APPROVED PATIENT INFORMATION LEAFLET

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TRYCOSIL 250 mg INJECTION (Sterile powder for injection)

TRYCOSIL 500 mg INJECTION (Sterile powder for injection)

TRYCOSIL 1 g INJECTION (Sterile powder for injection)

Ampicillin sodium

Read all of this leaflet carefully before TRYCOSIL is administered to you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **TRYCOSIL INJECTION** 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 TRYCOSIL INJECTION CONTAINS

The active substance is ampicillin sodium.

TRYCOSIL 250 mg INJECTION is available in vials containing the equivalent of 250 mg ampicillin as ampicillin sodium, presented as a sterile powder for reconstitution.

TRYCOSIL 500 mg INJECTION is available in vials containing the equivalent of 500 mg ampicillin as ampicillin sodium, presented as a sterile powder for reconstitution.

TRYCOSIL 1 g INJECTION is available in vials containing the equivalent of 1 g ampicillin as ampicillin sodium, presented as a sterile powder for reconstitution.

2. WHAT TRYCOSIL INJECTION IS USED FOR

TRYCOSIL INJECTION is an antibiotic medicine. It belongs to the penicillin group of antibiotics and it works by killing bacteria that cause certain infections. **TRYCOSIL INJECTION** is used to treat infections caused by ampicillin-sensitive bacteria.

3. BEFORE YOU RECEIVE TRYCOSIL INJECTION

TRYCOSIL INJECTION should not be administered to you:

- If you have ever had an unusual or allergic reaction to **TRYCOSIL INJECTION** or to antibiotics known as penicillins or cephalosporins.
- If the patient is a newborn baby whose mother is allergic to ampicillin.

Take special care with TRYCOSIL INJECTION:

- Before **TRYCOSIL INJECTION** is administered to you:

- Tell your doctor if you are allergic to penicillins, cephalosporins, any other medications, or have a history of allergy. Serious and sometimes fatal allergic reactions are more likely to occur in patients with a history of penicillin allergy or other allergies.

  TRYCOSIL INJECTION should be stopped and emergency help given if you have any of these signs of a severe allergic reaction: difficulty breathing; swelling of your face, lips, tongue or throat.
- Tell your doctor if you have syphilis, since a reaction called the “Jarisch-Herxheimer reaction” may occur shortly after starting treatment with **TRYCOSIL INJECTION**. Symptoms of this reaction include fever, chills and headaches.
- Tell your doctor if you are on a low sodium (salt) diet – **TRYCOSIL INJECTION** contains sodium.
- Tell your doctor if you have kidney problems. Your doctor may need to reduce your dosage.
- Tell your doctor if you have congestive heart failure.
- Tell you doctor if you have glandular fever, lymphatic leukaemia (cancer of the blood), or HIV infection, or if you are taking a medicine called allopurinol. There is an increased possibility of skin rashes occurring in patients taking **TRYCOSIL INJECTION** with these conditions.
- Tell you doctor if you have a bleeding or blood clotting disorder.

- If a skin rash occurs, **TRYCOSIL INJECTION** should be stopped.
- A serious form of diarrhoea (pseudomembranous colitis) may develop if you use **TRYCOSIL INJECTION** for a long period of time. Contact your doctor right away if stomach pain or cramps, severe diarrhoea, or bloody stools occur.
- During long-term treatment, your doctor may want to take routine blood tests to monitor your kidney function, liver function and levels of blood cells.

- **TRYCOSIL INJECTION** can cause interference in some tests for glucose in urine. Penicillins which are excreted in urine can cause a false-positive result. Your doctor will request a test which is not affected by penicillins.
- **TRYCOSIL INJECTION** may interfere with certain laboratory tests. Be sure your doctor and laboratory personnel know you are using **TRYCOSIL INJECTION**.
- Make sure that you take enough fluids.
- Avoid contact with skin

Taking TRYCOSIL INJECTION with food and drink:

- It is recommended that alcohol should be avoided during and for several days after treatment with **TRYCOSIL INJECTION**.

Pregnancy and Breast-feeding:

Tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding.

- The safety of **TRYCOSIL INJECTION** during pregnancy and breast-feeding has not been determined.
- **TRYCOSIL INJECTION** pass into breast milk. The use of **TRYCOSIL INJECTION** by breast-feeding mothers may cause sensitivity (allergic reaction) such as diarrhoea, thrush and skin rash in the baby.

If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before being given medicine.

Driving and using machinery:

TRYCOSIL INJECTION may cause dizziness. If you experience these symptoms while taking **TRYCOSIL INJECTION**, do not drive and do not use tools and machines.

Taking other medicines with TRYCOSIL INJECTION:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Some medicines may interact with **TRYCOSIL INJECTION**. Before taking **TRYCOSIL INJECTION**, tell your doctor if you are using any of the following medicines:

- Preparations for thinning blood (e.g. warfarin, heparin) – Your doctor may want to monitor your blood clotting time more frequently if you are receiving anticoagulant treatment in combination with **TRYCOSIL INJECTION**.
- NSAIDs (non-steroidal anti-inflammatory drugs) or salicylates (e.g. aspirin) – The risk of bleeding is increased when these medicines are used together with **TRYCOSIL INJECTION**.
- Methotrexate, used to treat cancer – **TRYCOSIL INJECTION** may decrease the removal of methotrexate from the body, increasing the risk of its side-effects. Your doctor may want to monitor the amount of methotrexate in your blood if you are receiving methotrexate treatment in combination with **TRYCOSIL INJECTION**.
- Allopurinol, medicine for gout - There is an increased possibility of skin rashes occurring in patients taking **TRYCOSIL INJECTION** together with allopurinol.
- Oral contraceptives – **TRYCOSIL INJECTION** may decrease the effectiveness of birth control pills. Use an alternative or additional method of birth control while taking **TRYCOSIL INJECTION** to protect against pregnancy.

