SCHEDULING STATUS

S4

ETAMEP 1 g (lyophilised powder for solution for injection)

Ertapenem

Read all of this leaflet carefully before you are given ETAMEP.

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

The active ingredient is ertapenem.

The other ingredient of **ETAMEP** is sodium bicarbonate.

2. WHAT ETAMEP IS USED FOR

ETAMEP is an antibiotic which contains a medicine called ertapenem.

ETAMEP is used to treat bacterial infections which may be moderate or severe and which are caused by particular micro-organisms. It is used particularly in conditions such as complicated infections within your abdomen, skin or skin structure infections such as foot infections which diabetic patients are prone to, pneumonia, complicated urinary tract infections and infections of your pelvis.

3. BEFORE YOU ARE GIVEN ETAMEP

You should not be given ETAMEP:

- if you are hypersensitive (allergic) to ertapenem or to any of the ingredients of **ETAMEP**.
- if you have previously suffered with bacterial meningitis (inflammation of the tissues that surround the brain or spinal cord).
- if you have previously had a serious allergic reaction to other antibiotics. You should tell your doctor about this as it may indicate whether you will be allergic to **ETAMEP** as well.

- if you have previously had an allergic reaction to any local anaesthetics or if you have suffered from severe shock or if you know you have a slow heart rate, you should tell your doctor as you may not be able to be given **ETAMEP** with certain anaesthetics.

Take special care with ETAMEP:

- **you must tell your doctor if you have previously had a serious allergic reaction (such as swelling of the face, tongue or throat, difficulty in breathing or swallowing, skin rash) to other antibiotics (penicillin, cephalosporin, other beta-lactams) or any other type of medicine, as it may suggest that you are allergic to ETAMEP as well.**
- if you suffer from seizures or impaired kidney function it may make you more prone to having fits while on treatment with **ETAMEP**.
- if you experience severe diarrhoea after being given **ETAMEP** it may indicate that you have another infection of your colon caused by **ETAMEP**. You should notify your doctor of this so that the correct treatment can be started as soon as possible.

Pregnancy and breastfeeding:

Safety has not been determined during pregnancy and breastfeeding, but **ETAMEP** is excreted in human milk, therefore it is not recommended if you are breastfeeding your baby.

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

Driving and using machinery:

Due to the possibility of the side effects such as dizziness, seizures and altered mental status occurring, you should not drive or operate any heavy machinery until you know what effect of **ETAMEP** has on you.

Taking other medicines with ETAMEP:

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

- Probenecid, a medicine typically used to treat gout, may delay the excretion of **ETAMEP** from your body, therefore making the effect last longer.
- **ETAMEP** may decrease your blood levels of valproic acid, a medicine used in the treatment of fits, if taken together. Therefore your doctor may need to monitor your blood levels if you are given **ETAMEP**.

4. HOW TO RECEIVE ETAMEP

The usual dose of **ETAMEP** in patients 13 years of age and older is 1 gram (g) given once a day.

The usual dose of **ETAMEP** in patients 3 months to 12 years of age is 15 mg/kg twice daily (not to exceed 1g/day).

The treatment duration will last from 3 to 14 days depending on the type of infection that you have.

ETAMEP can be administered directly into your muscle or into your veins. If it is administered directly into your vein, it will be done over a period of 30 minutes.

You will not be expected to give yourself **ETAMEP**. It will be given to you by a person who is qualified to do so.

If you have been given more ETAMEP than you should:

Since a healthcare professional will administer **ETAMEP**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. POSSIBLE SIDE EFFECTS

ETAMEP can have side effects.

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

pharmacist or other health care professional for advice

If any of the following happen, tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction with symptoms such as swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.

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

Tell your doctor immediately if you notice any of the following:

- fits
- chest pain
- diarrhoea
- increased or decreased blood pressure
- increase in heart rate
- dizziness
- changes in your mental wellbeing.

These are all very serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- headache
- anxiety
- difficulty sleeping
- hallucinations
- cough
- difficulty breathing
- nausea
- fever
- acid reflux

- itchy red rash
- leg pain
- tiredness, and loss of muscle strength
- constipation
- oral fungal infection.

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

5. STORING AND DISPOSING OF ETAMEP

Lyophilised powder:

Store at or below 25 °C.

Reconstituted solutions:

IV use: The reconstituted solution, immediately diluted in 0,9 % of sodium chloride injection, may be stored at room temperature (25 °C) and used within 6 hours or stored for 24 hours under refrigeration (5 °C) and used within 4 hours after removal from refrigeration.

IM use: The reconstituted solution should be used with in 1 hour after preparation.

Solutions of **ETAMEP** should not be frozen. Any unused portion of solutions of **ETAMEP** should be discarded.

STORE ALL VIALS OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. PRESENTATION OF ETAMEP

20 mL clear transparent type-I glass tubular vial of 20 mm neck stoppered with 20 mm grey bromobutyl rubber stopper and sealed with 20 mm white aluminium PP disc.

Pack size: Printed cardboard carton containing 1 vial only.

7. IDENTIFICATION OF ETAMEP

White to off white lyophilised cake or powder. When reconstituted, it is a clear colourless to pale yellow solution free from particles.

8. REGISTRATION NUMBER

51/20.1.1/0747

9. NAME AND ADDRESS OF REGISTRATION HOLDER

Aurogen SA (Pty) Ltd

Woodhill Office Park, Building 1, First Floor

53 Phillip Engelbrecht Avenue

Meyersdal, Ext. 12, 1448

Johannesburg

South Africa

10.DATE OF PUBLICATION

17 March 2020