Package leaflet: Information for the user

Amphotericin B SUN Pharma liposomal 50 mg powder for dispersion for infusion
liposomal amphotericin B

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Amphotericin B SUN Pharma liposomal is and what it is used for

Amphotericin B SUN Pharma liposomal is an antifungal antibiotic. The active ingredient in Amphotericin B SUN Pharma liposomal is amphotericin B.

Amphotericin B SUN Pharma liposomal is given as an infusion into a vein (a drip) in hospital by a doctor or nurse.

Amphotericin B SUN Pharma liposomal has been studied in patients aged one month and above.

Amphotericin B SUN Pharma liposomal is used to treat serious infections caused by fungi:
- fungal infections of one or more deep organs of the body
- Suspected fungal infections in patients who have a raised temperature and a low white blood cell count called neutropenia.

Before you are given Amphotericin B SUN Pharma liposomal your doctor will check that your fever is not due to bacteria or viruses and will try and treat the infection with a course of antibiotics
- visceral leishmaniasis, a disease caused by a parasite.

2. What you need to know before you are given Amphotericin B SUN Pharma liposomal

Before your first treatment
Before your first treatment your doctor may give you a small amount of Amphotericin B SUN Pharma liposomal. They will then wait for approximately 30 minutes to see whether you have an allergic reaction, before continuing the infusion of the full dose.

Your doctor will not give you Amphotericin B SUN Pharma liposomal
- If you are allergic (hypersensitive) to Amphotericin B or any of the other ingredients of this medicine (see section 6.1). However, if your condition is life-threatening you may be given Amphotericin B SUN Pharma liposomal if your doctor believes that only Amphotericin B SUN Pharma liposomal can help you.
- If you have previously experienced a severe allergic reaction (anaphylactic or anaphylactoid) to Amphotericin B SUN Pharma liposomal. Symptoms of such immediate and life-

threatening allergic reactions include: flushing, itching, sickness, swelling of the face, mouth, tongue and airways, often enough to cause difficulty breathing.
Tell your doctor if any of these applies to you, you must not be given Amphotericin B SUN Pharma liposomal

Warnings and precautions

Your doctor will take special care with Amphotericin B SUN Pharma liposomal
- If you have a severe allergic (anaphylactic) reaction. If this happens your doctor will stop the infusion.
- If you get other reactions related to the infusion. If this happens, your doctor may slow down the infusion, so you receive Amphotericin B SUN Pharma liposomal over a longer period of time (approximately 2 hours). Your doctor may also give you medicines to prevent or treat infusion-related reactions, such as diphenhydramine (an antihistamine), paracetamol, pethidine (for pain relief) and/or hydrocortisone (an anti-inflammatory medicine that works by reducing the response of your immune system).
- If you are taking other medicines that may cause kidney damage (see "Other medicines and Amphotericin B SUN Pharma liposomal"). Amphotericin B SUN Pharma liposomal may cause damage to the kidney. Your doctor or nurse will take blood samples. This is to test creatinine (a chemical in the blood that reflects kidney function), and electrolyte levels (particularly potassium and magnesium) before and during the treatment with Amphotericin B SUN Pharma liposomal because both of these can be abnormal if you have kidney problems. This is particularly important if you have previous renal damage or if you are taking other medicines that may cause damage to the kidney. The blood samples will also be tested for changes in your liver, and your body's ability to produce new blood cells and platelets. If blood tests show a change in kidney function, or other important changes. If this happens, your doctor may give you a lower dose of Amphotericin B liposomal or stop treatment.
- If blood tests show that your potassium levels are low. If this happens, your doctor may prescribe a potassium supplement for you to take while you are treated with Amphotericin B SUN Pharma liposomal.
- If blood test shows that your potassium levels are high you may suffer irregular heartbeat, sometimes severe.
- If you are receiving or recently had a white blood cell transfusion. Sudden and severe problems in the lungs can happen if you are given Amphotericin B SUN Pharma liposomal infusion during or shortly after a white blood cell transfusion. Your doctor will recommend that the infusions are separated by as long a period as possible. This will reduce the risk of lung problems, and your lungs will be monitored.
- If you have had kidney failure and are having dialysis. Your doctor may start Amphotericin B SUN Pharma liposomal treatment after the procedure has ended.
- If you have diabetes. Amphotericin B SUN Pharma liposomal contains approximately 900 mg of sucrose (sugar) in each vial. Tell your doctor if you have diabetes.

