PATIENT INFORMATION LEAFLET

Read this entire leaflet carefully before you start taking APEN 500 and APEN S.

• Keep this leaflet. You may need to read it again.

• If you have further questions, please ask your doctor, pharmacist or health care professional.

• **APEN 500** and **APEN S** 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.

SCHEDULING STATUS:

S 4

PROPRIETARY NAME AND DOSAGE FORM:

APEN 500 (Capsules)

APEN S (Suspension)

Ampicillin and Cloxacillin

WHAT APEN 500 AND APEN S CONTAIN:

APEN 500: The active ingredients in the capsules are 250 mg ampicillin and 250 mg cloxacillin.

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The other ingredients in the capsules are: magnesium stearate, gelatin, yellow iron oxide, black iron oxide, titanium dioxide, indigotine, erythrosine, red iron oxide. The capsules are sugar-free.

APEN S: This is a powder for preparing a fruit-flavoured suspension. When made up as directed each 5 ml contains 125 mg ampicillin and 125 mg cloxacillin.

The other ingredients in the suspension are: saccharin sodium (dried), monoammonium glycyrrhizinate, disodium edetate, sodium citrate (dried), simethicone, menthol dry flavour, tutti-frutti dry flavour, blood orange dry flavour.

Each 5 ml of **APEN S** contains sucrose 3,6 g.

The powder contains 0,13 % m/m sodium benzoate B.P. as a preservative.

WHAT APEN 500 AND APEN S ARE USED FOR:

APEN 500 capsules and **APEN S** suspension are used for the treatment of infections caused by certain sensitive organisms.

BEFORE YOU TAKE APEN 500 AND APEN S:

Do not take APEN 500 AND APEN S:

- If you are hypersensitive (allergic) to any of the ingredients in **APEN 500** capsules and **APEN S** suspension, as well as the antibiotics called penicillin and cephalosporin.

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- Do not give to a baby in the neonatal period, if the mother is allergic to ampicillin (this is one of the ingredients in **APEN 500** and **APEN S**).
- If you are pregnant or breast feeding.
- **APEN 500** and **APEN S** must not be used in the eyes.

Take special care with APEN 500 and APEN S:

Very serious allergic reactions with the use of **APEN 500** and **APEN S** have been reported.

Before starting your treatment you must tell your doctor about any previous hypersensitivity or allergic reactions you have ever had after taking penicillins, cephalosporins and or any other allergies.

These allergic reactions may occur within a short time of taking **APEN 500** or **APEN S** and you should contact your doctor or seek help at the nearest hospital immediately to receive appropriate emergency treatment.

If you develop a skin rash you must contact your doctor, pharmacist or health care professional immediately and tell them about it.

When you use this medicine over a long period, you could develop infections that would need further treatment.

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The ampicillin in **APEN 500** and **APEN S** may decrease the effectiveness of oestrogen which is used in some oral contraceptives, and it may also affect the absorption of other medicines because of the effect on the stomach.

The use of **APEN 500** and **APEN S** may lead to the appearance of resistance to certain bacteria and testing should be done whenever possible, to make sure of the appropriateness of your treatment.

Your doctor will also consider whether you should receive **APEN 500** or **APEN S**:

- If you have bleeding problems.
- If you have heart problems or high blood pressure.
- If you have cystic fibrosis (this is a dysfunction of certain glands characterised by signs of pancreatic deficiency for which you should be getting treatment).
- If you have gastrointestinal disorders.
- If you have infectious mononucleosis (an acute infectious disease characterised by a sudden onset and acute course, with fever and inflammatory swelling of the lymph nodes).
- If you have kidney problems. Your kidneys and blood should be monitored when you are treated on a high dose of **APEN 500** or **APEN S.**
- If you are on a low salt diet.

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Pregnancy and Breast feeding:

If you are pregnant or breast feeding your baby while receiving **APEN 500** and **APEN S**, please consult your doctor, pharmacist or other health care professional for advice. **APEN 500** and **APEN S** must not be used during pregnancy or during breast feeding. If you take oral contraceptives, you must take additional contraceptive measures during therapy. Please discuss this with your doctor. If you plan a pregnancy, discuss this with your doctor. Your doctor will find the best treatment option during pregnancy and breast feeding.

