## DBL™ Sodium Acetate Concentrated Injection

#### **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 treated with DBL Sodium Acetate Concentrated Injection?

DBL Sodium Acetate Concentrated Injection contains the active ingredient sodium acetate. DBL Sodium Acetate Concentrated Injection can be added to total parenteral nutrition (TPN) solutions as a source of sodium and acetate ions, or to increase the pH of the solution. It can also be used to treat low blood sodium (hyponatraemia). For more information, see Section 1. Why am I being treated with DBL Sodium Acetate Concentrated Injection? in the full CMI.

#### 2. What should I know before treatment with DBL Sodium Acetate Concentrated Injection?

Do not use if you have ever had an allergic reaction to sodium acetate 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 treatment with DBL Sodium Acetate Concentrated Injection? in the full CMI.

#### 3. What if I am taking other medicines?

Some medicines may interfere with DBL Sodium Acetate Concentrated Injection 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 DBL Sodium Acetate Concentrated Injection given?

- DBL Sodium Acetate Concentrated Injection should only be used under the supervision of your doctor.
- It is usually given as an intravenous injection or an infusion (i.e. a slow injection through a 'drip' into the vein).
- 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 4. How is DBL Sodium Acetate Concentrated Injection given? in the full CMI.

#### 5. What should I know during treatment with DBL Sodium Acetate Concentrated Injection?

Things you should do	<ul> <li>Tell your doctor, nurse or pharmacist if you have any concerns before, during or after administration of DBL Sodium Acetate Concentrated Injection.</li> <li>Remind any doctor, dentist and pharmacist who are treating you that you are being given DBL Sodium Acetate Concentrated Injection.</li> <li>If you plan to have surgery that needs a general anaesthetic, tell your doctor that you are being given DBL Sodium Acetate Concentrated Injection.</li> <li>If you are about to have any blood tests, tell your doctor that you are being given this medicine. It may interfere with the results of some tests.</li> </ul>
Looking after your medicine	<ul> <li>DBL Sodium Acetate Concentrated Injection will be stored in the pharmacy or on the ward.</li> <li>Keep in a cool, dry place, protected from light, where the temperature stays below 30°C.</li> <li>Do not use this medicine after the expiry date.</li> </ul>

For more information, see Section <u>5. What should I know during treatment with DBL Sodium Acetate Concentrated Injection?</u> in the full CMI.

#### 6. Are there any side effects?

Side effects include: thirst, dry mouth or eyes, fever, fast or irregular heart rate, headache, dizziness, restlessness, weakness, mood changes, muscle or twitching, or pain at the infusion site. Serious side effects include: sleepiness or confusion, convulsions or difficulty breathing.

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.

## **DBL™ Sodium Acetate Concentrated Injection**

Active ingredient: sodium acetate

#### **Consumer Medicine Information (CMI)**

This leaflet provides important information about DBL Sodium Acetate Concentrated Injection. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being treated with DBL Sodium Acetate Concentrated Injection.

#### Where to find information in this leaflet:

- 1. Why am I being treated with DBL Sodium Acetate Concentrated Injection?
- 2. What should I know before treatment with DBL Sodium Acetate Concentrated Injection?
- 3. What if I am taking other medicines?
- 4. How is DBL Sodium Acetate Concentrated Injection given?
- 5. What should I know during treatment with DBL Sodium Acetate Concentrated Injection?
- 6. Are there any side effects?
- 7. Product details

# 1. Why am I being treated with DBL Sodium Acetate Concentrated Injection?

DBL Sodium Acetate Concentrated Injection contains the active ingredient sodium acetate. DBL Sodium Acetate Concentrated Injection can be added to total parenteral nutrition (TPN) solutions as a source of sodium and acetate ions, or to increase the pH of the solution. It can also be used to treat low blood sodium (hyponatraemia).

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why DBL Sodium Acetate Concentrated Injection has been prescribed for you.

# 2. What should I know before treatment with DBL Sodium Acetate Concentrated Injection?

#### Warnings

## Do not use DBL Sodium Acetate Concentrated Injection if you:

- have an allergy to sodium acetate. Symptoms of an allergic reaction may include:
  - o shortness of breath, wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body
  - o rash, itching or hives on the skin.
- have any of the following conditions:
  - o high blood sodium
  - o fluid retention
  - o severe kidney disease
  - o severe burns
  - o severe or prolonged diarrhoea or vomiting
  - o uncontrolled diabetes mellitus
  - high blood pH

- low blood calcium
- low blood chloride
- o low blood potassium.

