Approved Patient Information Leaflet for Medicines for Human Use:

ATHLONE PHENOXYMETHYLPENICILLIN

SCHEDULING STATUS: S4

ATHLONE PHENOXYMETHYLPENICILLIN 125/5 mL Powder for solution

ATHLONE PHENOXYMETHYLPENICILLIN 125/5 mL Powder for solution

Phenoxymethylpenicillin

Contains sugar

ATHLONE PHENOXYMETHYLPENICILLIN 125/5 mL Powder for solution

Each 5 mL of reconstituted suspension contains 2795,76 mg sucrose.

ATHLONE PHENOXYMETHYLPENICILLIN 250/5 mL Powder for solution

Each 5 mL of reconstituted suspension contains 2898,02 mg sucrose.

Read all of this leaflet carefully before you start taking ATHLONE PHENOXYMETHYLPENICILLIN.

- 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.
- ATHLONE PHENOXYMETHYLPENICILLIN 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

1. What ATHLONE PHENOXYMETHYLPENICILLIN is and what it is used for
2. What you need to know before you take ATHLONE PHENOXYMETHYLPENICILLIN
3. How to take ATHLONE PHENOXYMETHYLPENICILLIN

4. Possible side effects

5. How to store ATHLONE PHENOXYMETHYLPENICILLIN

6. Contents of the pack and other information

1. What ATHLONE PHENOXYMETHYLPENICILLIN is and what it is used for

ATHLONE PHENOXYMETHYLPENICILLIN contains the active substance called phenoxymethylpenicillin is an antibiotic, which belongs to group of medicines called penicillins, which are used to kill bacteria that cause infections in your body.

Your medicine is used to:

- treat bacterial infections of the ear, throat, respiratory tract, periodontal infections
- prevent recurrent infections of rheumatic fever.

2. What you need to know before you take ATHLONE PHENOXYMETHYLPENICILLIN

Do not take ATHLONE PHENOXYMETHYLPENICILLIN:

- If you are allergic (hypersensitive) or have a history of allergy to penicillins or cephalosporins or any of the other ingredients in ATHLONE PHENOXYMETHYLPENICILLIN.

Some of the symptoms of an allergic reaction may include:

- skin rash (redness and itching),
- swelling of the hands, feet, ankles, face, lips, throat or tongue which may cause difficulty in swallowing or breathing,
- wheezing or shortness of breath (asthma).

- If you have chronic, severe, or deep infections such as subacute bacterial endocarditis, meningitis or syphilis.
- In severe empyema, bacteraemia, pericarditis and arthritis during the acute phase.
- To babies born of allergic mothers in the neonatal period.
- As adjunctive prophylaxis for genito-urinary instrumentation or surgery, lower intestinal tract surgery, sigmoidoscopy and child birth.

Warnings and precautions

Take special care with ATHLONE PHENOXYMETHYLPENICILLIN

- if you suffer from any kidney problems
- if you suffer from allergies and/or asthma
- if you suffer from any stomach problems, e.g. nausea, vomiting, bloating, difficult to swallow.

Other medicines and ATHLONE PHENOXYMETHYLPENICILLIN

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

Tell your doctor or pharmacist if you are using:

Methotrexate (a drug used to treat cancers and psoriasis)

Anticoagulants (e.g. warfarin - to prevent blood clots)

Sulfinpyrazone or Probenecid (medicines used to treat gout)

Oral Typhoid vaccine (penicillin can stop this from working)

Some other antibiotics (Tetracycline, Erythromycin, Chloramphenicol, and Neomycin)

ATHLONE PHENOXYMETHYLPENICILLIN with food, drink and alcohol

ATHLONE PHENOXYMETHYLPENICILLIN should be given half an hour before meals.

Pregnancy, 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 ATHLONE PHENOXYMETHYLPENICILLIN.

Driving and using machines

This medicine should not affect your ability to drive or to use machinery.

ATHLONE PHENOXYMETHYLPENICILLIN contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

ATHLONE PHENOXYMETHYLPENICILLIN contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 5 mL, that is to say essentially "sodium-free".

ATHLONE PHENOXYMETHYLPENICILLIN contains benzoic acid

Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take ATHLONE PHENOXYMETHYLPENICILLIN

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

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

ATHLONE PHENOXYMETHYLPENICILLIN is available as a powder for reconstitution. The powder for reconstitution is prepared by the pharmacist before dispensing by adding water to the powder to give 100 ml of oral solution.

Shake the bottle before use.

ATHLONE PHENOXYMETHYLPENICILLIN should be given in divided doses (6 hourly) and preferably half an hour before meals.

The following dosage schedule applied to ATHLONE PHENOXYMETHYLPENICILLIN.

Adults and children older than 12 years:

Preventative use: 125 to 250 mg [one to two medicine measures (5 ml - 10 ml of the 125 mg/ml)] twice a day.

One to two medicine measures (5 ml-10 ml of the 125 mg/ ml) every six hours, depending on the

severity.

For infants and small children, the suggested daily dosage is 15 mg to 50 mg per kg in 3 to 6 divided doses.

Children up to 1 year:

62,5 mg [half a medicine measure (2,5 ml)] every 6 hours.

