AMPHOTERICIN LIPOSOMAL SUN

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given AMPHOTERICIN LIPOSOMAL SUN?

AMPHOTERICIN LIPOSOMAL SUN contains the active ingredient liposomal amphotericin B (amphotericin). AMPHOTERICIN LIPOSOMAL SUN is used to help the body overcome serious fungal infections by either killing the fungus or stopping it spreading. For more information, see Section 1. Why am I being given AMPHOTERICIN LIPOSOMAL SUN? in the full CMI.

2. What should I know before I am given AMPHOTERICIN LIPOSOMAL SUN?

Do not use if you have ever had an allergic reaction to this medicine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given AMPHOTERICIN LIPOSOMAL SUN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with this medicine and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is AMPHOTERICIN LIPOSOMAL SUN given?

AMPHOTERICIN LIPOSOMAL SUN is to be administered only by or under the supervision of your doctor.

More instructions can be found in Section 4. How is AMPHOTERICIN LIPOSOMAL SUN given? in the full CMI.

5. What should I know while being given AMPHOTERICIN LIPOSOMAL SUN?

Things you should do	Remind any doctor, dentist or pharmacist or other health professionals you visit that you are using this medicine.	
Driving or using machines	Be careful before you drive or use any machines or tools until you know how this medicine affects you.	
Drinking alcohol	Tell your doctor if you drink alcohol.	
Looking after your medicine	 AMPHOTERICIN LIPOSOMAL SUN should be stored in the pharmacy or on the hospital ward. Keep out of reach of children. Do not keep or use the medicine after the expiry date marked on the packet. Unopened vials of AMPHOTERICIN LIPOSOMAL SUN should be stored below 25 °C. Do not use this medicine after the expiry date. 	

For more information, see Section 5. What should I know while being given AMPHOTERICIN LIPOSOMAL SUN? in the full CMI.

6. Are there any side effects?

You may experience the following side effects: back pain, joint pain and bone pain, fever, chills, chest tightness, kidney problems, and liver problems. Tell your doctor if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about using this medicine. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using this medicine.

Where to find information in this leaflet:

- 1. Why am I being given AMPHOTERICIN LIPOSOMAL SUN?
- 2. What should I know before I am given AMPHOTERICIN LIPOSOMAL SUN?
- 3. What if I am taking other medicines?
- 4. How is AMPHOTERICIN LIPOSOMAL SUN given?
- 5. What should I know while being given

AMPHOTERICIN LIPOSOMAL SUN?

- 6. Are there any side effects?
- 7. Product details

1. Why am I being given AMPHOTERICIN LIPOSOMAL SUN?

AMPHOTERICIN LIPOSOMAL SUN contains the active ingredient liposomal amphotericin B (amphotericin). AMPHOTERICIN LIPOSOMAL SUN belongs to a group of medicines called antifungals.

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

Amphotericin B (amphotericin) is also used to treat a disease which is rare in Australia called leishmaniasis.

2. What should I know before I am given AMPHOTERICIN LIPOSOMAL SUN?

Warnings

Do not use this medicine if:

- you are allergic to amphotericin B (amphotericin), or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes. have any other medical conditions
- have, or have had, any of the following medical conditions:
 - o kidney disease
 - liver disease
 - o diabetes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and

how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

AMPHOTERICIN LIPOSOMAL SUN is not recommended during breastfeeding, as it may pass into breast milk.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and AMPHOTERICIN LIPOSOMAL SUN may interfere with each other. These include:

- 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)

Some medicines may interfere with AMPHOTERICIN LIPOSOMAL SUN and affect how it works.

You may need different amounts of the medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect AMPHOTERICIN LIPOSOMAL SUN.

4. How is AMPHOTERICIN LIPOSOMAL SUN given?

How will it be given?

AMPHOTERICIN LIPOSOMAL SUN is to be administered only by or under the supervision of your doctor.

AMPHOTERICIN LIPOSOMAL SUN 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).

If you use too much this medicine

AMPHOTERICIN LIPOSOMAL SUN is most likely given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose.

Severe side effects due to AMPHOTERICIN LIPOSOMAL SUN are more likely to occur at high doses, particularly if

you receive an overdose. Symptoms of AMPHOTERICIN LIPOSOMAL SUN overdose include the side effects listed, but are usually of a more severe nature.

However, if you experience any severe side effects after being given AMPHOTERICIN LIPOSOMAL SUN, tell your doctor or nurse immediately.

5. What should I know while being given AMPHOTERICIN LIPOSOMAL SUN?

Things you should do

Tell your doctor if you notice anything else that is making you feel unwell.

Remind any doctor, dentist or pharmacist you visit that you are using this medicine.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how this medicine affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

AMPHOTERICIN LIPOSOMAL SUN should be stored in the pharmacy or on the hospital ward.

Unopened vials of AMPHOTERICIN LIPOSOMAL SUN should be stored below 25 °C.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects		What to do
•	Nausea and vomiting Rash Mild headaches	Speak to your doctor or nurse if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
 Back pain Joint pain and bone pain Fever, chills Chest tightness Kidney problems Liver problems 	Call your doctor or nurse straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or nurse if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What this medicine contains

Active ingredient (main ingredient)	Amphotericin equivalent to 50 mg of amphotericin B (amphotericin)
Other ingredients (inactive ingredients)	 hydrogenated soy phosphatidylcholine, cholesterol, 1,2-distearoyl-sn-glycero-3-phospho-(1'-rac-glycerol) sodium dl-alpha tocopherol, sucrose and sodium succinate hexahydrate.

Do not take this medicine if you are allergic to any of these ingredients.

What this medicine looks like

AMPHOTERICIN LIPOSOMAL SUN is a sterile, yellow coloured lyophilised product for intravenous infusion. AUST R 380963

Who distributes this medicine

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