PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

INOXIPHIN 250 mg (Powder for Solution for Injection)

INOXIPHIN 500 mg (Powder for Solution for Injection)

INOXIPHIN 1 g (Powder for Solution for Injection)

INOXIPHIN 2 g (Powder for Solution for Injection or Infusion)

"Sugar free"

Read all of this leaflet carefully before you start taking INOXIPHIN

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **INOXIPHIN** 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

What is in this leaflet

INOXIPHIN is contains an antibiotic called ceftriaxone, given to adults and children (including newborn babies). It works by killing bacteria that cause infections. It belongs to a group of medicines called cephalosporins.

WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN INOXIPHIN

Do not receive INOXIPHIN if:

- You are allergic to ceftriaxone or any of the other ingredients of **INOXIPHIN** listed in section 6.
- You have had a sudden or severe allergic reaction to penicillin or similar antibiotics (such as cephalosporins, carbapenems or monobactams). The signs include
- sudden swelling of the throat or face which might make it difficult to breath or swallow, sudden swelling of the hands, feet and ankles, and a severe rash that develops quickly
- You are allergic to lidocaine (lignocaine) and you are to be given **INOXIPHIN** injection into a muscle

INOXIPHIN Injection must not be given to babies if:

- The baby is premature
- The baby is newborn (up to 28 days of age) and has certain blood problems or jaundice (yellowing of the skin or whites of the eyes) or is about to be given a product that contains calcium into their vein

Warnings and precautions

Take special care with INOXIPHIN if:

- You have recently received or are about to receive products that contain calcium
- If your child has recently been given or is to be given a product that contains calcium into their vein
- You have recently had diarrhoea after having an antibiotic medicine.
- You have ever had problems with your gut, in particular colitis (inflammation of the bowel)
- You have liver or kidney problems
- You have gall stones or kidney stones
- If you have other illnesses, such as haemolytic anaemia (a reduction in your red blood cells that may make your skin pale yellow and cause weakness or breathlessness)
- If you are on a low sodium diet.
- If you need a blood or urine test. **INOXIPHIN** injection can affect the results of urine tests for sugar and a blood test known as the Coombs test (A test checks your blood for antibodies that attack red blood cells)
- Tell the person taking the sample that you have been given **INOXIPHIN**

- If you are given **INOXIPHIN** for a long time, you may need to have regular blood tests.
- You experience or have previously experienced a combination of any of the following symptoms: rash, red skin, blistering of the lips eyes and mouth, skin peeling, high fever, flu-like symptoms, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes (signs of severe skin reactions, see also section 4 “Possible side effects”).
- If you are diabetic or need to have your blood glucose level monitored you should not use certain blood glucose monitoring systems which may estimate blood glucose incorrectly while you are receiving **INOXIPHIN**. If you use such systems check the instructions for use and tell your healthcare professional Alternative testing methods should be used if necessary.

Children

Talk to your doctor or pharmacist or nurse before your child is administered **INOXIPHIN** if:

- He/ She has recently been given or is to be given a medicine that contains calcium into their vein.

Other medicines and INOXIPHIN

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

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- A type of antibiotic called an aminoglycoside like amikacin, gentamycin and neomycin which is used to treat certain infections. **INOXIPHIN** may intensify the effects of the aminoglycosides.
- An antibiotic called chloramphenicol (used to treat infections, particularly of the eyes). **INOXIPHIN** can weaken the effectiveness of chloramphenicol.
- Anticoagulants like warfarin used to thin the blood as **INOXIPHIN** can intensify the effect of anticoagulants and cause increased bleeding.
- Alcohol. When [**PRODUCT NAME]** is used with alcohol it can increase the effects of alcohol, and cause side effects like vomiting, nausea and abdominal pain.

INOXIPHIN with food and drink and alcohol

INOXIPHIN should not be taken with alcohol.

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Breastfeeding mothers should take care as ceftriaxone as contained in **INOXIPHIN** is excreted in breastmilk.

Driving and using machines

INOXIPHIN can cause dizziness. If you feel dizzy, do not drive or use any tools or machines. Talk to your doctor if you experience these symptoms. You should not drive or operate machines until you know hoe **INOXIPHIN** affects you.

INOXIPHIN contains:

INOXIPHIN contains only ceftriaxone in the form of a sodium salt. Talk to your doctor or pharmacist if you need more than 4g daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

INOXIPHIN 2g contains 166 mg sodium in each 2 g bottle.

INOXIPHIN 1g contains 83 mg sodium in each 1 g bottle.

INOXIPHIN 500 mg contains 41,5 mg sodium in each 500 mg bottle.

INOXIPHIN 250 mg contains 20,75 mg sodium in each 250 mg bottle.

2. HOW INOXIPHIN IS GIVEN:

Do not share medicines prescribed for you with any other person.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will decide how much **INOXIPHIN** to give you. He or she will also decide how often you need it and for how long.

INOXIPHIN is usually given by a doctor or nurse.

It can be given as a drip (intravenous infusion) or as an injection directly into a vein or into a muscle. **INOXIPHIN** is made up by the doctor, pharmacist or nurse and will not be mixed with or given to you at the same time as calcium-containing injections.

Your doctor will decide the correct dose of **INOXIPHIN** for you. The dose will depend on the severity and type of infection; whether you are on any other antibiotics; your weight and age; how well your kidneys and liver are working. The number of days or weeks that you are given **INOXIPHIN** depends on what sort of infection you have.