#### Check with your doctor if you:

- have or have had any other medical conditions, especially the following:
  - o heart failure
  - o fluid retention or oedema
  - o kidney disease
  - o liver disease
  - o high blood pressure
  - o low or no urine production.
- 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 6. Are there any side effects?

#### Pregnancy and breastfeeding

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

Your doctor will discuss the possible risks and benefits of being given DBL Sodium Acetate Concentrated Injection during pregnancy.

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

Your doctor will discuss the possible risks and benefits of being given DBL Sodium Acetate Concentrated Injection during breastfeeding.

#### 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 Sodium Acetate Concentrated Injection and affect how it works. These include:

- corticosteroids or corticotrophin
- pain killers such as aspirin
- barbiturates, medicines used to treat epilepsy
- antibiotics, medicines used to treat infections, particularly doxycycline
- quinidine, a medicine used to control heart rhythm
- ephedrine or pseudoephedrine
- lithium, a medicine used to treat some psychiatric disorders
- diuretics (fluid tablets), such as bumetanide, frusemide or thiazide diuretics
- potassium supplements.

These medicines may be affected by DBL Sodium Acetate Concentrated Injection or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while being given DBL Sodium Acetate Concentrated Injection.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Sodium Acetate Concentrated Injection.

# 4. How is DBL Sodium Acetate Concentrated Injection given?

#### How is it given?

- DBL Sodium Acetate Concentrated Injection should only be used under the supervision of your doctor.
- It is usually given as an intravenous injection or an infusion (i.e. a slow injection through a 'drip' into the vein).

#### How much is given?

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

#### If too much is given (overdose)

As this medicine is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

If you think that you have been given too much DBL Sodium Acetate Concentrated Injection, you may need urgent medical attention.

Symptoms of a sodium acetate overdose include the side effects listed under Section 6. Are there any side effects? but are usually of a more severe nature.

#### 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 during treatment with DBL Sodium Acetate Concentrated Injection?

#### Things you should do

- Tell your doctor, nurse or pharmacist if you have any concerns before, during or after administration of DBL Sodium Acetate Concentrated Injection.
- Remind any doctor, dentist and pharmacist who are treating you that you are being given DBL Sodium Acetate Concentrated Injection.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor that you are being given DBL Sodium Acetate Concentrated Injection.
- If you are about to have any blood tests, tell your doctor that you are being given this medicine. It may interfere with the results of some tests.

#### **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how DBL Sodium Acetate Concentrated Injection affects you.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

#### Looking after your medicine

- DBL Sodium Acetate Concentrated Injection will be stored in the pharmacy or on the ward.
- Keep in a cool, dry place, protected from light, where the temperature stays below 30°C.
- Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

#### Getting rid of any unwanted medicine

DBL Sodium Acetate Concentrated Injection will be disposed of by a nurse or pharmacist.

#### 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.

#### Common side effects

Common side effects	What to do
<ul> <li>thirst</li> <li>dry mouth or eyes</li> <li>fever</li> <li>fast or irregular heart rate</li> <li>headache</li> <li>dizziness</li> <li>restlessness</li> <li>weakness</li> <li>mood changes</li> <li>muscle weakness or twitching</li> <li>pain at the infusion site</li> </ul>	Speak to your doctor if you notice any of these side effects and they worry you.

#### Serious side effects

Serious side effects	What to do
<ul> <li>sleepiness or confusion</li> <li>convulsions</li> <li>difficulty breathing</li> </ul>	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.
	You may need urgent medical attention. Serious side

Serious side effects	What to do
	effects are
	rare.

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

Do not be alarmed by this list of possible side effects. You may not experience any of them. 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 <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. 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

### What DBL Sodium Acetate Concentrated Injection contains

Active ingredient (main ingredient)	sodium acetate
Other ingredients (inactive ingredients)	water for injections

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

DBL Sodium Acetate Concentrated Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

## What DBL Sodium Acetate Concentrated Injection looks like

DBL Sodium Acetate Concentrated Injection is a clear, colourless solution.

It is available in the following strength and pack size:

 50 x 1.64 grams in 10 mL ampoule (20 mmol/10 mL AUST R 16262

# Who distributes DBL Sodium Acetate Concentrated Injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

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