Other medicines and Amphotericin B SUN Pharma liposomal
Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription and herbal medicines.

Medicines that may cause kidney damage
- medicines that suppress the immune system (immunosuppressants), such as ciclosporin and tacrolimus
- certain antibiotics called aminoglycosides (including gentamicin, neomycin and streptomycin) and polymixins
- pentamidine a medicine used to treat pneumonia in people with AIDS and leishmaniasis.

Tell your doctor if you are taking any of these medicines. Amphotericin B SUN Pharma liposomal may make any kidney damage caused by the medicine worse. If you are taking any of these medicines, your doctor or nurse will take regular blood samples to check your kidneys.

Medicines that may lower your potassium levels
- corticosteroids, anti-inflammation medicines that work by reducing the response of your immune system
- corticotropin (ACTH), used to control the amount of corticosteroid produced by your body. The body produces corticosteroid in response to stress.
- diuretics, medicines that increase the amount of urine your body produces. This includes furosemide
- digitalis glycosides, medicines produced from the foxglove plant and used to treat heart failure. Amphotericin B SUN Pharma liposomal may worsen the side effects of digitalis, such as heart rhythm changes
- muscle relaxants usually used during surgery, such as tubocurarine. Amphotericin B SUN Pharma liposomal may increase the muscle relaxant effect.

Tell your doctor if you are taking any of these medicines or have had recent surgery where these drugs may have been used.

Other medicines
- antifungal medicines, such as flucytosine. Amphotericin B SUN Pharma liposomal may worsen the side effects of flucytosine. This includes changes in the body's ability to produce new blood cells. This may be seen in blood tests.
- certain cancer medicines, such as methotrexate, doxorubicin, carmustine and cyclophosphamide. Taking this type of medicine with Amphotericin B SUN Pharma liposomal may cause kidney damage, wheezing or trouble breathing and low blood pressure.
- white blood cell (leukocyte) transfusions. Sudden and severe problems in the lungs can happen if you are given Amphotericin B SUN Pharma liposomal infusion during or shortly after a white blood cell transfusion. Your doctor will recommend that the infusions are separated by as long a period as possible. This will reduce the risk of lung problems and your lungs will be monitored

Tell your doctor if you are taking any of these medicines or receiving such transfusions.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Your doctor will only prescribe Amphotericin B SUN Pharma liposomal if they think the benefits of treatment outweigh the risks to you and your unborn child or your baby.

Driving and using machines
Do not drive or operate machinery.
Some of the possible side effects of Amphotericin B SUN Pharma liposomal could affect your ability to drive or use machines safely (see section 4 "Possible side effects").

Amphotericin B SUN Pharma liposomal contains sugar
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Amphotericin B SUN Pharma liposomal contains sodium
Amphotericin B SUN Pharma liposomal contains less than 1 mmol sodium (23 mg) per maximum daily dose, that is to say, 'sodium- free'.

Amphotericin B SUN Pharma liposomal contains soya oil

Amphotericin B SUN Pharma liposomal contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

3. How to use Amphotericin B SUN Pharma liposomal
Amphotericin B SUN Pharma liposomal is always given to you by a doctor or nurse. It is given into a vein (a drip). Amphotericin B SUN Pharma liposomal must not be given by any other method.

To prepare the infusion Amphotericin B SUN Pharma liposomal must be dissolved in sterile water for injection and then diluted with a solution containing dextrose.
Amphotericin B SUN Pharma liposomal must not be mixed with saline (salt) solutions or with other medicinal products or electrolytes.

Amphotericin B SUN Pharma liposomal is not interchangeable with other amphotericin products.