If you are using any of these medicines, you may not be able to take **TRYCOSIL INJECTION**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side-effects.

4. HOW TRYCOSIL INJECTION will be given

- **TRYCOSIL INJECTION** is usually given as an injection at your doctor's office, hospital, or clinic.
- **TRYCOSIL INJECTION** may be given by injection into a muscle or vein or as directed by your doctor.
- Based on the type and seriousness of the infection, your doctor will determine the dosage and time between dosages.
- Your doctor will decide for how long you will require **TRYCOSIL INJECTION** therapy.
- In children and newborn babies, the dosage is based on body weight.
- If you have kidney problems, your doctor may need to adjust the dose of **TRYCOSIL INJECTION**.

If you have the impression that the effect of **TRYCOSIL INJECTION** is too strong or too weak, talk to your doctor healthcare professional.

If you given more TRYCOSIL INJECTION than you should receive:

As **TRYCOSIL INJECTION** is administered by a medical professional, he/she will control the dosage. However in the event of overdosage your doctor will manage the overdosage.

Overdose symptoms may include increased gastrointestinal side effects such as nausea, vomiting and diarrhoea.

If a dose of TRYCOSIL INJECTION is missed:

- Your medication will usually be given to you by a healthcare professional. If you think that a dose has been skipped, please tell your doctor or nurse.

5. POSSIBLE SIDE-EFFECTS

TRYCOSIL INJECTION can have side-effects.

You will require emergency medical help if you have any of these **signs of a severe allergic reaction:**

- Hives; difficulty breathing; swelling of your face, lips, tongue, or throat, difficulty in swallowing or breathing.

Tell your doctor at once if you have any of these serious side-effects:

- Diarrhoea that is watery or bloody
- Easy/unusual bruising or bleeding, nose bleeds
- Severe skin rash or hives; widespread redness of the skin, blistering or severe peeling of the skin
- Seizures (convulsions)
- Hives, fever, joint pains
- Fever, chills, headache.
- Yellow pigmentation of skin and eyes.
- Urinating less than usual or not at all

Tell your doctor if you notice any of the following side-effects and they worry you or if any of these symptoms are severe or do not go away:

- Too few white blood cells (sore throat and fever); anaemia (tiredness, being short of breath and looking pale); numbness, tingling, pins and needles; thrush (white patches inside your mouth or

throat, vaginal itching or discharge); increased muscular activity; dizziness; nausea (queasiness, feeling that one is about to vomit); vomiting; diarrhoea; inflammation of the mouth; inflammation of the tongue; black hairy tongue; heartburn; inflammation of the blood vessels;-crystals found in the urine.

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

6. STORING AND DISPOSING OF TRYCOSIL INJECTION

Dry Powder: Store in a dry place at or below 25 °C (room temperature). Protect from light.

Solutions: Solutions prepared for injection into a muscle or vein should be given immediately after reconstitution. Unused solution INJECTION should be discarded. Do not freeze.

TRYCOSIL INJECTION is usually stored and handled by a healthcare provider. If you are using **TRYCOSIL** at home, store **TRYCOSIL INJECTION** as directed by your pharmacist or healthcare provider.

Store all medicines out of the reach and sight of children.

7. PRESENTATION OF TRYCOSIL INJECTION

PRESENTATION

TRYCOSIL 250 mg INJECTION:

10 ml clear transparent tubular glass vial fitted with a 20 mm grey bromobutyl rubber stopper and sealed with a 20 mm taxim blue colour flip off seal.

Pack size: Single vial packed in printed carton with a package insert.

TRYCOSIL 500 mg INJECTION:

10 ml clear transparent tubular glass vial fitted with a 20 mm grey colour bromobutyl rubber stopper and sealed with a 20 mm yellow colour flip off seal.

Pack size: Single vial packed in printed carton with a package insert.

TRYCOSIL 1 g INJECTION:

15 ml clear transparent tubular glass vial fitted with a 20 mm grey colour bromobutyl rubber stopper and sealed with a 20 mm dark green flip off seal.

Pack size: Single vial packed in printed carton with a package insert.

8. IDENTIFICATION OF TRYCOSIL INJECTION

TRYCOSIL 250 mg INJECTION:

White to off white crystalline powder filled in 10 ml tubular vial, stoppered with a 20 mm grey colour bromobutyl rubber stopper and sealed with a 20 mm taxim blue colour flip off seal.

TRYCOSIL 500 mg INJECTION:

White to off white crystalline powder filled in 10 ml tubular vial, stoppered with 20 mm grey colour bromobutyl rubber stopper and sealed with 20 mm Yellow colour flip off seal.

TRYCOSIL 1 g INJECTION:

White to off white crystalline powder filled in 15 ml tubular vial, stoppered with 20 mm grey colour bromobutyl rubber stopper and sealed with 20 mm dark green colour flip off seal.

9. REGISTRATION NUMBER/REFERENCE NUMBER

TRYCOSIL 250 mg INJECTION: 45/20.1.2/0785

TRYCOSIL 500 mg INJECTION: 45/20.1.2/0786

TRYCOSIL 1 g INJECTION: 45/20.1.2/0787

10. NAME AND ADDRESS OF REGISTRATION HOLDER

~~Aurobindo Pharma (Pty) Ltd~~ Aurogen South Africa (Pty) Ltd

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11. DATE OF PUBLICATION

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