



*Direttorat tat-Tabib Ewlieni tal-Gvern*

*Office of the Chief Medical Officer*

**DH CIRCULAR No. 126/2016**  
DH 1170/2016

**14 April 2016**

**Attention All:** Consultants  
Medical Officers  
Pharmacists  
Pharmacy Technicians  
Nurses

**Re: Ledipasvir-Sofosbuvir 90mg/400mg Tablets and Ribavirin 200mg Tablets**

It is being brought to your attention that Ledipasvir-Sofosbuvir 90mg/400mg tablets and Ribavirin 200mg tablets are now available on the Government Formulary List for the treatment of Hepatitis C.

Ledipasvir-Sofosbuvir and Ribavirin are protocol regulated by protocol 112 (Annex 1) and 171 (Annex 2) respectively and can be prescribed by Consultant Infectious Diseases Physicians and Consultant Gastroenterologists, belonging to the Hepatitis C Virus (HCV) Patient Management Committee. Treatment duration is for a maximum 12 weeks.

For your attention please.

Dr. Denis Vella Baldacchino  
Chief Medical Officer

## **Ledipasvir 90mg + Sofosbuvir 400mg Tablets**

**Prescriber Criteria:** Consultant Gastroenterologist (HCV Patient Management Committee)  
Consultant Infectious Disease Physician (HCV Patient Management Committee)

### **Outpatient and In-patient use:**

1. Hepatitis C

Treatment of patients with **Chronic Hepatitis C** genotype 1, 4, 5 and 6 infection *with or without Ribavirin* affected by any of the following:

- Decompensating cirrhosis secondary to HCV
- Cirrhosis secondary to HCV
- Liver transplant for HCV
- Type 2 or 3 Essential mixed Cryoglobulinaemia with end organ manifestations secondary to HCV
- Significant renal disease secondary to HCV
- Rapidly progressive hepatic fibrosis secondary to HCV
- HCV/HIV co infection

### **Duration of Approval:**

Maximum 12 weeks

## **Ribavirin 200mg Tablets/Capsules**

**Prescriber Criteria:** Consultant Gastroenterologist (HCV Patient Management Committee)  
Consultant Infectious Disease Physician (HCV Patient Management Committee)

### **Outpatient and In-patient use:**

1. Hepatitis C

Treatment of **Chronic Hepatitis C** infection in combination with other agents in affected patients suffering from any of the following:

- Decompensating cirrhosis secondary to HCV
- Cirrhosis secondary to HCV
- Liver transplant for HCV
- Type 2 or 3 Essential mixed Cryoglobulinaemia with end organ manifestations secondary to HCV
- Significant renal disease secondary to HCV
- Rapidly progressive hepatic fibrosis secondary to HCV
- HCV /HIV co infection

### **Duration of Approval:**

12 weeks (for use with Ledipasvir/Sofosbuvir combination)