shown to result in some clinical problems.

Monitoring:
Serum concentration of digoxin may be expressed in nanograms/ml (ng/ml). The serum concentration of digoxin can be determined by radioimmunoassay test. Blood should be taken 6 hours or more after the last dose of digoxin. Dose toxicity is most commonly associated with serum digoxin concentration greater than 2ng/ml. However, toxicity may occur with lower digoxin serum concentrations. In deciding whether a patients symptoms are due to digoxin, the patients clinical state together with the serum potassium level and thyroid function are important factors to be considered.

If you have any further questions on the use of this product ask your doctor or pharmacist.

If you think you have been given more Digoxin Injection than you should have
As the injection will be administered under the supervision of a doctor, it is unlikely that you will be given more than is necessary. However, if you have any concerns about the dose of your medicine discuss them with your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines Digoxin Injection can sometimes cause side effects, although not everybody gets them. All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

Tell your doctor or nurse immediately if:
• you have palpitations, chest pain, shortness of breath or sweating. There can be symptoms of serious heart problem caused by new irregular heart beats. If these happen, tell your doctor immediately.

Other side effects may include:
Common (affects less than 1 in 10 people):
• slow or irregular heart rate
• feeling sick, being sick or loose stools
• skin rash that may be itchy
• drowsiness or dizziness
• visual disturbances, with blurred or yellow-green sight.

Uncommon (affects less than 1 in 100 people):
• depression.

Very rare (affects less than 1 in 10,000 people):
• bruising or bleeding more easily than normal
• stomach pain caused by lack of blood supply or damage to the gut
• mental disturbances, you may feel confused, indifferent or unable to judge clearly
• weakness,tiredness or a general feeling of being unwell
• breast enlargement in men
• loss of appetite
• headache
• rapid heart rate.

Digoxin injection can very rarely cause serious irregular heart rates. Your doctor may do regular checks to make sure digoxin injection is working safely for you. If you get any of these side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor at once.

5. HOW TO STORE DIGOXIN INJECTION

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Keep the ampoule in the outer carton in order to protect from light.

Do not use after the expiry date shown on the ampoule and carton. The expiry date refers to the last day of that month.

If only part of an ampoule is used, the remainder should be discarded.

Do not use the ampoule if the contents are discoloured in any way.

The active substance is digoxin.

The other ingredients are ethanol, propylene glycol, citric acid monohydrate, sodium phosphate and water for injections.

What Digoxin Injection looks like and contents of pack
Digoxin injection is a clear, colourless sterile solution presented in clear glass ampoules. Each ampoule contains 2ml of solution and each 2ml of solution contains 500 micrograms (mcg) of digoxin.

The injection is available in packs of 10 ampoules.

Marketing authorisation holder
Mercury Pharma International Ltd., 4045, Kingswood Road, City West Business Park, Co Dublin, Ireland.

Manufacturer
B. Braun Melsungen AG, Mistelweg 2, 12357 Berlin, Germany.

This leaflet was last revised in September 2012.