**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS**

S4

**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM**

INVANZ® Sterile Powder for Injection

**Read all of this leaflet carefully before you are given INVANZ.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist
- INVANZ has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

## 1. WHAT INVANZ CONTAINS

- The active substance is ertapenem 1 g.
- The other ingredients are sodium bicarbonate and sodium hydroxide.

INVANZ is available as intramuscular and intravenous route of administration.

## 2. WHAT INVANZ IS USED FOR

INVANZ is an antibiotic that has the ability to kill a wide range of bacteria that cause infections.

Your doctor has prescribed INVANZ to treat your infections:

- Intra-abdominal infection
- Skin infection, including diabetic lower extremity and diabetic foot infections

- Community acquired pneumonia
- Urinary tract infection, including kidney infection
- Acute pelvic infection.

## 3. BEFORE YOU USE INVANZ

**INVANZ should not be given intravenously:**

- If you or your child are allergic to any of its ingredients.
- If you or your child are allergic to beta-lactams, such as penicillins or cephalosporins.
- If you or your child have bacterial meningitis (infection and inflammation of the membranes and cerebrospinal fluid surrounding the brain and spinal cord.

**INVANZ should not be given intramuscularly:**

- If you or your child are allergic to any of its ingredients.
- If you or your child are allergic to beta-lactams, such as penicillins or cephalosporins.
- If you or your child are allergic to local anaesthetics of the amide type, particularly lidocaine hydrochloride.
- If you or your child have bacterial meningitis (infection and inflammation of the membranes and cerebrospinal fluid surrounding the brain and spinal cord).

**Special care should be taken with INVANZ**

Tell your doctor or any other healthcare professional about any medical condition you or your child has now or has had, including:

- kidney disease
- allergies to any drugs, including antibiotics
- inflammation of the large bowel or any other gastrointestinal disease
- epilepsy.

Tell your doctor if you are taking a medicine containing valproic acid (used for epilepsy and depression).

**Pregnancy and breastfeeding**

INVANZ has not been studied in pregnant women.

INVANZ is secreted in human milk. Women who are receiving INVANZ should not breastfeed their babies.

**If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking INVANZ.**

**Use in children**

INVANZ can be given to children 3 months of age and older. INVANZ is not recommended in children under 3 months of age as no data are available.

**Use in the elderly**

The recommended dosage of INVANZ can be administered without regard to age.

**Using other medicines with INVANZ**

In general, INVANZ can be used with other medicine. You should tell your doctor about all medicine that you or your child is taking or plan to take, including those obtained without a prescription, as some medicine may affect each other's action.

Tell your doctor if you are taking a medicine containing valproic acid (used to treat epilepsy, bipolar disorder, migraine, or schizophrenia). Your doctor will decide whether you should use INVANZ in combination with this medicine.

**Always tell your healthcare professional if you are taking any other medicine. (This includes complimentary or traditional medicines.)**

**Driving and using machinery**

There is no information to suggest that INVANZ affects the ability to drive or operate machinery.

## 4. HOW INVANZ IS ADMINISTERED

INVANZ may be infused into a vein (intravenous infusion) or injected into a muscle (intramuscular injection). When administered intravenously, INVANZ should be infused over a period of 30 minutes.

INVANZ will be given to you or your child by a medical practitioner or another healthcare professional who will determine the most appropriate method and dose.

It is very important that you or your child continues to receive INVANZ for as long as your doctor prescribes it. Your doctor will let you or your child know when you may stop receiving INVANZ.

**If you receive more INVANZ than you should**

The injection schedule will be set by your doctor, who will monitor your response and condition to determine what treatment is needed. However, if you or your child is concerned

that you may have been given too much INVANZ, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**Do not share medicines prescribed for you with others.**

**If you forget to use INVANZ**

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

Do not take a double dose to make up for forgotten individual doses.

## 5. POSSIBLE SIDE EFFECTS

INVANZ may have side effects.

The most common side effects in adults are diarrhoea, inflammation of the vein, nausea and headache.

Other side effects in adults include: irritation of the vein at the infusion site, vomiting, rash, vaginitis, dizziness, sleepiness, sleeplessness, seizure, confusion, altered mental status (including agitation, aggression, delirium, disorientation, mental status changes), abnormal movements, swelling at injection site, low blood pressure, shortness of breath, oral thrush, constipation, acid regurgitation, dry mouth, teeth staining, indigestion, loss of appetite, skin redness, itching, hives, severe allergic reactions (anaphylaxis), abdominal pain, fungal infections, abnormal taste, fatigue, swelling of the lower limbs, feeling unwell, fever, pain,

chest pain, vaginal itching, alterations in some laboratory blood tests, and a combination of high fever, feeling unwell and skin rash.

Side effects in children are generally similar to those in adults. The most common side effects in children are diarrhoea, pain and redness at the infusion site.

Other side effects in children include: inflammation of the vein at the infusion site, vomiting, rash, swelling, formation of a lump, itching and warmth at the infusion site, inflammation of the vein and alterations in some laboratory blood tests.

If you experience raised or fluid-filled skin spots over a large area of your body, tell your doctor or nurse straight away.

Your doctor or healthcare professional has a more complete list. Tell your doctor or healthcare professional promptly about these or any other unusual symptoms.

**Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.**

## 6. STORING AND DISPOSING OF INVANZ

Store the dry powder at or below 25 °C.

Please consult the professional information for information on storage periods for reconstituted solutions. Any unused portion of solutions of INVANZ should be discarded.

Store all medicines out of reach of children.

Do not use this medicine after the month and year following EXP.: on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 7. PRESENTATION OF INVANZ

INVANZ is supplied in 15 ml glass vials.

## 8. IDENTIFICATION OF INVANZ

INVANZ Sterile Powder for Injection: solid, white to off-white essentially uniform cake.

INVANZ Reconstituted Solution: the reconstituted solution ranges from colourless to pale yellow and is essentially free of visual foreign matter particles.

## 9. REGISTRATION NUMBER

37/20.1.1/0424

## 10. NAME AND ADDRESS OF REGISTRATION HOLDER

MSD (Pty) Ltd

117 16th Road

Halfway House

1685

Tel. No.: 011 655 3000

## 11. DATE OF PUBLICATION

Date of registration certificate: 28 May 2004

Date of the most recently revised as approved: 19 June 2018 (SR-PIN: 20 September 2019)

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