DBL[™] Sodium Acetate Concentrated Injection

Sodium acetate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL[™] Sodium Acetate Concentrated Injection.

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 or pharmacist has weighed the risks of you being given sodium acetate against the benefits they expect it will have for you.

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

Keep this leaflet in a safe place.

You may need to read it again.

What DBL[™] Sodium Acetate Concentrated Injection is used for

Sodium acetate 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.

Sodium acetate can also be used to treat low blood sodium (hyponatraemia).

Your doctor may have prescribed sodium acetate for another reason. Ask your doctor if you have any questions about why sodium acetate has been prescribed for you.

DBLTM Sodium Acetate Concentrated Injection is not addictive.

Before you are given DBL[™] Sodium Acetate Concentrated Injection

When you must not be given it

You should not be given DBL[™] Sodium Acetate Concentrated Injection if you have an allergy to sodium acetate.

Symptoms of an allergic reaction to sodium acetate 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.

You should not be given DBL[™] Sodium Acetate Concentrated Injection if you have any of the following conditions:

- high blood sodium
- fluid retention
- severe kidney disease
- severe burns
- · severe or prolonged diarrhoea or vomiting
- uncontrolled diabetes mellitus
- high blood pH
- low blood calcium
- low blood chloride
- low blood potassium.

If you are not sure whether you should be given DBLTM Sodium Acetate Concentrated Injection, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor or pharmacist if you have allergies to:

any other medicines

• any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant. Your doctor or pharmacist will discuss the possible risks and benefits of being given sodium acetate during pregnancy.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed. Your doctor or pharmacist will discuss the possible risks and benefits of being given sodium acetate during breast-feeding.

Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:

- heart failure
- fluid retention or oedema
- kidney disease
- liver disease
- high blood pressure
- low or no urine production.

If you have not told your doctor or pharmacist about any of the above, tell them before you are given sodium acetate.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from yor pharmacy, supermarket or health food shop. Some medicines and sodium acetate may interfere with each other. 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, ethacrynic acid, frusemide or thiazide diuretics
- potassium supplements.

These medicines may be affected by sodium acetate, 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 sodium acetate.

How DBL[™] Sodium Acetate Concentrated Injection is given

How it is given

Sodium acetate should only be used under the supervision of your doctor. It is usually given as an intravenous injection or an infusion (ie. a slow injection through a 'drip' into the vein).

How much is given

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

If you take too much (overdose)

As sodium acetate 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 or anyone else may have been given too much DBL[™] Sodium Acetate Concentrated Injection tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital or immediately contact the Poisons Information Centre for advice on management. (In Australia, call 13 11 26; in New Zealand call 0800 764 766). Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of a sodium acetate overdose include the side effects listed in the 'Side effects' section, but are usually of a more severe nature.

While you are being given DBL™ Sodium Acetate Concentrated Injection

Things you must do

Tell your doctor, nurse or pharmacist if you have any concerns before, during or after administration of sodium acetate.

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given sodium acetate.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are being given sodium acetate.

If you plan to have surgery that needs a general anaesthetic, tell your doctor that you are being given sodium acetate.

If you become pregnant after being given sodium acetate, tell your doctor or pharmacist.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Things to be careful of

Be careful driving or operating machinery 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given sodium acetate.

Sodium acetate helps most people with low blood sodium levels, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- thirst
- dry mouth or eyes
- fever
- fast or irregular heart rate
- headache
- dizziness

- restlessness
- weakness
- mood changes
- muscle weakness or twitching
- pain at the infusion site.

These are the more common side effects of sodium acetate.

Tell your doctor or pharmacist immediately if you notice the following:

- sleepiness or confusion
- convulsions
- difficulty breathing.

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After being given DBL[™] Sodium Acetate Concentrated Injection

Storage

DBLTM Sodium Acetate Concentrated Injection will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 30° C.

Product description

What it looks like

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

Ingredients

- Active ingredients:
- sodium acetate
- Other ingredients
- water for injections.

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

Supplier

Australian Sponsor: Hospira Australia Pty Ltd ABN 58 097 064 330 Level 3 500 Collins Street Melbourne VIC 3000 Australia New Zealand Sponsor: Hospira NZ Limited 23 Haining Street Te Aro, Wellington New Zealand DBLTM Sodium Acetate Concentrated Injection is available in the following strength and pack size:

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

This leaflet was updated in November 2011.