

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

INVANZ®

**ertapenem for injection,
1 g /vial (as ertapenem sodium)**

Read this carefully before you start taking INVANZ® and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about INVANZ®.

Serious Warnings and Precautions

- Some people taking beta-lactam antibiotics like INVANZ® have reported serious allergic reactions (serious skin rashes), that can occasionally lead to death.
- Some people have had seizures and other nervous system problems such as dizziness while taking INVANZ®. This occurs mostly in people who:
 - have had seizures in the past
 - currently take certain medicines (valproic acid, sodium valproate, and divalproex sodium) for seizures
 - have brain injuries or other brain diseases
 - have problems with their kidneys
- For further information and symptoms see:
 - the “To help avoid side effects and ensure proper use...” section
 - the “Serious side effects and what to do about them” table

What is INVANZ® used for?

INVANZ® is used in children and adolescents (3 months to 17 years of age) and adults to treat one of the following bacterial infections:

- Infection in the abdomen.
- Infection of the skin, including diabetic foot infections in adults.
- Lung infections caught outside of hospitals or other health care facilities (Community Acquired Pneumonia).
- Urinary Tract Infection (UTIs). UTIs happen when bacteria (germs) get into the bladder or kidneys.
- Pelvic infection.
- prevent infections at the surgical site following surgery of the colon or rectum in adults. The colon and rectum are parts of the digestive system.

Antibacterial drugs like INVANZ® treat only bacterial infections. They do not treat viral infections. Although you may feel better early in treatment, INVANZ® should be used exactly as directed. Misuse or overuse of INVANZ® could lead to the growth of bacteria that will not be killed by INVANZ® (resistance). This means that INVANZ® may not work for you in the future.

How does INVANZ® work?

INVANZ[®] is an antibiotic. It contains a medicine called ertapenem. Ertapenem belongs to the carbapenem class of antibiotics. INVANZ[®] has the ability to kill a wide range of bacteria that cause infections.

What are the ingredients in INVANZ[®]?

Medicinal ingredients: Ertapenem sodium

Non-medicinal ingredients: Sodium Bicarbonate and Sodium Hydroxide

INVANZ[®] comes in the following dosage forms:

sterile lyophilized powder, 1 g ertapenem/vial (as ertapenem sodium)

Do not use INVANZ[®] if you are allergic to:

- ertapenem or any of the ingredients in INVANZ[®] (see **What are the ingredients in INVANZ[®]**).
- other beta-lactams antibiotics such as medications from the:
 - penicillins class.
 - cephalosporins class.

Do not inject INVANZ[®] into a muscle if you:

- are allergic to medications such as local anesthetics of the amide type especially lidocaine hydrochloride. Lidocaine is used to relieve pain when injecting INVANZ[®] into the muscle.
- are in severe shock.
- have a problem with your heart rhythm called heart block.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take INVANZ[®]. Talk about any health conditions or problems you may have, including if you or your child has now or has had:

- Any medical conditions, especially:
 - kidney disease.
 - history of seizures or other brain diseases.
- Allergies to:
 - other antibiotics, in particular penicillins and cephalosporines. If you are allergic to any of these antibiotics you may be allergic to INVANZ[®].
 - any other drugs or any other substances such as foods, preservatives or dyes.
- Are pregnant or plan on getting pregnant. INVANZ[®] has not been studied in pregnant women. You will need to talk with your healthcare professional about the potential benefit and risk of using INVANZ[®] while you are pregnant.
- Are breast-feeding or planning to breastfeed. INVANZ[®] is excreted in human milk. If you intend to breast-feed, you will need to talk with your healthcare professional about any risks to your baby.

Children: Do not give INVANZ[®] to a child younger than 3 months of age.

Other warnings you should know about:

While taking INVANZ[®]:

- If you develop severe diarrhea (very loose or watery stool), tell your healthcare professional right away. Do this even if it occurs several weeks after you stopped taking INVANZ[®]. Diarrhea may mean

that you have a serious condition affecting your bowel (colitis). You may need urgent medical care. Do not try to treat loose stools without first checking with your healthcare professional (see the “Serious side effects and what to do about them” table below).

- Stop taking INVANZ® at the first sign of a skin rash and call your healthcare professional. Skin rash may be a sign of a more serious reaction to INVANZ® (see the “Serious side effects and what to do about them” table below).

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with INVANZ®:

- medicines called valproic acid or sodium valproate or divalproex sodium (used to treat seizures). INVANZ® may affect how well these medicines work to prevent seizures. You may need different amounts of this medicine, or you may need to take another medicine. Your healthcare professional will decide whether you should use INVANZ® with these medicines.
- a medication called probenecid (usually used to treat or prevent gout).

