DBL™ Aciclovir

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 using DBL Aciclovir?

DBL Aciclovir contains the active ingredient aciclovir. DBL Aciclovir is an antiviral medicine, used for the management of certain infections caused by viruses, such as herpes and shingles.

For more information, see Section <u>1. Why am I using</u> <u>DBL Aciclovir?</u> in the full CMI.

2. What should I know before I use DBL Aciclovir?

Do not use if you have ever had an allergic reaction to aciclovir, valaciclovir, 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 use DBL Aciclovir? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Aciclovir 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 do I use DBL Aciclovir?

- DBL Aciclovir is given by slow infusion directly into the bloodstream. It is administered by a doctor or nurse.
- Your doctor will decide what dose you will receive.
 This depends on your condition and other factors, such as your weight.

More instructions can be found in Section <u>4. How do I</u> use DBL Aciclovir? in the full CMI.

5. What should I know while using DBL Aciclovir?

Things you should do

 You should drink plenty of fluids as instructed by your doctor or nurse. If you are unable to drink, due to your condition, your doctor will ensure

	that you receive plenty of fluids.
Things you should not do	 Do not use if you have ever had an allergic reaction to aciclovir, valaciclovir, or any of the ingredients listed at the end of the CMI.
Driving or using machines	 Be careful before you drive or use any machines or tools until you know how DBL Aciclovir affects you. DBL Aciclovir may cause dizziness in some people
Looking after your medicine	 DBL Aciclovir will be stored in the pharmacy or on the ward under correct conditions

For more information, see Section <u>5. What should I know while using DBL Aciclovir?</u> in the full CMI.

6. Are there any side effects?

Side effects may include discomfort or swelling, redness or heat at the injection site, fatigue, headaches, nausea and/or vomiting, loss of appetite, pins and needles sensation on skin, feeling unwell. Serious side effects may include difficulty breathing, swelling of the face, lips, tongue or other parts of the body (allergic reaction), abdominal pain, diarrhoea or bloody diarrhoea, abnormal bleeding or bruising, blood in stool or urine, dark coloured urine, seizures or tremors, confusion, delusion, loss of coordination, difficulty in speech, yellowing of the skin or eyes, fever. For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

DBL[™] Aciclovir – intravenous infusion

Active ingredient(s): Aciclovir

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Aciclovir. 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 DBL Aciclovir.

Where to find information in this leaflet:

- 1. Why am I using DBL Aciclovir?
- 2. What should I know before I use DBL Aciclovir?
- 3. What if I am taking other medicines?
- 4. How do I use DBL Aciclovir?
- 5. What should I know while using DBL Aciclovir?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using DBL Aciclovir?

DBL Aciclovir contains the active ingredient aciclovir. DBL Aciclovir is an antiviral medicine.

DBL Aciclovir is used for the management of certain infections caused by viruses, such as herpes and shingles.

It works by preventing the reproduction of the virus which is causing the condition.

2. What should I know before I use DBL Aciclovir?

Warnings

Do not use DBL Aciclovir if:

- 1. you are allergic to any medicine containing aciclovir, valaciclovir, or any of the ingredients listed at the end of this leaflet.
 - 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.
- 2. Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions including:
 - kidney disease
 - liver disease
 - any condition affecting your nervous system
 - irregular electrolyte levels

- hypoxia (inadequate oxygen supply to the cells of the body).
- take any medicines for any other condition
 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 <u>6</u>. Are there any side effects?

This medicine is not addictive.

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.

Your doctor can discuss with you the risks and benefits involved.

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 may interfere with DBL Aciclovir and affect how it works. These include:

- probenecid, a medicine used to treat gout
- cimetidine, a medicine used for stomach ulcers or heartburn

- diuretics, that is, medicines to prevent fluid retention
- zidovudine, a medicine used for HIV infection or AIDS
- ciclosporin, mycophenolate, tacrolimus, or interferon, medicines used to control the immune system
- methotrexate, a medicine used for cancer and conditions of the immune system
- lithium, a medicine used for treatment of mental illness
- theophylline, a medicine used to treat lung diseases.

These medicines may be affected by aciclovir, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Aciclovir.

4. How is DBL Aciclovir given?

How it is given and how much

DBL Aciclovir is given by slow infusion directly into the bloodstream. It is administered by a doctor or nurse.

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight.

If you use too much DBL Aciclovir

As DBL Aciclovir 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.

Symptoms of an overdose may include the side effects listed below in the 'Side Effects' section, but are usually of a more severe nature.

If you think that you have used too much DBL Aciclovir, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using DBL Aciclovir?

Things you should do

You should drink plenty of fluids as instructed by your doctor or nurse. If you are unable to drink due to your condition, your doctor will ensure that you receive plenty of fluids.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DBL Aciclovir affects you.

DBL Aciclovir may cause dizziness in some people

This medicine may cause dizziness, light-headedness, tiredness, or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Looking after your medicine

DBL Aciclovir will be stored in the pharmacy or on the ward under appropriate conditions.

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.

If you are over 65 years of age you may have an increased chance of getting side effects.

Less serious side effects

Less serious side effects	What to do
Injection site reactions: • discomfort, swelling, redness or heat at the injection site Gastrointestinal reactions:	Speak to your doctor if you have any of these less serious side effects and they worry you.
nausea and/or vomitingloss of appetite	

Serious side effects

Serious side effects	What to do
Allergic reaction symptoms: • shortness of breath; wheezing or difficulty breathing	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
 swelling of the face, lips, tongue or other parts of the body 	
 rash, sores, itching, ulcers or hives on the skin 	
Bleeding and related side effects:	
 abnormal bleeding or bruising severe blisters and bleeding in the lips, eyes, mouth and genitals 	
Gastrointestinal related symptoms:	
 pain or problems in passing urine blood in urine or dark urine diarrhage bloody 	
diarrhoea, bloody diarrhoeaabdominal pain	
Liver related symptoms:	
 jaundice or hepatitis Psychological related symptoms: 	

Serious side effects	What to do
• seizures (fits)	
 agitation, confusion or reduced ability to concentrate 	
feeling sad or changes in thinking	
• tremor	
hallucinations or delusions	
• dizziness	
 loss of coordination, or voluntary muscle movements 	
pins and needles sensation on skin	
difficulty in speech	
Injection site reactions:	
 sudden pain or inflammatory reaction at the injection site 	
Skin and eye reactions:	
yellowing of the skin and eyes	
• itching	
purplish spots or patches	
General:	

Serious side effects	What to do
feeling generally unwell	
looking pale	
• fever	
• tiredness	
• headaches	
being short of breath when exercising	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell. Your doctor may request blood test in order to monitor your progress, some side effects can only be detected by blood testing.

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 DBL Aciclovir contains

Active ingredient	aciclovir
(main ingredient)	
Other ingredients (inactive ingredients)	sodium hydroxidewater for injection

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

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What DBL Aciclovir looks like

DBL Aciclovir is a clear, colourless or almost colourless solution.

DBL Aciclovir is available in the following strengths:

- 250 mg /10 mL AUST R 56809
- 500 mg /20 mL AUST R 56810

Who distributes DBL Aciclovir

Pfizer Australia Pty Ltd

Sydney, NSW

Toll Free number: 1800 675 229

www.pfizer.com.au

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