▼ **This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.**

APLIDIN

(a-PLI-din)

plitidepsin (pli-tee-dep-sin) powder for solution for infusion

Consumer Medicine Information

What Is In This Leaflet

This leaflet answers some common questions about Aplidin powder for solution for infusion.

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 being given Aplidin against the benefits they expect it will have for you.

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

Keep this leaflet
You may want to read it again.

What Aplidin Is Used For

Aplidin contains the active substance plitidepsin. It is a type of medicine used to treat multiple myeloma which is a cancer of plasma cells (a type of white blood cell).

Aplidin is given to patients that have received prior treatments for their multiple myeloma. It will be given to you together with dexamethasone, which is another medicine used to your condition.

Ask your doctor or nurse if you have any questions about why this medicine has been prescribed for you.

This medicine is only available with a prescription from a doctor experienced with chemotherapy treatment.

There is no evidence that this medicine is addictive.

Before you are given Aplidin

When you should not be given it

You should not be given this medicine if you have an allergy to:

- plitidepsin
- the excipient, PEG-35 castor oil
- any of the other ingredients of this medicine, listed at the end of this leaflet.

If you think you may be allergic to Aplidin, ask your doctor for advice.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Unless you are advised by your doctor that it is necessary to be given Aplidin, you should not be given this medicine if:

- **you are pregnant**
- **you are breast-feeding**
- **you are a child or adolescent**
- **you have abnormal liver function**

You should not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

This medicinal product contains 15% vol ethanol (alcohol), i.e. up to 2137.5 mg per dose, which is equivalent to 54 mL beer or 22.5 mL wine per dose. The ability to drive and use machines may be affected. Patients should not drive or operate machinery during therapy with Aplidin.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Muscular symptoms:
Aplidin has been associated with muscle symptoms. Tell your doctor or nurse if you feel muscle weakness or muscular pain prior to starting treatment with Aplidin because this situation must be carefully assessed by your doctor before starting this therapy.

Tell your doctor if you:

1. **Are pregnant or plan to become pregnant**

   Women treated with Aplidin should avoid becoming pregnant, as potential risks exist for the unborn child.
   Men being treated with Aplidin should avoid fathering a child during treatment.
   Effective contraception must be used during treatment and for 6 months after the treatment.
   Only use Aplidin during pregnancy if your doctor tells you it is absolutely necessary.
   If a pregnancy should occur, you must tell your doctor immediately. Genetic counselling is recommended, since Aplidin can cause genetic damage.
   Your doctor can discuss with you the risks and benefits involved.

2. **Are breast-feeding or plan to breastfeed**

   Aplidin must not be given to patients who are breast-feeding. Stop breast-feeding before starting treatment with Aplidin, and do not begin breast-feeding again until your doctor has told you it is safe to do so.
   It is not known if Aplidin passes into breast milk.

3. **Have any gastrointestinal problems**

   Diarrhoea, nausea or vomiting may occur with Aplidin.

4. **Have any liver problems**

   Abnormal liver tests may occur with Aplidin.

5. **Have heart problems, or have ever taken medicine for your heart**

   Aplidin may cause heart problems, including abnormal hearth rhythm.

Aplidin should not be used in children and adolescents because it has not been studied in this population.

Aplidin contains ethanol and may moderately affect your ability to drive and use machines.

Taking other medicines

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

In particular, tell your doctor if you are using medicines containing any of the following active substances:

- ketoconazole, itraconazole or voriconazole, used to treat fungal infections
- rifampicin, telithromycin, clarithromycin, antibiotics used to treat bacterial infections
- carbamazepine, phenytoin or phenobarbital used to treat epilepsy
- St. John's Wort (*Hypericum perforatum*) or nefazodone, used for depression or other conditions.

How Aplidin is given

Aplidin is given to you in the hospital or clinic under the supervision of a physician experienced in the use of chemotherapy. Its use should be confined to qualified oncologists or other health professionals specialised in the administration of cytotoxic medicines.

How much is given

Aplidin is given in combination with dexamethasone, and the duration of each cycle of treatment is 28 days: Aplidin will be given to you on days 1 and 15 of each cycle, at the dose of 5 mg/m^2 of body surface area. Your doctor will determine the exact dose based on your height and weight. You will take dexamethasone on Day 1, 8, 15 and 22 of each cycle. So on days 1 and 15 you will receive the two medicines, first dexamethasone, and then Aplidin starting approximately one hour later. From day 23 to day 28 you will not receive either dexamethasone or Aplidin. Day 29 will be the first day of the next cycle of treatment.

How it is given

Before Aplidin is given to you, it will be reconstituted and diluted for intravenous use.