Children 1 - 5 years; 125 mg [one medicine measure (5 ml) of the 125 mg/ml] every six hours.

Children 6- 12 years: 250 mg [two medicine measures (10 ml) of the 125 mg/ml] every six hours.

Beta-haemolytic streptococcus infections without associated bacteraemia may be treated with 125 mg to 250 mg [one to two medicine measures (5 ml- 10 ml of the 125 mg/ml)] every six to eight hours.

Therapy should be continued for a minimum of ten days with a therapeutic dose to prevent development of rheumatic fever and/or other serious complications. Dosage for routine streptococcus prophylaxis in patients with a history of rheumatic fever or congenital heart disease may be 125 mg [one medicine measure (5 ml) of the 125 mg/ml] once or twice daily, on a continuing basis.

Duration of administration

Your doctor will tell you how long your treatment with ATHLONE PHENOXYMETHYLPENICILLIN will last. Keep taking ATHLONE PHENOXYMETHYLPENICILLIN until your doctor tells you to stop.

Do not stop taking it just because you feel better. If you stop taking this medicine, your condition may re-occur or get worse.

Method of administration

ATHLONE PHENOXYMETHYLPENICILLIN is for oral administration.

If you take more ATHLONE PHENOXYMETHYLPENICILLIN than you should

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

If you forget to take ATHLONE PHENOXYMETHYLPENICILLIN

Take the missed dose as soon as you remember it. However, if it is almost time for your next regular dose, do not take your missed dose. If you miss two or more doses, consult your doctor. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

ATHLONE PHENOXYMETHYLPENICILLIN can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- severe skin rash, itching, fever, blistering of the skin,

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea (feeling sick)
- vomiting
- stomach pain
- diarrhoea
- itching
- skin rashes

Less frequent side effects:

- anaemia (may cause lack of energy or tiredness)
- problems with blood clotting (unusual bleeding or bruising)
- sore throat
- jaundice - yellowing of skin or whites of the eyes
- kidney problems, which might cause blood in the urine or reduced amounts of urine

Side effects with frequency unknown:

- infections or fever (may be caused by low white blood cells)
- sore mouth
- black hairy tongue
- pins and needles or numbness
- uncontrollable shaking and limb movement
- hypersensitivity reaction that affects your arteries that pump blood away from your heart, this may cause a heart attack or other heart problems.
- hypersensitivity reaction that causes blisters in the skin (in the mouth, genitals or eyes).

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, pharmacist or nurse. You can also report side effects to

SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ATHLONE PHENOXYMETHYLPENICILLIN.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za

5. How to store ATHLONE PHENOXYMETHYLPENICILLIN

Store all medicine out of reach of children.

Unopened container: Store in a dry place, at or below 25 °C. Protect from light.

Reconstituted oral solution: Store for 7 days in a refrigerator (2- 8°C)

Keep it in the pack in which it was given to you.

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

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 ATHLONE PHENOXYMETHYLPENICILLIN contains

- The active substance is phenoxymethylpenicillin.
- The other ingredient are sodium benzoate, saccharin sodium, Trusil orange flavour J1978, 175788 Euroblend orange, sucrose.

ATHLONE PHENOXYMETHYLPENICILLIN 125/5 mL powder for solution

Each 5 mL of reconstituted suspension contains the equivalent of 125 mg phenoxymethylpenicillin as phenoxymethylpenicillin potassium.

The powder contains sodium benzoate 0,32 % m/v as preservative.

ATHLONE PHENOXYMETHYLPENICILLIN 250/5 mL powder for solution

Each 5 mL of reconstituted suspension contains the equivalent of 250 mg phenoxymethylpenicillin as phenoxymethylpenicillin potassium.

The powder contains sodium benzoate 0,32 % m/v as preservative.

What ATHLONE PHENOXYMETHYLPENICILLIN looks like and contents of the pack

ATHLONE PHENOXYMETHYLPENICILLIN 125/5 mL powder for solution

A pale orange dry granular powder.

After reconstitution: A clear orange solution with orange odour & flavour.

ATHLONE PHENOXYMETHYLPENICILLIN 250/5 mL powder for solution

A pale orange dry granular powder.

After reconstitution: A clear orange solution with orange odour & flavour.

ATHLONE PHENOXYMETHYLPENICILLIN 125/5 mL powder for solution supplied in clear white polyethylene bottles with a polypropylene tamper evident or HOPE polypropylene tamper evident/child resistant cap containing 60 g powder for reconstitution of 100 mL syrup.
ATHLONE PHENOXYMETHYLPENICILLIN 250/5 mL powder for solution supplied in natural high density polyethylene bottles with a polypropylene tamper evident or HOPE polypropylene tamper evident/child resistant cap containing 65 g powder for reconstitution of 100 mL syrup.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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ATHLONE PHENOXYMETHYLPENICILLIN 125/5 mL: 33/20.1.2/0047

ATHLONE PHENOXYMETHYLPENICILLIN 250/5 mL: 33/20.1.2/0048

Access to the corresponding Professional Information

Professional Information and Afrikaans Patient Information Leaflet for this medicine is available on the following URL:

https://shanur.co.za/product-info/

Shanur Healthcare (Pty) Ltd

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