PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PRODUCT NAME, strength and pharmaceutical form

FRAXONE 250 mg and Fraxone 1 g Injection

Each vial contains ceftriaxone sodium (sterile) equivalent to ceftriaxone.

Sugar free

Water for injection (injection)

For fill list of excipients: **see section 6**

Read all this leaflet carefully before you start taking FRAXONE

What is in this leaflet

1. What FRAXONE is and what is it used for:

Date of PIL: 01 October 2024

FRAXONE contains the active ingredient ceftriaxone sodium, which is an antibacterial agent used for treatment of infections caused by bacteria.

FRAXONE is an antibiotic used for the treatment of bacterial infections. It is also used prior to some surgical operations to reduce the risk of bacterial infections.

2. What you need to know before you take FRAXONE:

FRAXONE should not be administered to you:

- If you are allergic to **FRAXONE** or other medicines containing related antibiotics such as cephalosporins or penicillins.
- If **FRAXONE** is mixed together with calcium-containing solutions or products, or if **FRAXONE** is going to be administered to you through an intravenous infusion line which contains calcium- containing fluid, it could cause a precipitation of ceftriaxone-calcium salt.
- If you have had a bad reaction to a lidocaine/lignocaine injection in the past.

FRAXONE must not be given to babies if:

- The baby is premature
- The baby is newborn (up to 28 days) and has certain blood problems or jaundice (yellowing of the skin or the whites of the eyes) or is about to be given another injection that contains calcium.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you have both a liver and a kidney condition.
- If you have recently received or are about to receive calcium.

- If you have ever had problems with your gut, in particular colitis (inflammation of the bowel).
- If you have other illnesses, such as blood problems in children (such as jaundice).
- If you have allergies, particularly to cephalosporins, penicillins, or similar antibiotics.
- If you are on a low sodium diet.
- If 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 if 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 section 4).

Children and adolescents:

Newly born babies, infants and children will receive a dose based on their age and bodyweight.

Other medicines and FRAXONE:

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

- Before starting treatment, make sure your doctor knows if you are taking other medicine. This is extremely important, as using more than on medicine at the same time can strengthen or weaken the effect of the medicines. For example, if you are taking oral contraceptives you will need to use another

additional method of contraception while you are being treated with **FRAXONE** and for one month after finishing your treatment.

- **FRAXONE** should not be added to solutions containing calcium.
- Unwanted effects have been observed with the combination of medicines containing chloramphenicol and ceftriaxone.
- If you are taking medicine to reduce the clotting of your blood, tell your doctor before you receive **FRAXONE**.

If you need a blood or urine test

If you are given **FRAXONE** for a long time, you may need to have regular blood tests. **FRAXONE** can affect the results of urine tests for sugar and a blood test known as the Coombs test. If you are having tests:

• Tell the person taking the sample that you have been given **FRAXONE**.

• 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 **FRAXONE**. If you use such systems check the instructions for use and tell your doctor, pharmacist or nurse. Alternative testing methods should be used if necessary.

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 healthcare provider for advice before taking this medicine.

Safety and efficacy has not been established. You should not receive **FRAXONE** when you are pregnant or breastfeeding your baby.

Driving and using machines:

FRAXONE can cause drowsiness. If you feel dizzy, do not drive or use any tools or machines. Talk to your doctor if you experience these symptoms.

3. How FRAXONE is given:

Depending on the nature of your illness, your bodyweight, your age and your individual response to **FRAXONE**, your doctor will administer the correct dose into your muscle (*IM*) or vein (*IV*).

If you receive FRAXONE than you should

Your doctor will prescribe the appropriate care for you should you receive more than the required amount of **FRAXONE**

If you did not receive your FRAXONE therapy:

Your doctor will prescribe the appropriate care you should receive.

Effects when treatment with FRAXONE is stopped:

The duration of **FRAXONE** therapy varies, depending on the nature of your illness and your individual response to the treatment.

You will receive **FRAXONE** for at least 2 - 3 days after starting to recover from your illness or after a surgical operation to prevent infections from occurring.