How to take INVANZ®:

Your healthcare professional may give INVANZ® by:

- intravenous infusion (injected slowly into a vein) over a period of 30 minutes.
- intramuscular injection (as a shot into a muscle).

Usual dose:

- The dose of INVANZ® will depend on the type of infection you or your child may have and how well your kidneys are working.
- Your healthcare professional will work out the right dose of INVANZ® for you or your child.
- Your healthcare professional will also tell you how long to use INVANZ®.
- Ask your healthcare professional if you have any questions about how many doses of INVANZ® you or your child will need or when you or your child will receive them.

Overdose:

If you think you, or a person you are caring for, have taken too much INVANZ®, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

The injection schedule will be set by your healthcare professional, who will monitor your response and condition to determine what treatment is needed. However, if you are concerned that you or your child may have missed a dose, contact your healthcare professional immediately.

What are possible side effects from using INVANZ®?

These are not all the possible side effects you may have when taking INVANZ[®]. If you experience any side effects not listed here, tell your healthcare professional.

Adults 18 years of age and older:

The most common side effects are:

- loose stool (diarrhea), nausea, vomiting
- problems with the vein where you had the INVANZ[®] shot. For example pain, tenderness, redness, swelling
- inflammation of blood vessels which may lead to blood clots
- headache

Other side effects in adults include:

- sore, creamy-yellow, raised patches in the mouth (oral thrush)
- teeth staining
- loss of appetite
- confusion, dizziness, sleepiness, sleeplessness
- low blood pressure, slow heart rate, shortness of breath
- abdominal pain
- acid regurgitation, constipation, indigestion
- dry mouth
- skin redness, itching, swelling at the injection site
- swelling, redness, burning, itching, or irritation of the vagina
- unusual tiredness or weakness, swelling, feeling unwell, fever, pain, chest pain, fungal infection, change in taste
- swelling of the lower limbs
- changes in some laboratory blood tests

Children and adolescents (3 months to 17 years of age):

Side effects in children are generally similar to those in adults.

The most common side effects in children are:

- loose stools (diarrhea), vomiting
- rash
- pain, redness, swelling in the area where the child received the INVANZ[®] shot

Other side effects in children include:

- oral thrush
- loss of appetite
- hot flush, high blood pressure
- wheezing
- pain in the abdomen, toothache, loose stools, gas, nausea
- diaper rash, skin redness, skin itching, skin rash (red or purple), flat pinhead spots under the skin
- burning, itching, redness and warmth at infusion site, redness or formation of lump at the injection site
- changes in some laboratory blood tests

| Serious side effects and what to do about them | | | |
|--|--------------------------------------|--------------|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| UNCOMMON | | | |
| Seizures | | ✓ | |
| Serious and sometimes deadly allergic reactions: <ul style="list-style-type: none"> • severe rash with or without high fever, itching, hives on the skin • swelling of the face, lips, tongue or other parts of the body • shortness of breath, wheezing or trouble breathing | | | ✓ |
| Bowel infection (Clostridium difficile colitis): <ul style="list-style-type: none"> • diarrhea (very loose stool) that does not go away (bloody or watery) with or without : <ul style="list-style-type: none"> ○ fever ○ stomach cramps | | ✓ | |
| UNKNOWN | | | |
| Nervous system problems <ul style="list-style-type: none"> • decreased consciousness e.g. symptoms such as <ul style="list-style-type: none"> ○ persistent drowsiness ○ reduced response or awareness, slow to respond ○ shallow or irregular breathing, or stupor • abnormal movements tremors (shaking) | | ✓ | |
| Problems that affect behavioral health: <ul style="list-style-type: none"> • aggression • feeling restless • feeling lost or confused • seeing or hearing things that are not there (hallucinations) • mental status changes | | ✓ | |

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|--|--------------------------------------|--------------|---|
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| | Only if severe | In all cases | |
| <ul style="list-style-type: none"> change in thinking clearly | | | |
| <p>Severe Cutaneous Adverse Reactions (SCAR): severe skin reactions that may also affect other organs:</p> <ul style="list-style-type: none"> Skin peeling, scaling, or blistering (with or without pus) which may also affect your eyes, mouth, nose or genitals, itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish) Swelling and redness of eyes or face Flu-like feeling, fever, chills, body aches, swollen glands, cough Shortness of breath, chest pain or discomfort | | | ✓ |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store the dry powder at room temperature between 15°C and 25°C.
Most of the time, INVANZ® will be given in a hospital or physician's office.

Keep INVANZ® and all medicines safely out of reach and sight of children.

If you want more information about INVANZ®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.merck.ca, or by calling 1-800-567-2594.

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