

INVANZ®

for injection

Ertapenem

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about INVANZ. 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 using INVANZ against the benefits they expect it will have for you or your child.

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

Keep this leaflet.

You may need to read it again.

What INVANZ is used for

INVANZ is an antibiotic used to treat infections caused by bacteria (germs).

These infections include:

- infections within the abdomen (stomach)
- pelvic infections
- diabetic foot infections in patients without osteomyelitis

INVANZ may also be used in patients not responding to, or unable to tolerate, other antibiotics.

INVANZ belongs to a class of antibiotics called carbapenems. It works by killing the bacteria causing your infection.

Your doctor may have prescribed INVANZ for another reason.

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

Before you are given INVANZ

When you or your child must not be given it

Do not use INVANZ if:

- you have an allergy to INVANZ or any of the ingredients listed at the end of this leaflet
- you have an allergy to other antibiotics in the same class as INVANZ
- you have had a serious allergic reaction (anaphylaxis) to beta-lactam antibiotics, including penicillins or cephalosporins
- the vial cap shows signs of tampering
- the expiry date printed on the pack has passed

If you use this medicine after the expiry date has passed, it may not work.

Do not use INVANZ by injection into a muscle if:

- you have an allergy to amide-type local anaesthetics, particularly lidocaine (lignocaine)
- you are in severe shock
- you have heart block

Do not use INVANZ in children under 3 months of age

The safety and effectiveness in children younger than 3 months of age have not been established.

Before you or your child are given it

Tell your doctor if:

- 1. you have or have had any medical conditions, especially the following:**
 - seizures or fits, or a predisposition to seizures (eg brain scarring)
 - kidney disease, or are undergoing dialysis
 - bowel problems while using antibiotics or after finishing them, including severe abdominal or stomach cramps, or watery and severe diarrhoea
- 2. you have allergies to other antibiotics, in particular penicillins and cephalosporins.**

If you are allergic to any of these you may be allergic to INVANZ.
- 3. you are pregnant or intend to become pregnant**

Like most medicines, INVANZ is generally not recommended during pregnancy. However, if there is a need to consider using INVANZ during pregnancy, your doctor will discuss the possible risks and benefits to you and your unborn baby.
- 4. you are breast-feeding or intend to breast-feed**

Like most medicines, the use of INVANZ is generally not recommended while breast-

feeding. INVANZ is secreted into human milk.

- 5. you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes**
- 6. you are taking a medicine containing valproic acid**

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

Taking other medicines

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

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

- Sodium valproate (Epilim*), used to control different types of epilepsy and mania

These medicines may be affected by INVANZ, 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 will decide whether you should use INVANZ in combination with this medicine.

Make sure your doctor and pharmacist know about all of the medicines you are taking, as they have more information on medicines to be careful with or avoid while taking INVANZ.

How INVANZ is given

INVANZ can be given in two ways:

- as a slow injection into a vein, known as an intravenous infusion
- as a deep injection into a large muscle, known as an intramuscular injection.

INVANZ must only be given by a doctor or nurse.

Your doctor will decide what dose and how long you or your child will receive INVANZ. This depends on your condition and other factors, such as your kidney function. No dose adjustment is necessary if you are elderly.

When preparing INVANZ for use, do not reconstitute or dilute in solutions containing dextrose (α -D-glucose).

INVANZ is not compatible with dextrose.

If you receive too much (overdose)

If you are concerned that you or your child have received too much INVANZ, tell your doctor, nurse or pharmacist immediately.

While you or your child are using INVANZ

Things you must do

If you develop severe diarrhoea, tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after INVANZ has been stopped.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without first checking with your doctor.

If you develop a severe skin reaction such as painful red areas, fluid filled bumps, large blisters, or peeling layers of skin whilst being given INVANZ, tell your doctor immediately.

You may need urgent medical care.

