Liposomal Amphotericin B 50mg
Powder for Concentration for Dispersion for
Infusion
(Gilead Sciences Ireland UC Ireland) HA705

WHOPAR part 5
supplier's submission

March 2021

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON (10 VIALS)

1.	NAME OF THE MEDICINAL PRODUCT

AmBisome®

Liposomal Amphotericin B 50mg

Powder for Concentrate for Dispersion for Infusion

2.	STATEMENT OF ACTIVE SUBSTANCE(S)

Each vial contains 50mg of amphotericin B encapsulated in liposomes consisting of

3.	LIST OF EXCIPIENTS

hydrogenated soy phosphatidylcholine
cholesterol
distearoylphosphatidylglycerol
and alpha-tocopherol
together with 900mg sucrose
disodiumsuccinate hexahydrate
sodium hydroxide and hydrochloric acid

See leaflet for further information

4.	PHARMACEUTICAL FORM AND CONTENTS

10 Single dose vials, sterile

5.	METHOD AND ROUTE(S) OF ADMINISTRATION

FOR INTRAVENOUS INFUSION ONLY.
See package insert for reconstitution and administration.
This product is intended to be reconstituted with water for injection and diluted with a dextrose solution.
Follow directions exactly.
For use on one occasion only.
Discard any unused surplus.
See package insert for guidance on reconstitution and administration

6.	SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the sight and reach of children.

Liposomal Amphotericin B 50mg
Powder for Concentration for Dispersion for
Infusion
(Gilead Sciences Ireland UC Ireland) HA705

WHOPAR part 5
supplier's submission

March 2021

7.	OTHER SPECIAL WARNING(S), IF NECESSARY

AmBisome is not interchangeable with other amphotericin products.

8.	EXPIRY DATE

Expiry Date:

9.	SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

10.	SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11.	NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Product authorization holder:
Gilead Sciences Ireland UC
Ida Business & Technology Park
Carrigtohill,
Co Cork,
Ireland

Manufacturer:
Gilead Sciences Ireland UC,
Carrigtohill, County Cork, Ireland

12.	MARKETING AUTHORISATION NUMBER(S)

P.A. 2322/001/001

13.	BATCH NUMBER

Lot:

14.	GENERAL CLASSIFICATION FOR SUPPLY

15.	INSTRUCTIONS ON USE

16.	INFORMATION IN BRAILLE

17.	UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18.	UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC: {number}
SN: {number}