Adults, older people and children aged 12 years and over with a body weight greater than or equal to 50 kilograms (kg):

The usual dose is 1 to 2 g once a day

Newborn babies, infants and children aged 15 days to 12 years with a body weight of less than 50 kg:

The usual dose is 20-80 mg of **INOXIPHIN** for each kg of the child's body weight once a day

Newborn babies (0-14 days)

The usual dose is 20 – 50 mg of **INOXIPHIN** for each kg of the child's body weight once a day

People with liver and kidney problems

You may be given a different dose to the usual dose. Your doctor will decide how much of **INOXIPHIN** injection you will need and will check you closely depending on the severity of the liver and kidney disease.

If you take more INOXIPHIN than you should

Since a health care provider will administer **INOXIPHIN,** he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to take INOXIPHIN

Since a health care provider will administer **[PRODUCT NAME**], it is unlikely that the dose will be missed.

If you stop taking INOXIPHIN

Your doctor will determine when you will be stop taking **INOXIPHIN.**

3. POSSIBLE SIDE EFFECTS

INOXIPHIN can have side-effects.

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

If any of the following happens, stop taking INOXIPHIN and tell your doctor immediately or go to the casualty department at your nearest hospital:

The signs may include:

- Sudden swelling of the face, throat, lips or mouth. This can make it difficult to breathe or swallow.
- Sudden swelling of the hands, feet and ankles.

A severe rash that develops quickly, with blisters or peeling of the skin and possibly blisters in the mouth (Stevens-Johnson syndrome and toxic epidermal necrolysis which are also known as SJS and TEN).

- A combination of any of the following symptoms: widespread rash, high body temperature, liver enzyme elevations (yellowing of skin and the whites of the eyes, swollen abdomen, fatigue), enlarged lymph nodes and other body organs involvement (fever, night sweats, weight loss) [Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome].
- Jarisch-Herxheimer reaction which causes fever, chills, headache, muscle pain, and skin rash that is usually self-limiting. This occurs shortly after starting **INOXIPHIN** treatment for infections with spirochete such as Lyme disease.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to **INOXIPHIN.** You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent:

• Loose stools or diarrhoea

• Rash

Less frequent:

- Fungal infections (for example, thrush)
- Problems with the way your blood clots. The signs may include bruising easily and pain and swelling of your joints
- Headache
- Dizziness
- Feeling sick or being sick
- Pruritis (itching)
- Pain or a burning feeling along the vein where **INOXIPHIN** has been given. Pain where the injection was given
- A high temperature (fever)
- Inflammation of the large bowel (colon). The signs include diarrhoea, usually with blood and mucus, stomach pain and fever
- Difficulty in breathing (bronchospasm)
- A lumpy rash (hives) that may cover a lot of your body, feeling itchy and swelling
- Blood or sugar in your urine
- Oedema (swelling)

- Shivering

Not known (Frequency cannot be estimated from the available data)

- Liver Damage

Laboratory results:

- Abnormalities with your white blood cells (such as a decrease of leucocytes and an increase of eosinophils) and platelets (decrease of thrombocytes)
- Changes in the results of blood tests for liver functions
- Abnormal kidney function test (blood creatinine increased)
- A decrease in the number of white blood cells (granulocytopenia)
- Reduction in number of red blood cells (anaemia)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse drug Reaction reporting Form**", found online under SAHPRA's publications : https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **INOXIPHIN**

4. HOW TO STORE INOXIPHIN

KEEP OUT OF REACH OF CHILDREN

Store at or below 25 °C. Keep product in outer container until required for use.

Storage Directions for Reconstituted Product

Store for up to 6 hours at or below 25 °C or 24 hours in the refrigerator at or below 2 - 8 °C. This medicine should not be used after the expiry date (EXP) shown on the pack

5. CONTENTS OF THE PACK AND OTHER INFORMATION

What INOXIPHIN contains

Each vial contains ceftriaxone sodium equivalent to**:**

250 mg ceftriaxone (IM or IV)

500 mg ceftriaxone (IM or IV)

1 g ceftriaxone (IM or IV)

2 g ceftriaxone for IV infusion

Excipients: There are no other ingredients in **INOXIPHIN.**

INOXIPHIN contains sodium.

What INOXIPHIN looks like and contents of the pack

INOXIPHIN 250 mg, INOXIPHIN 500 mg and INOXIPHIN 1g:

Almost white or yellowish crystalline powder filled in 15 mL moulded Type I clear glass vials with 20 mm grey bromobutyl rubber stoppers and sealed with aluminium seal with

a white coloured poly propylene disc for the 250 mg strength, cream coloured poly propylene disc for the 500 mg strength and chrome yellow for the 1 g strength.

INOXIPHIN 2 g

Almost white or yellowish crystalline powder filled in 50 mL moulded Type I clear glass vials with 20 mm grey bromobutyl rubber stoppers and sealed with aluminium seal with a lemon-yellow coloured poly propylene disc.

Packs for IM or IV injection containing:

INOXIPHIN 250 mg: 1vial with dry substance equivalent to 250 mg ceftriaxone packed in a unit carton

INOXIPHIN 500 mg: 1vial with dry substance equivalent to 500 mg ceftriaxone packed in a unit carton

INOXIPHIN 1 g: 1 vial with dry substance equivalent to 1 g ceftriaxone packed in a unit carton.

Pack for IV infusion containing:

INOXIPHIN 2 g: 1 vial with dry substance equivalent to 2 g ceftriaxone packed in a unit carton.

Holder of Certificate of Registration

Innovata Pharmaceuticals (Pty) LTD

Crownwood Office Park

100 Northern Parkway

Ormonde

Johannesburg

2091

South Africa

This leaflet was revised in

22 August 2023

Registration number

INOXIPHIN 250 mg 51/20.1.1/0770

INOXIPHIN 500 mg 51/20.1.1/0771

INOXIPHIN 1 g 51/20.1.1/0772

INOXIPHIN 2 g 51/20.1.1/0773

Access to the corresponding Professional information.

A copy of the professional Information is contained in the packaging of **INOXIPHIN.**