

Consumer Medicine Information

AmBisome[®] (liposomal amphotericin) for injection

Please read this leaflet carefully before you start to take your medicine, even if you have taken this medicine before.

The medicine your doctor has prescribed for you is called AmBisome[®] for Injection. This is the brand name of a drug called **liposomal amphotericin**.

This leaflet is only a summary of information. Ask your doctor or pharmacist if you have any questions or are not sure about your treatment with AmBisome. They will have more detailed information.

WHAT IS AMBISOME USED FOR AND HOW DOES IT WORK?

AmBisome contains amphotericin which is an antibiotic that belongs to a group of medicines called antifungals.

It is used to help the body overcome serious fungal infections by either killing the fungus or stopping it spreading.

Amphotericin is also used to treat a disease which is rare in Australia called leishmaniasis.

WHAT DO I NEED TO KNOW BEFORE AND WHILE TAKING THE MEDICINE?

You should always follow the advice given to you by your

doctor or pharmacist. This leaflet is not a substitute for things that your doctor or pharmacist tell you or should tell you, based on your individual circumstances.

DO NOT TAKE AmBisome IF YOU:

- have ever had a reaction to amphotericin or any other ingredient in the injection. For information on ingredients, see the section headed **“What is in AmBisome?”**

If you have not done so already, it is important to tell your doctor or pharmacist immediately about the following things, which may have particular relevance to your treatment.

- **Medical problems.** Tell your doctor or pharmacist if you presently have, or have ever had, any medical problems especially any of the following:
 - kidney disease
 - liver disease
 - diabetes
- **Current medicines.** Tell your doctor or pharmacist about any other medicines you are currently taking, whether they are prescription or non-prescription medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines (not all brand names included):

- anticancer agents (chemotherapy)
- digoxin (e.g. Lanoxin[®])
- flucytosine (e.g. Ancotil[®])

- cortisone-like medicine (e.g. hydrocortisone, betamethasone, dexamethasone, prednisolone, methylprednisolone)
- corticotrophin (e.g. Acthargel)
- dipyridamole (e.g. Persantin[®])
- **Other medicines.** While taking AmBisome do not take any other medicines, whether they are prescription or non-prescription medicines unless they have been approved or recommended by a doctor or pharmacist. Before any doctor or pharmacist gives you any other medicines, make sure they know you are receiving treatment with AmBisome.
- **Allergies.** Tell your doctor or pharmacist if you are sensitive or allergic to:
 - amphotericin
 - any of the ingredients listed under **“What is in AmBisome?”**
 - any foods, dyes or preservatives
 - any other medicines
- **Pregnancy.** Tell your doctor or pharmacist if you are pregnant or if you become pregnant while you are receiving treatment with AmBisome.
- **Breast-feeding.** Tell your doctor or pharmacist if you are breast-feeding or if you want to start breast-feeding whilst taking AmBisome.

HOW DO I TAKE AMBISOME PROPERLY?

AmBisome is to be administered only by or under the supervision of your doctor.

AmBisome must be reconstituted using Water for Injection and then filtered using a 5-micron filter into the correct amount of 5% Glucose Injection. It is given as a long running infusion (e.g. a slow injection via a “drip” into a vein).

WHAT ABOUT THE SIDE EFFECTS?

Like other medicines AmBisome may cause side effects. If they occur most are minor and temporary. However, some side effects may be serious and require medical attention.

Check with your doctor immediately if you have any problems while you are taking AmBisome, even if you do not think the problems are connected with the medicine or if the effects are not listed in this leaflet. Your doctor will be able to tell you what to do.

Before you begin treatment with AmBisome, it is advised you and your doctor talk about the good this medicine can do as well as the risks of using it.

- **Common side effects.**
 - nausea and vomiting
 - rash
 - mild headaches

- **Less common side effects.** The following side effects have been reported:

- back pain
- joint pain and bone pain
- fever, chills
- chest tightness
- kidney problems
- liver problems

Check with your doctor or pharmacist if you experience or do not understand any of the side effects described above.

The above list is **not** a complete list of all possible side effects. Other side effects not listed above may occur in some patients. Also, as with any medicine, there may be other effects which are not yet known. If you notice any other effects, check with your doctor.

WHAT IF I TAKE TOO MUCH AMBISOME?

Severe side effects due to AmBisome are more likely to occur at high doses, particularly if you receive an overdose. Symptoms of AmBisome overdose include the side effects listed above, but are usually of a more severe nature.

As AmBisome is most likely to be given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose. However, if you experience severe side effects tell your doctor immediately.

WHAT ABOUT STORING AMBISOME?

It is important to store your medicine properly. Guidelines for proper storage include:

- Keep out of reach of children.
- Do not keep or use the medicine after the expiry date marked on the packet.
- Store AmBisome below 25 °C.

AmBisome can only be obtained with a prescription.

REMEMBER THIS MEDICINE IS FOR YOU.

Never give it to anyone else even if his or her symptoms seem to be the same as yours.

WHAT IS IN AMBISOME?

Each injection contains amphotericin equivalent to 50 mg of amphotericin B plus hydrogenated soy phosphatidylcholine, cholesterol, distearoylphosphatidylglycerol (as the sodium salt), alpha tocopherol, sucrose and sodium succinate hexahydrate.

AUST R 53783

SPONSOR

Australia
Gilead Sciences Pty Ltd
Level 6, 417 St Kilda Road
Melbourne, Victoria 3004

New Zealand
Gilead Sciences (NZ)
c/- PricewaterhouseCoopers
Level 8 PricewaterhouseCoopers
Tower
188 Quay Street
Auckland 1010

AmBisome[®] is a registered trademark licensed to Gilead Sciences Pty. Limited.

Date of Preparation: 10
September 2014