B. BRAUN GENTAMICIN injection, intravenous infusion

Gentamicin (jen-tah-mi-sin)

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about B. BRAUN GENTAMICIN injection, intravenous infusion (gentamicin).

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 B. BRAUN GENTAMICIN injection, intravenous infusion against the benefits they expect it will have for you.

This medicine is likely to be used while you are at the clinic or in hospital. If possible, please read this leaflet carefully before this medicine is given to you. In some cases this leaflet may be given to you after the medicine has been used.

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

Keep this leaflet in a safe place.

You may need to read it again.

What B. BRAUN GENTAMICIN injection, intravenous infusion is used for

Gentamicin is an antibiotic that belongs to a group of medicines called aminoglycosides (pronounced a-my-noe-GLY-koe-sides). It is used to treat serious bacterial infections.

This medicine works by killing bacteria or preventing their growth. It is used for the treatment of serious infections, including:

- septicaemia (infection of the blood)
- · respiratory tract infections
- infected wounds
- · bone or tissue infections
- infected burns
- · urinary tract infections.

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

This medicine is available only with a doctor's prescription.

Before you are given B. BRAUN GENTAMICIN injection, intravenous infusion

When you must not be given it You must not be given B. BRAUN GENTAMICIN injection, intravenous infusion if you have an allergy to gentamicin or other aminoglycoside antibiotics such as:

- amikacin
- tobramycin
- neomycin
- streptomycin
- netilmicin

or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to gentamicin may include:

hearing loss or kidney problems

- 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 must also not be given B. BRAUN GENTAMICIN injection, intravenous infusion if you have myasthenia gravis.

B. BRAUN GENTAMICIN injection, intravenous infusion should not be given to you if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given B. BRAUN GENTAMICIN injection, intravenous infusion, 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.

Like most aminoglycoside antibiotics, gentamicin is not recommended for use during pregnancy as it may affect your developing baby if you take it during pregnancy. If there is a need for you to be given gentamicin, your doctor or pharmacist will discuss with you the benefits and risks of using it during your pregnancy.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.

If there is a need for you to be given gentamicin, your doctor or pharmacist will discuss the possible risks and benefits of using it during breastfeeding.

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

- kidney disease or any kidney problems
- muscular disorders (e.g. Parkinson's disease)
- · hearing problems.

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

Taking other medicines

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

Some medicines and gentamicin may interfere with each other. These include:

- fluid tablets (e.g. frusemide, ethacrynic acid, bumetanide)
- cisplatin, a medicine used to treat cancer
- antibiotics to treat infection such as colistin, vancomycin, clindamycin, cephalosporins and penicillins
- · amphotericin B, an antifungal medicine
- anaesthetics (e.g. halothane)
- muscle relaxants (e.g. succinylcholine).
- vitamin K
- any drug that may cause kidney or hearing problems

These medicines may be affected by gentamicin, or may affect how well it works. You may need different amounts of your medicine, or you may need to take/use 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 receiving gentamicin.

How B. BRAUN GENTAMICIN injection, intravenous infusion 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 and kidney function.

How it is given

Gentamicin is given intravenously over a period of 30 to 60 minutes. This medicine should only be given by a doctor, nurse or other trained person.

If you take too much (overdose)

As B. BRAUN GENTAMICIN injection, intravenous infusion is usually given to you in hospital under the supervision of your doctor, it is very unlikely that you will receive an overdose. However, if you are given too much gentamicin, you may experience some of the effects listed under "Side Effects" below.

If you experience severe side effects, tell your doctor immediately, or go to the nearest hospital emergency department.

Your doctor or pharmacist has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given gentamicin or after the injection.

Gentamicin helps most people with certain infections, 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.

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

You may not experience any of them.

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

- · tiredness or weakness
- confusion
- · depression
- decreased appetite
- weight loss
- fever
- headache
- · nausea or vomiting
- increased salivation
- problems with eyes

- · sore mouth, gums and mouth ulcers
- unusual bleeding or bruising under the skin
- · hair loss
- joint pain
- · pain at the injection site.

These side effects are usually mild.

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

- swelling of the limbs, face, lips, mouth or throat
- shortness of breath or breathing difficulties
- rash, itching, hives or severe skin reaction.

These symptoms are signs of an allergic reaction to gentamicin.

If any of the following happen, tell your doctor or nurse immediately:

- · severe headache
- hearing loss
- dizziness
- problems with your balance
- · ringing in the ears
- · numbness
- · skin tingling
- · muscle twitching
- fits (convulsions)
- increase or decrease in urination.

These are very 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, nurse or pharmacist if you notice anything that is making you feel unwell.

After using B. BRAUN GENTAMICIN injection, intravenous infusion

Storage

B. BRAUN GENTAMICIN injection, intravenous infusion will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place where the temperature stays below 25°C.

Product description

What it looks like

B. BRAUN GENTAMICIN injection, intravenous infusion is a clear, colourless liquid and comes in plastic bottles.

Ingredients

Active ingredients:

· gentamicin sulphate

Other ingredients:

- disodium edetate (3 mg/mL solution only)
- sodium chloride
- water

Genatmicin intravenous infusion is available in the following strengths:

AUST R: 280508: B. BRAUN GENTAMICIN Gentamicin (as Sulfate) 80 mg/80 mL injection, intravenous infusion, bottle.

One 80 mL bottle of B. BRAUN GENTAMICIN Gentamicin (as Sulfate) 1 mg/mL injection, intravenous infusion contains 80 mg gentamicin. AUST R: 280507: B. BRAUN GENTAMICIN Gentamicin (as Sulfate) 240 mg/80 mL injection intravenous infusion

mg /80 mL injection, intravenous infusion, bottle.

One 80 mL bottle of B. BRAUN GENTAMICIN Gentamicin (as Sulfate) 3

mg/mL injection, intravenous infusion contains 240 mg gentamicin.

AUST R: 280495: B. BRAUN

GENTAMICIN Gentamicin (as Sulfate) 360 mg /120 mL injection, intravenous infusion, bottle.

One 120 mL bottle of B. BRAUN

GENTAMICIN Gentamicin (as Sulfate) 3 mg/mL injection, intravenous infusion

contains 360 mg gentamicin.

Supplier / Sponsor

B. Braun Australia Pty Ltd Level 5, 7-9 Irvine Place Bella Vista NSW 2153

Australia

This leaflet was prepared in November 2020

B. BRAUN GENTAMICIN injection, intravenous infusion Published by MIMS March 2021