Before your first treatment
Before your first treatment your doctor may give you a small amount of Amphotericin B SUN Pharma liposomal. They will then wait for approximately 30 minutes to see whether you have an allergic reaction, before continuing the infusion of the full dose.

Use in adults and in elderly people
Your dose of Amphotericin B SUN Pharma liposomal will depend on your body weight and your own particular needs.

Fungal infections of one or more organs of the body
Treatment is normally started at 1 mg per kg of body weight, every day over 2 to 4 weeks. Your doctor may decide to increase the amount you receive to as high as 3 mg per kg of body weight.
For mucormycosis the starting dose is normally 5 mg per kg of body weight per day. The duration of therapy will be determined on an individual basis by your doctor.

Suspected fungal infections in patients with a raised temperature and neutropenia
Treatment is normally started at 1 mg per kg body weight, per day. Your doctor may decide to increase the amount you receive to as high as 3 mg per kg body weight.

Visceral leishmaniasis
The usual dose is 1 to 1.5 mg per kg body weight, per day for 21 days, or 3 mg per kg body weight for 10 days.

If you have a severely weakened immune system (for instance, if you are HIV positive), the dose is 1 to 1.5 mg per kg body weight for 21 days. Due to the risk of re-infection, on-going treatment or a further course of treatment may be needed.

Use in children
Amphotericin B SUN Pharma liposomal has been used to treat children. The dose of Amphotericin B SUN Pharma liposomal for a child is calculated per kg of body weight in the same way as for adults.
Amphotericin B SUN Pharma liposomal is not recommended in babies under 1 month old.
Use in patients with kidney problems
No change in dose or frequency of infusion is required. Your doctor or nurse will take regular blood samples to test for changes in kidney function during Amphotericin B SUN Pharma liposomal treatment.

How long will the infusion take?
Normally the infusion will take 30 to 60 minutes. For doses greater than 5 mg per kg of body weight per day, the infusion could take up to 2 hours.

If you receive a higher dose of Amphotericin B SUN Pharma liposomal than you should

You should tell your doctor immediately if you think you received too much Amphotericin B SUN Pharma liposomal.
If you have any further questions on the use of this product, ask your doctor.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.
Tell your doctor immediately if you have a severe allergic reaction, chest pain, develop an irregular heart beat or kidney problems (signs include tiredness and passing less urine).

Severe allergic reaction side effects may include: skin rash, difficulty breathing, wheezing, chest tightness, swelling of the airways/tongue/face/hands or feet, loss of consciousness, confusion or dizziness, rapid or irregular heart beat, vomiting and nausea.

Side effects during the infusion
You may get side effects during the infusion:

Very common (may affect more than 1 in 10 people)
- fever, chills, and shivering.

Less frequent infusion-related side effects include
- chest tightness
- chest pain
- breathlessness
- difficulty breathing (possibly with wheezing)
- flushing
- a faster heart rate than normal
- low blood pressure
- musculoskeletal pain (described as joint pain, back pain, or bone pain).

These side effects clear up quickly when the infusion is stopped. These reactions may not happen with future infusions of Amphotericin B SUN Pharma liposomal or with a slower infusion (over 2 hours). Your doctor may give you other medicines to prevent infusion-related reactions, or to treat the symptoms if you do get them. If you have a severe infusion-related reaction, your doctor will stop the Amphotericin B SUN Pharma liposomal infusion and you should not receive this treatment in the future.

Very common side effects (may affect more than 1 in 10 people)
- low blood potassium levels, leading to feeling tired, confused, having muscle weakness or cramps
- feeling sick or being sick
- fever, chills or shivering.

Common side effects (may affect up to 1 in 10 people)
- low magnesium, calcium or sodium blood levels, leading to feeling tired, confused, muscle weakness or cramps
- high blood sugar levels
- headache
- a faster heart rate than normal
- widening of the blood vessels, causing low blood pressure and flushing
- breathlessness
- diarrhoea
- stomach (abdominal) pain
- rash
- chest pain

- back pain
- abnormal results for liver or kidney function showing up in blood tests or urine tests.
- high blood potassium levels

Uncommon side effects (may affect up to 1 in 100 people)
- bleeding into the skin, unusual bruising and bleeding for a long time after injury
- severe allergic (anaphylactoid) reaction
- fits or seizures (convulsions)
- difficulty breathing, possibly with wheezing.