Side Effects

Tell your doctor, nurse, or pharmacist as soon as possible if you or your child do not feel well

while you are being given INVANZ.

INVANZ helps most people with infection, 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.

While being given it

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

- discomfort of the vein where you had the injection, for example pain, tenderness, redness, swelling or firm swelling.
- swelling, clotting, tenderness, swelling and inflammation
- headache
- nausea, vomiting
- diarrhoea
- vaginal itching or redness
- alterations in some laboratory blood tests, and a combination of high fever, feeling unwell, and skin rash

These are the more common side effects of INVANZ. For the most part, these have been mild.

INVANZ may cause dizziness or sleepiness in some patients. Make sure you know how you react to INVANZ before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy or sleepy.

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

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody

- high temperature, also called fever
- seizures or fits
- shortness of breath
- chest pain
- slow heart rate
- skin rash, redness, itchiness or hives
- severe skin reactions, such as painful red areas, fluid-filled bumps, large blisters, or peeling of layers of skin have been reported for the beta-lactam class of antibiotics
- formation of lump and warmth at injection site
- strange or disturbing thoughts or moods (including agitation, aggression, severe confusion, disorientation, mental status changes)
- tremors or uncontrollable twitching, jerking or writhing movements
- decreased consciousness

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

Also, tell your doctor if you notice:

- dizziness, light-headedness or unsteady walking
- unusual tiredness or weakness
- sore, creamy-yellow, raised patches in the mouth (oral thrush)
- teeth staining

These are other side effects that have been reported with INVANZ. These side effects are rare.

A few people may be allergic to some medicines. Tell your doctor or nurse immediately if you notice any of the following. These are examples of acute allergy:

- throat or chest tightness, difficulty breathing
- swelling of the mouth, lips, eyes or face
- flushing (sudden redness) of the face

- vomiting

If you or your child have these, you may have had a serious allergic reaction to INVANZ. You may need urgent medical attention. These side effects are very rare.

After finishing it

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with INVANZ:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- fever, in combination with one or both of the above

These are rare but serious side effects. You may have a serious condition affecting your bowel. This is because antibiotics such as INVANZ can change the type of bacteria in the bowel. As a result, this allows bacteria, normally present in the bowel and normally harmless, to multiply and cause the above symptoms. Therefore, you may need urgent medical attention. However, this side effect is rare.

Do not take any diarrhoea medicine without first checking with your doctor.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Storage

INVANZ will usually be stored in the pharmacy or on the ward.

The powder for injection should be kept in a cool dry place where the temperature stays below 25°C.

Discard any unused vials containing solution of INVANZ which has been prepared but not used.

Vials of INVANZ are intended for single-use only. They do not contain a preservative and there is a possibility of contamination with repeated use.

Do not freeze the solutions of INVANZ.

Intravenous Injection

Use solutions of INVANZ as soon as possible after reconstitution and further dilution. If storage is unavoidable, store the solution in the refrigerator where the temperature is kept between 2°C to 8°C, for not more than 24 hours, and use as soon as practicable within 4 hours after removal from the refrigerator.

As INVANZ does not contain a preservative, there is a risk that any prepared solution that has not been stored in a refrigerator may be contaminated with germs and cause an infection.

Intramuscular Injection

Use the reconstituted solution immediately. If storage is unavoidable, the solution should be kept in a refrigerator where the temperature is between 2°C to 8°C.

Do not store the solution of INVANZ for injection for more than one hour.

Product Description

What it looks like

INVANZ comes as a white to off-white powder in a glass vial.

Ingredients

Active ingredient:

- ertapenem 1 g (1.046 g as the sodium salt) per vial

Inactive ingredients:

- sodium bicarbonate
- sodium hydroxide

Supplier

INVANZ is supplied in Australia by:

Merck Sharp & Dohme (Australia)
Pty Limited
A.B.N. 14 000 173 508
Level 1, Building A,
26 Talavera Road
Macquarie Park NSW 2113

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