4. Possible side effects

FRAXONE can have side effects.

Not all side effects reported for **FRAXONE** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **FRAXONE**, please consult your health care provider for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist. **FRAXONE** may cause side effects, even when used as directed.

The following side effects may occur in patients during treatment:

Severe allergic reactions

If you have a severe allergic reaction, tell your doctor as soon as possible.

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.

Severe skin reactions

If you get a severe skin reaction, tell your doctor as soon as possible.

The signs may include:

• 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, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome).

Other possible side effects:

<u>Frequent</u>

- Abnormalities with your white blood cells (such as a decrease of leucocytes and an increase of eosinophils) and platelets (decrease of thrombocytes). • Loose stools or diarrhoea.
- Changes in the results of blood tests for liver functions.
- Rash.

<u>Less frequent</u>

- Fungal infections (for example, thrush).
- A decrease in the number of white blood cells (granulocytopenia)
- Reduction in number of red blood cells (anaemia).
- 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 **FRAXONE** has been given.
- Pain where the injection was given.
- Abnormal kidney function test (blood creatinine increased).
- Fever
- shivering,
- wheezing
- temporary liver problems
- fungal infections affecting the genital regions
- other types of infection, e.g. yeasts.
- 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 (fluid build-up).
- Shivering.

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

- A secondary infection that may not respond to the antibiotic previously prescribed
- Form of anaemia where red blood cells are destroyed (haemolytic anaemia). • Severe decrease in white blood cells (agranulocytosis).

- Convulsions.
- Vertigo (spinning sensation).
- Inflammation of the pancreas (pancreatitis). The signs include severe pain in the stomach which spreads to your back.Inflammation of the mucus lining of the mouth (stomatitis).
- Inflammation of the tongue (glossitis). The signs include swelling, redness and soreness of the tongue.
- Problems with your gallbladder, which may cause pain, feeling sick and being sick.
- A neurological condition that may occur in neonates with severe jaundice (kernicterus). • Kidney problems caused by deposits of calcium ceftriaxone. There may be pain when passing water (urine) or low output of urine.
- A false positive result in a Coombs' test (a test for some blood problems).
- A false positive result for galactosaemia (an abnormal build up of the sugar galactose).
- **FRAXONE** may interfere with some types of blood glucose tests - please check with your doctor.
- Liver damage

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 **FRAXONE.**

5. How to store FRAXONE

Store at or below 25 °C, protected from light and moisture. Do not freeze.

Reconstituted solution to be stored in original vials and used within 6 hours, if stored at 25 °C or within 24 hours if stored at 2 – 8 °C in a refrigerator.

KEEP OUT OF REACH OF CHILDREN.

Do not use after the expiry date stated on the label and carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems

(e.g., toilets).

6. Contents of the pack and other information

What FRAXONE contains:

The vials contain 250 mg or 1 g of ceftriaxone sodium equivalent to ceftriaxone.

There are no other ingredients.

What FRAXONE looks like and contents of the pack

FRAXONE 250: White to yellowish orange, crystalline powder in 15 ml clear glass USP type I, vials with orange coloured flip-off seals. Cartons containing 1 clear glass USP Type I vial.

FRAXONE 1 g: White to yellowish orange, crystalline powder in 15 ml clear glass USP type I, vials blue flip-off seals Cartons containing 1 clear glass USP Type I vial.

On constitution a pale yellow to reddish orange clear solution is obtained.

Holder of Certificate of Registration

Innovata Pharmaceuticals

Crownwood Office Park

100 Northern Parkway

Ormonde

Johannesburg

2091

South Africa

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Registration number

Fraxone 250: 34/20.1.1/0320

Fraxone 1 g: 34/20.1.1/0321

Access to the corresponding Professional information is contained in the

packaging or

Follow the link for the corresponding Professional Information for **FRAXONE**:

pi-pil-repository.innovata.co.za,

alternatively, please scan the QR code below:

PLACE HOLDER: The QR code to be included after approval.