Aplidin will be given to you as an infusion (a drip) into a vein (intravenously) over a period of 3 hours.

If a peripheral venous line (an infusion into a blood vessel in your arm) is not possible, a central venous line (an infusion into a blood vessel in your chest or neck) will be used.

Before each infusion of Aplidin, you will be given other medicines to reduce the risk of nausea and vomiting, and allergic reactions.

How long it will be given for

The length of your whole treatment period will depend on your progress and how well you feel. Your doctor will tell you how long your treatment lasts. **If you have any further questions on the use of this medicine, ask your doctor.**

If too much is given (overdose)

As this medicine is being given by your doctor or nurse, it is unlikely that you will be given too much. In the unlikely event of an overdose, your doctor will monitor you for side effects treat any of your symptoms as required.

If you have any further questions on the use of this medicine, ask your doctor.

While You Are Being Given Aplidin

Things you must do

If you are about to be started on any new medicine, remind your doctor that you are being given Aplidin.

Tell any other doctors, dentists, and pharmacists who treat you that you are being given this medicine.

If you become pregnant while being given this medicine, tell your doctor immediately.

Things you must not do

If you experience side effects that impair your vision or balance, your ability to drive a car or operate machinery could be impaired.

Side Effects

All medicines may have some unwanted side effects, although not everybody gets them. Sometimes they are serious, most of the time they are not. Your doctor has weighed the risks of being given this medicine against the benefits they expect it will have for you.

Do not be alarmed by the following lists of side effects.

Tell your doctor as soon as possible if you do not feel well while you are taking Aplidin.
You may need medical attention if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Your doctor will perform certain checks periodically to test for side effects that may affect the blood, liver, kidneys, heart and muscle.

Tell your doctor if you notice any of the following side effects and they worry you:

Very common side effects (may affect more than 1 in 10 people):

- Nausea *(sickness)*, vomiting, diarrhoea
- Fatigue *(feel tired)*, oedema peripheral *(swelling of the arms or legs)*
- Decreased appetite.
- Myalgia *(muscle pain)*
- Muscular weakness

The above list includes the most common side effects of your medicine.

This is not a complete list of side effects. For any unexpected effects while taking Aplidin, contact your doctor immediately.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- Fever
- Aching muscles, muscle tenderness or weakness, not caused by exercise
- Dark (brown/black/cola) coloured urine
- Redness, pain or swelling at the injection site

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you get any of the following side effects:

Symptoms of an allergic reaction which may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin.

Symptoms of heart problems which may include:

- faster than normal heart beat
- irregular heart beats

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

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.

You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

After Being Given Aplidin

If you receive Aplidin and feel any of the symptoms mentioned above during the treatment, your doctor or nurse has to be informed. In case you suffer these symptoms, the Aplidin and/or dexamethasone dose may be omitted temporarily or reduced depending on the severity.

Allergic reactions to the infusion
Tell your doctor or nurse straight away if you feel unwell during infusion. Typical symptoms associated with allergic reactions are redness of the face or chest, itching, coughing, shortness of breath, chest discomfort, etc.Other symptoms may occur as well.

These side effects mostly occur during or after the infusion of the first dose. You will be monitored for signs of these effects during and after the infusion.

Depending on the seriousness of the allergic reactions, your infusion of Aplidin may be interrupted. You may require additional treatment to prevent complications and reduce your symptoms.

When the symptoms go away or improve, the infusion can be continued more slowly, and speeded up gradually if the symptoms do not recur. Your doctor may decide not to continue Aplidin treatment if you have a strong infusion reaction.

Your doctor may want to take additional precautions.

Storage

Aplidin will be stored in the pharmacy or the on the ward.

The medicine is kept in its original packaging in the refrigerator where the temperature stays between 2°C and 8°C.

Product Description

What it looks like

Aplidin is a powder for solution for intravenous infusion. Each carton contains 1 vial of powder (2 mg) and 1 ampoule of solvent (4 mL).

The powder is a white to off-white powder or solid cake. The solvent is a clear, slightly viscous liquid free of visible particles.

Ingredients

The active substance is plitidepsin.

The other ingredients are:

Powder
Mannitol

Solvent
PEG-35 castor oil
Ethanol
Water for injections

Sponsor

Specialised Therapeutics Pharma Pty Ltd
Level 2, 17 Cotham Road,
Kew, Victoria, 3101
Ph: 1300 798 820
Fax: 1800 798 829
www.stbiopharma.com

Australian Register Number

1 single pack containing 2 mg powder (1 vial) and 4 mL solvent (1 ampoule): AUST R 291661

This leaflet was prepared by Specialised Therapeutics Pharma Pty Ltd

Last revised: 10 December 2018