DBL[™] Acetylcysteine Injection Concentrate

Acetylcysteine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL Acetylcysteine Injection Concentrate. 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 DBL Acetylcysteine Injection Concentrate 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 with the medicine.

You may need to read it again.

What DBL Acetylcysteine Injection Concentrate is used for

This medicine is used to treat paracetamol (acetaminophen) poisoning.

It works by reacting with a toxic metabolite of paracetamol to prevent it damaging the liver.

This medicine is most effective when started within 8 hours of exposure to paracetamol.

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

Before you are given DBL Acetylcysteine Injection Concentrate

When you must not be given it

You should not be given DBL Acetylcysteine Injection Concentrate if you have an allergy to:

- Any medicine containing acetylcysteine
- 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.

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

Before you are given it

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

Tell your doctor if you have or have had any of the following medical conditions:

- · asthma or difficulty breathing
- · stomach ulcers
- · kidney problems
- · liver problems
- a history of chronic or long-term alcohol abuse.

Tell your doctor if you weigh less than 40 kilograms.

Your doctor may have to adjust the amount of acetylcysteine you will receive.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor will discuss the risks and benefits involved

If you have not told your doctor about any of the above, tell him/ her before you are given DBL Acetylcysteine Injection Concentrate.

Taking other medicines

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

Tell your doctor especially if any of the following medicines:

isoniazid and/or rifampicin

 (antibiotics often used together
 for the treatment of tuberculosis

[TB])

 anti-seizure medications including carbamazepine, phenytoin, phenobarbitone, primidone, sodium valproate.

DBL Acetylcysteine Injection Concentrate may interfere with the results of some urinary dipstick tests.

Your doctor or pharmacist have more information on medicines to avoid while being treated with this medicine.

How DBL Acetylcysteine Injection Concentrate is given

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.

How it is given

DBL Acetylcysteine Injection Concentrate is given as a slow infusion into a vein. The duration of treatment is approximately 20 hours. It must only be given by a doctor or nurse.

You will receive two separate infusions, containing different doses, as determined by your doctor.

You may also be given treatment for nausea at the same time.

If you experience side effects to DBL Acetylcysteine Injection Concentrate, you may be given an antihistamine.

If you receive too much (overdose)

As DBL Acetylcysteine Injection Concentrate is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience severe side effects tell your doctor immediately.

Ask your doctor if you have any concerns.

While you are being given DBL Acetylcysteine Injection Concentrate

Things you must do

Your doctor may do some tests to make sure the medicine is working and to prevent unwanted side effects.

Things to be careful of

Be careful before driving or using any machines or tools until you know how DBL Acetylcysteine Injection Concentrate affects you.

As with some other medicines, acetylcysteine may cause dizziness or light-headedness in some people. It may also cause blurred vision or seizures.

Make sure you know how you react to this medicine before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed, or if you have blurred vision or a seizure. If any of these occur, do not drive.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given DBL Acetylcysteine Injection Concentrate.

This medicine helps most people with paracetamol overdose, 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.

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

You may not experience any of them.

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

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

- nausea or vomiting
- · generally feeling unwell
- · excessive shivering
- · fever or sweating
- pain in your bones
- pain and inflammation at the injection site
- bleeding or bruising more easily than normal.

Tell your doctor, nurse or pharmacist immediately if you notice any of the following:

- allergic reactions including flushing, rashes, itching, swelling of the face or difficulty breathing.
- chest pain
- · fast or irregular heartbeat
- · dizziness or light headedness
- seizure
- jaundice (yellowing of skin and/ or eyes)
- · blurred vision or any eye pain
- pain in your face.

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

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

After using DBL Acetylcysteine Injection Concentrate

Storage

DBL Acetylcysteine Injection Concentrate 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 25°C.

Product description

What it looks like

DBL Acetylcysteine Injection Concentrate is supplied as a clear, colourless solution. It is supplied in 10 mL glass ampoules, packs of 10.

Ingredients

DBL Acetylcysteine Injection Concentrate contains 200 mg/mL of acetylcysteine as the active ingredient.

It also contains:

- sodium hydroxide
- · disodium edetate
- · water for injections.

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

Sponsor

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229 www.pfizermedicalinformation.com.

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DBL Acetylcysteine Injection Concentrate is supplied in the following strength:

• 2 g/10 mL x 10 amps

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