Not known (frequency cannot be estimated from the available data)
- low red blood cell levels (*anaemia*), with symptoms of excessive tiredness, being out of breath after light activity, and a pale complexion
- Heart attacks
- Kidney failure
- Severe swelling of the skin around the lips, eyes or tongue
- Breakdown of muscle
- Bone pain and joint pain

Interference with phosphorus blood test results
This medicine may interfere with a particular blood test that measures levels of phosphorus (called the PHOSm assay). Please tell your doctor that you are receiving this medicine before such blood tests.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Amphotericin B SUN Pharma liposomal
Amphotericin B SUN Pharma liposomal is stored in the pharmacy.

Keep this medicine out of the sight and reach of children.

Do not use Amphotericin B SUN Pharma liposomal after the date which is stated on the label after {EXP}. The expiry date refers to the last day of the month.

This product does not require any special storage condition. Do not store partially used vials for future patient use.

Amphotericin B SUN Pharma liposomal is a single dose, unpreserved, sterile, freeze-dried yellow powder to be dissolved in water for injection and diluted with a dextrose solution before infusion into a vein. From a microbiological point of view, the product should be used immediately once dissolved and diluted. If it is not used immediately, in-use storage times and conditions prior to use are the responsibility of the doctor or pharmacist and would normally not be longer than 24 hours at 2°C to 8°C unless reconstitution (dissolving the powder in water for injection) and dilution have taken place in controlled conditions to prevent microbial contamination.
Where reconstitution (dissolving the powder in water for injection) and dilution with dextrose solution are carried out under controlled conditions the storage time varies depending on the concentration of dextrose used and the storage temperature. Please refer to the Summary of Product Characteristics for further information.

Do not use Amphotericin B SUN Pharma liposomal if there is any evidence of deterioration or foreign matter.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Amphotericin B SUN Pharma liposomal contains

- The active substance is liposomal amphotericin B. Each vial contains 50 mg of amphotericin B enclosed inside liposomes (small fat particles).
- The other ingredients are hydrogenated soy phosphatidylcholine, distearoylphosphatidylglycerol sodium, cholesterol, alpha tocopherol, sucrose, disodium succinate hexahydrate, sodium hydroxide and hydrochloric acid.

What Amphotericin B SUN Pharma liposomal looks like and contents of the pack
Amphotericin B SUN Pharma liposomal is a sterile yellow to dark yellow lyophilised cake or powder packed in 20 ml Type I clear glass vials with a grey butyl rubber stopper and a golden flip-off seal.

Amphotericin B SUN Pharma liposomal is supplied in packs of 1 vial or 10 vials together with 1 or 10 filters, respectively.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Sun Pharmaceuticals Industries Europe B.V.
Polarisavenue 87
2132 JH Hoofddorp
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Manufacturers
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This leaflet was last revised in June 2025

The following information is intended for healthcare professionals only:
READ THIS ENTIRE SECTION CAREFULLY BEFORE BEGINNING RECONSTITUTION.
Amphotericin B SUN Pharma liposomal is NOT interchangeable with other amphotericin products.
Amphotericin B SUN Pharma liposomal must be reconstituted using Sterile Water for Injection (without a bacteriostatic agent) and diluted in Dextrose solution (5%, 10% or 20%) for infusion only.
The use of any solution other than those recommended, or the presence of a bacteriostatic agent (e.g. benzyl alcohol) in the solution, may cause precipitation of Amphotericin B SUN Pharma liposomal.
Amphotericin B SUN Pharma liposomal is NOT compatible with saline and must not be reconstituted or diluted with saline or administered through an intravenous line that has previously been used for saline unless first flushed with dextrose solution (5%,10% or 20%) for infusion. If this is not feasible, Amphotericin B SUN Pharma liposomal should be administered through a separate line.

