

Witness Name: Barry Fitzgerald

Statement No.: WITN2819001

Exhibits: WITN2819002 -

WITN2819015

Dated: 12 August 2019

INFECTED BLOOD INQUIRY

EXHIBIT WITN2819008

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Hepatitis C Nurses

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31/7/14



Dear Doctor,

Re: JANE FITZGERALD DOB: GRO-C 1961 HOSP.NO 3889014

THIS DOCUMENT CONTAINS ESSENTIAL INFORMATION. PLEASE READ

Sofosbuvir, Ribavirin and Ledipasvir

Your patient has commenced anti-viral therapy with **Sofosbuvir, Ribavirin and Ledipasvir** today for the treatment of chronic hepatitis C.

This is part of an early access programme as your patient has cirrhosis and has been assessed as needing priority access to these drugs. **Ledipasvir** is not licensed.

The treatment

Sofosbuvir, Ribavirin and Ledipasvir are used in combination. These drugs are not for single use.

What will happen to your patient?

The duration of therapy will be for 12 weeks.

Sofosbuvir (400mg) and Ledipasvir (90mg) is a combined tablet taken once a day.

Ribavirin tablets (weight-based dosing) are to be taken in the morning and evening each day with or after food. We will advise the patient what dose of this to take.

Ribavirin has been shown to be teratogenic and embryotoxic and is secreted in semen. It is therefore essential that patients and their partners use 2 forms of contraception (condoms plus a 2nd contraceptive) for the duration of their treatment and for six months after. Female patients are required to have a pregnancy test on the day of initiation and monthly thereafter

Monitoring during treatment

Patients will have regular visits at the hospital. These are weekly for the first 4 weeks and fortnightly thereafter until the end of treatment. Additional blood tests may be required if clinically indicated; these can be performed locally if needed. At the end of treatment patients will be required to attend at weeks 2, 4, 8 and 12 -post cessation of therapy.

At each visit blood tests will be performed and adverse drug reactions will be monitored. Virological response will be assessed by a HCV RNA test which will be checked at week 2, 4, 8 and 12 of treatment.

6 months post-treatment a HCV RNA test will be performed, if negative this means the patient has cleared their virus. However, they will always remain hepatitis c antibody positive, these are not protective and patients are advised that they will be susceptible to infection if re-exposed.

Common side effects

Sofosbuvir

- Fatigue
- Headache
- Nausea
- Insomnia
- Pruritus
- Asthenia (weakness)

Ribavirin

- Anaemia. This is usually mild and is reversible. On occasion dose reduction and/or discontinuation may be required.
- Localised or generalised itching
- Rash
- Dry cough
- Muscular aches

Ledipasvir

- Fatigue
- Nausea
- Anaemia
- Upper respiratory tract infection
- Headaches
- Insomnia

If patients develop any signs of infection or decompensation it is essential the hepatology service is contacted as soon as possible (see contact details below).

Additional Information

If side effects are not tolerable the dose of Ribavirin may be reduced or discontinued. **It is not possible to stop, or reduce the dose of Sofosbuvir or Ledipasvir.**

There are potential drug-drug interactions with Ledipasvir and Sofosbuvir and care should be taken when prescribing any additional medications for this patient. Interaction data is available for Sofosbuvir at www.hep-druginteractions.org. For drug interaction advice on Ledipasvir please contact:

- Hepatology pharmacist (Julie Major) on bleep **GRO-C**
- Medicines Information (Mon-Fri 9am - 5pm) 02381 20 6908 or MedicinesInformation@uhs.nhs.uk
- Hepatology nurses team on 02381 20 4617
- Hepatology Registrar/Consultant via switchboard (02380 777222)

Should you have any further queries please contact us by phone or at the above address.

Yours sincerely

GRO-C: R. Robbins

Hepatology Nurse Specialist