

ABELCET® Amphotericin Lipid Complex

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ABELCET (Amphotericin Lipid Complex). It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ABELCET against the benefits it is expected to have for you.

If you have any concerns about this medicine, ask your doctor or pharmacist.

Read this leaflet carefully before ABELCET is given to you and keep it. You may need to read it again.

What is ABELCET used for

ABELCET contains amphotericin, 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. It is not used to treat bacterial or viral infections.

ABELCET is only available with a doctor's prescription. It is not addictive.

If you have any questions about using ABELCET ask your doctor.

Before you start ABELCET

You must tell your doctor if:

- 1. You have ever had an allergic reaction to amphotericin, the active ingredient in ABELCET or an allergic reaction to any of the other ingredients of ABELCET listed at the end of this leaflet.**

You should not receive ABELCET if you are allergic to amphotericin or any of the

other ingredients in ABELCET, unless your doctor believes it is important for you to take it.

Symptoms of an allergic reaction may include:

- hives or an itchy skin rash
- swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing
- wheezing or troubled breathing
- faintness

- 2. You have kidney or liver problems or any other serious illness.**

Your doctor may need to consider whether you should receive ABELCET or change the way it is given to you.

- 3. You are pregnant or intend to become pregnant.**

Like most medicines ABELCET is not recommended during pregnancy or while breastfeeding. It is uncertain whether or not ABELCET can affect the unborn child. If it is necessary for you to receive this medicine, your doctor will discuss the risks and benefits of taking ABELCET.

- 4. You are breastfeeding or want to start breastfeeding.**

Some medicines can have harmful effects on the breast feeding baby. It is not known if ABELCET is passed into breast milk and therefore is not recommended for mothers who breast feed their babies.

- 5. You are taking medicines which may affect your kidneys.**

Some medicines may affect the way ABELCET works. As you are probably unsure which medicines may affect your kidneys, it is important to tell your doctor about any other medicines you are taking, including medicines you buy from a pharmacy, supermarket or health food shop.

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 (Lanoxin®)
- corticosteroids (e.g., hydrocortisone, betamethasone, dexamethasone,

prednisolone, methylprednisolone) and corticotrophin (ACTH, Acthar®)

- zidovudine (Retrovir®)
- cyclosporin (Neoral®, Sandimmun®)

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking ABELCET.

If you have not told your doctor about any of these things, tell him/her before you take ABELCET.

How to use ABELCET

ABELCET will be given to you by your doctor or nurse. It is usually given while in hospital.

The correct amount of ABELCET will be filtered and added to an IV bag containing glucose solution. It is given by intravenous infusion (slow injection into one of your veins via a "drip").

How much ABELCET to use

The amount of ABELCET you will be given depends on your body weight and will be decided by your doctor. The usual daily dose is 5.0 mg of ABELCET for every kilogram of body weight given as a single infusion over approximately 2 hours.

How long to use ABELCET

Treatment with ABELCET is usually for at least 14 days. Your doctor may decide to treat you for a longer or shorter time than this depending on the type of fungal infection you have and your body's response to ABELCET.

If you take too much (overdose)

Since ABELCET is given to you by a doctor or nurse, it is unlikely that you will receive an overdose. However if you experience any side effects tell your doctor immediately.

Should an overdose occur, your doctor will know how to treat you.

Side effects

Tell your doctor or pharmacist if you do not feel well while you are taking ABELCET, even if you do not think it is connected with the medicine.

Like other medicines, ABELCET may cause some side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects. Your doctor will know how to treat you if these occur.

The most common side effects of ABELCET are chills and fever.

You may be given medicine such as paracetamol (e.g. Panadol®) to help stop these side effects.

Tell your doctor or nurse immediately if you experience any of the following side effects:

- hives or an itchy skin rash
- swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing
- wheezing or troubled breathing
- faintness

These side effects could be signs of a serious allergic reaction which would require urgent medical attention and treatment. Your doctor will know how to treat you if these occur.

Some side effects may not give you any symptoms and can only be found when tests are done. While you are being treated with ABELCET, your doctor will conduct blood tests to frequently check your kidney, liver and blood functions to watch for possible side effects.

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

Tell your doctor if you notice anything that worries you or that is making you feel unwell, even if it is not on this list.

How ABELCET is stored

ABELCET is stored at 2°C - 8°C (refrigerate - do not freeze) and protected from light. It will usually be kept in the pharmacy department of the hospital where you are receiving the treatment and the infusion prepared there for you individually. Any unused solution from the preparation would be discarded.

The infusion is given to you as soon as practicable after the preparation. If it cannot be given to you immediately after preparation, it can be held at 2°C - 8°C for up to 24 hours.

Product Description

What it looks like

ABELCET is supplied as a yellow, opaque suspension for infusion in glass vials containing 20 mL. Each vial comes with a filter needle and is individually packed.

Ingredients

The active ingredient in ABELCET is amphotericin B.

Other ingredients:

- dimyristoylphosphatidylcholine
- dimyristoylphosphatidylglycerol
- sodium chloride
- water for injections

Manufacturer

ABELCET is manufactured in the USA by Sigma-Tau PharmaSource, Inc.

ABELCET is supplied in Australia by:

Orphan Australia Pty Ltd
300 Frankston-Dandenong Road
Dandenong 3175, Australia
www.orphan.com.au

Australian Registration Number

ABELCET AUST R 65406

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