Do NOT mix Amphotericin B SUN Pharma liposomal with other drugs or electrolytes. Aseptic technique must be observed in all handling, since no preservative or bacteriostatic agent is present in Amphotericin B SUN Pharma liposomal, or in the material specified for reconstitution and dilution. Vials of Amphotericin B SUN Pharma liposomal containing 50 mg of Amphotericin B are prepared as follows:

- Add 12 ml of water for injection to each Amphotericin B SUN Pharma liposomal vial, to yield a preparation containing 4 mg/ml amphotericin B.

- IMMEDIATELY after the addition of water, SHAKE THE VIAL VIGOROUSLY for 30 seconds to completely disperse the Amphotericin B SUN Pharma liposomal. After reconstitution the concentrate is a translucent, yellow dispersion. Visually inspect the vial for particulate matter and continue shaking until complete dispersion is obtained. Do not use if there is evidence of precipitation of foreign matter.

- Calculate the amount of reconstituted Amphotericin B SUN Pharma liposomal (4 mg/ml) to be further diluted (see table below).

- The infusion solution is obtained by dilution of the reconstituted Amphotericin B SUN Pharma liposomal with between one (1) and nineteen (19) parts dextrose solution (5%, 10% or 20%) for infusion by volume, to give a final concentration in the recommended range of 2.00mg/ml to 0.20mg/ml amphotericin B as Amphotericin B SUN Pharma liposomal (see table below).

- Withdraw the calculated volume of reconstituted Amphotericin B SUN Pharma liposomal into a sterile syringe. Using the 5-micron filter provided, instill the Amphotericin B SUN Pharma liposomal preparation into a sterile container with the correct amount of Dextrose solution (5%, 10% or 20%) for infusion.

An in-line membrane filter may be used for intravenous infusion of Amphotericin B SUN Pharma liposomal. However, the mean pore diameter of the filter should not be less than 1.0 micron.

Preparation of Amphotericin B SUN Pharma liposomal for Infusion
An example is provided in the table below of the preparation of Amphotericin B SUN Pharma liposomal dispersion for infusion at a dose of **3mg/kg/day** in dextrose 5% solution for infusion. Note that this table relates to doses of **3mg/kg/day** only, however other doses than this may be prescribed for a patient. If a dose other than **3mg/kg/day** has been prescribed for a patient, then the appropriate calculations must be undertaken and the table cannot be used.

Example of the preparation of Amphotericin B SUN Pharma liposomal solution for infusion at a dose of **3mg/kg/day** in dextrose 5% solution for infusion

Weight (kg)	Number of vials	Amount Amphotericin B SUN Pharma liposomal (mg) to be withdrawn for further dilution	Volume of reconstituted Amphotericin B SUN Pharma liposomal (ml)*	To make up a 0.2 mg/ml concentration (1 in 20 dilution)		To make up a 2.0 mg/ml concentration (1 in 2 dilution)	
				Volume of 5% dextrose needed (ml)	Total volume (ml; Amphotericin B SUN Pharma liposomal plus 5% dextrose)	Volume of 5% dextrose needed (ml)	Total volume (ml; Amphotericin B SUN Pharma liposomal plus 5% dextrose)

10	1	30	7.5	142.5	150	7.5	15
25	2	75	18.75	356.25	375	18.75	37.5
40	3	120	30	570	600	30	60
55	4	165	41.25	783.75	825	41.25	82.5
70	5	210	52.5	997.5	1050	52.5	105
85	6	255	63.75	1211.25	1275	63.75	127.5

* The full contents of a vial(s) may not be required to prepare a dose for a patient.
Each vial of Amphotericin B SUN Pharma liposomal (50 mg) is reconstituted with 12 ml Water for Injection to provide a concentration of 4 mg/ml amphotericin B.

For single use only. Discard any unused contents.
Any unused product or waste material should be disposed of in accordance with local requirements.