If you are pregnant or breast feeding your baby while taking APEN 500 or APEN S, please consult your doctor, pharmacist or other health care professional for advice.

Taking other medicines with APEN 500 and APEN S:

- **APEN 500** and **APEN S** may interact with medicines such as chloramphenicol and tetracycline (antibiotics used to treat infections).

- If you take medicines to help stop blood clots, **APEN 500** and **APEN S** may interact with these medicines and this could increase the possibility of bleeding problems.

- **APEN 500** and **APEN S** may reduce the effectiveness of the oral contraceptive pill. You should take extra precautions, for instance using a condom during treatment.

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- If you use **APEN 500** and **APEN S** together with allopurinol (a medicine for the treatment of gout) (see **SIDE EFFECTS**).

- Alcohol should be not be used when you are taking **APEN 500** and **APEN S** and for several days after treatment is stopped.

- The effects of methotrexate (a medicine for treating cancer) may be increased by **APEN 500** and **APEN S.**

Important information about some of the ingredients of APEN S:

APEN S contains sucrose which is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine.

HOW TO TAKE APEN 500 AND APEN S:

Always take **APEN 500** and **APEN S** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Dosage:

Adults and children over 10 years:

500 mg - 1 g (1 - 2 x 500 mg capsules) every 6 hours.

Children 2 - 10 years:

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250 - 500 mg (5 - 10 ml of 250 mg/5 ml suspension) every 6 hours. (Your doctor will adjust the dosage to correspond to a daily dosage of 50 – 150 mg/kg).

Children up to 2 years:

250 mg (5 ml of 250 mg/5 ml suspension) every 6 hours.

Note:

1. The best results are obtained if **APEN 500** and **APEN S** are taken half to one hour before your meals.
2. If you have kidney problems you may receive a reduced dosage.
3. If you need treatment beyond the maximum period, your doctor will re-evaluate your condition.

Do not share medicines prescribed for you with others.

If you take more APEN 500 and APEN S than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take the APEN 500 and APEN S:

If you forget to take a dose, take it as soon as you remember.

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

POSSIBLE SIDE EFFECTS:

APEN 500 and **APEN S** may cause side effects.

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Frequent:

- Diarrhoea, nausea, vomiting, indigestion, abdominal pain.

  Skin rashes may occur and appear as nettle rash or spotty pimples.

  If you are getting treatment with a medicine called allopurinol and you also take **APEN 500** and **S**, you may have an increased risk of developing skin rashes.

  Abnormal taste.

  Headache, dizziness, tiredness and hot flushes.

Less frequent:

- Allergy or hypersensitivity reactions including swelling of the face, lips, throat or tongue or breathing problems.

Frequency unknown:

- Fever, joint pains and kidney infection.
- Blood disorders.
- Convulsions.
- Jaundice (yellow colour in the skin and whites of the eyes).

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

Not all side effects reported for APEN 500 and APEN S are included in this leaflet. Should your general health worsen while taking APEN 500

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or APEN S, please consult your doctor, pharmacist or health care professional for advice.

STORAGE AND DISPOSAL OF APEN 500 AND APEN S:

Containers of **APEN 500** and **APEN S** should be kept tightly closed in a cool, dry place at or below 25 °C.

Once reconstituted **APEN S** should be used within 7 days, if stored in a cool place at or below 25 ^{o}, or 14 days if stored in a refrigerator (5 ^{o}C).

Do not use after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

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

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

PRESENTATION OF APEN 500 AND APEN S:

APEN 500: Glass bottles containing 20 or 100 capsules.

APEN S: Glass bottles containing powder for the reconstitution of 100 ml of suspension.

IDENTIFICATION OF APEN 500 AND APEN S:

APEN 500: Grey / Aubergine capsules imprinted “APEN 500”.

APEN S: Glass bottles containing powder for the reconstitution of 100 ml of suspension.

REGISTRATION NUMBERS:

Signature:

APEN 500: 27/20.1.2/0108

APEN S: 27/20.1.2/0109

THE NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE:

Viatris South Africa (Pty) Ltd

4 Brewery Street,

Isando

Johannesburg,

1609

THE DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

02 March 2012

Signature: