PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

BINDOCLAV 375 mg, tablet.

BINDOCLAV 625 mg, tablet.

BINDOCLAV 1 000 mg, tablet.

Amoxicillin and Clavulanic acid

Sugar free.

Read all of this leaflet carefully before you start taking BINDOCLAV.

- 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.
- BINDOCLAV 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 BINDOCLAV is and what it is used for
2. What you need to know before you take BINDOCLAV
3. How to take BINDOCLAV
4. Possible side effects
5. How to store BINDOCLAV
6. Contents of the pack and other information.

1. What BINDOCLAV is and what it is used for

BINDOCLAV is an antibiotic which contains two active ingredients. One of these is a penicillin called amoxicillin (present as amoxicillin trihydrate) and the other is clavulanic acid (present as potassium clavulanate).

BINDOCLAV formulations are indicated for the treatment of the following infections:

- Upper respiratory tract infections, such as sinusitis, recurrent otitis media, tonsillitis.
- Lower respiratory tract infections, such as bronchitis and bronchopneumonia.
- Genito-urinary tract infections, such as cystitis, urethritis, pyelonephritis.
- Skin and soft tissue infections.
- BINDOCLAV formulations will also be effective in the treatment of infections caused by amoxicillin sensitive organisms at the appropriate amoxicillin dosage since in this situation the clavulanic acid component does not contribute to the therapeutic effect.

2. What you need to know before you take BINDOCLAV

Do not take BINDOCLAV:

- If you are hypersensitive (allergic) to penicillin or cephalosporins, or any of the ingredients of BINDOCLAV (listed in section 6).
- If you have a previous history of amoxicillin/clavulanic-associated liver dysfunction.

Warnings and precautions

Take special care with BINDOCLAV:

- If an allergic reaction occurs, you must see your doctor as he/she may decide to stop and then change your treatment (see **section 4**).
- Allergic reactions may also result in a serious condition that presents with chest pains and might lead to a heart attack (Kounis syndrome).
- BINDOCLAV should be avoided if infectious mononucleosis (symptoms include fever, tiredness, sore throat) is suspected or if you have lymphatic leukaemia (type of blood cancer) as you are more prone to getting a skin rash.
- Periodic assessment of organ function, including renal (kidney), hepatic (liver) and haematopoietic (blood) functions, is advisable during prolonged therapy.
- If you suffer from kidney or liver disease.
- If you have syphilis.

- When high doses are administered, adequate fluid intake and urinary output must be maintained. This is important to prevent the formation of crystals in the urine (crystalluria). Regular checks must be done if you are on a catheter.
- Tell your doctor if you are on a sodium restricted diet.
- Prolonged use may result in the overgrowth of non-susceptible organisms which could result in other infections including superinfections (infections that are difficult to treat).
- If you present with severe diarrhoea, during or upon completion of treatment, you must see your doctor.
- Tell your doctor if you are taking medicines used to thin your blood. BINDOCLAV may enhance the effects of these medicines and increase your chance of bruising and bleeding (see **other medicines and BINDOCLAV**).
- Convulsions (fits) may occur if you have kidney problems or are taking a high dose of BINDOCLAV.
- Allergic skin reactions may occur if you take BINDOCLAV together with allopurinol (medicine used in the treatment of gout (see **Other medicines and BINDOCLAV**)).
- If you develop a severe skin reaction characterised by redness, inflamed or swollen skin, blisters, hives, and sometimes peeling or pain, you must see your doctor immediately (see **section 4**).

Other medicines and BINDOCLAV

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.) The use of BINDOCLAV with these medicines may cause undesirable interactions.

Tell your doctor if you are taking:

- Oral contraceptives (hormone medicines used to prevent pregnancy) as BINDOCLAV may make these medicines less effective.
- Tetracyclines and other bacteriostatic medicines (medicine used to treat infections).

- Probenecid and allopurinol (medicines used in the treatment of gout).
- Anticoagulants (medicines used to thin your blood).
- Methotrexate (medicine used in cancer treatment and to suppress your immune system).
- Mycophenolate mofetil (medicine used to suppress your immune system).

Tell your doctor if you are testing for sugar in your urine or doing a Coomb's test (antiglobulin test) as BINDOCLAV may affect the results of these tests.

Pregnancy, breastfeeding, and fertility

Pregnancy

If you are pregnant or breast feeding, 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 this medicine.

The safety of BINDOCLAV in pregnancy has not been established. BINDOCLAV should not be used during pregnancy.

Breastfeeding

BINDOCLAV is distributed into breast milk. The use of amoxicillin by breastfeeding mothers may lead to sensitisation, diarrhoea, candidiasis, and skin rash in the infant which may result in your doctor stopping treatment with BINDOCLAV.

Driving and using machines

BINDOCLAV may cause headache, dizziness, allergic reactions, and convulsions which may affect your ability to drive a vehicle and use machines. It is not always possible to predict to what extent BINDOCLAV may interfere with your daily activities. You should ensure that you do not engage in the above activities until you know how BINDOCLAV affects you.

BINDOCLAV contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially

‘sodium free’.

3. How to take BINDOCLAV

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

Always take BINDOCLAV exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. If you have the impression that the effect of BINDOCLAV is too strong or too weak, talk to your doctor or pharmacist.

Tablets should be taken immediately before a meal.

Adults

The adult dose of BINDOCLAV is one BINDOCLAV 375 mg tablet every eight hours at the start of a meal. For more severe infections and infection of the respiratory tract, the dose should be one BINDOCLAV 625 mg tablet every eight hours at the start of a meal, or one BINDOCLAV 1 000 mg tablet every 12 hours at the start of a meal.

Children

The dose of BINDOCLAV in children will be decided by your doctor and should be given in divided doses every eight hours, at the start of a meal.

If you take more BINDOCLAV than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison centre. Take this leaflet and the remaining BINDOCLAV tablets with you so the doctor will know what you have taken.

Overdosage with amoxicillin may result in nausea, vomiting, diarrhoea, and dehydration.

If you forget to take BINDOCLAV

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

4. Possible side effects

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

If any of the following happens, stop taking BINDOCLAV 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.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to BINDOCLAV. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Yellowing of the skin, eyes, dark urine, and tiredness which may be symptoms of liver problems.
- Blood in the urine, crystals in the urine, fever, increase or decrease in urination and changes in your mental status which may indicate a kidney problem.
- Convulsions (fits).
- Skin reactions such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP) and drug rash with eosinophilia and systemic symptoms (DRESS) These reactions can be life-threatening and are characterised by redness, inflamed or swollen skin, blisters, hives, and sometimes peeling or pain.
- Chest pain and palpitations (changes in the way your heart beats, for example if you notice it beating faster).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Thick, cracked, discoloured nails.
- Headache.
- Nausea (feeling sick), vomiting (being sick), diarrhoea (frequent, loose watery stools), abnormal taste.
- Change in colour, odour, or amount of vaginal discharge.
- Hot flushes.

Less frequent side effects:

- Swelling under the skin.
- Dizziness.
- Chills, mouth sores, urine that smells and pain when urinating.
- Confusion or changes in speech and burning pain in the hands or feet.
- Pain in multiple joints.
- Glossitis (pain in the tongue, redness and swelling of tongue), black hairy tongue, indigestion (pain or discomfort in your upper abdomen).
- Blood test that indicates an increase in your liver enzymes.

Side effects which may occur, but the frequency is unknown:

- Overgrowth of other bacteria in your body resulting in infection.
- Reduction in red blood cells which can make the skin pale, and cause weakness and bruising.
- Prolongation of bleeding and prothrombin time (takes longer for your blood to clot).
- Nosebleeds, bleeding gums and blood in stools.
- Weight loss, night sweats, cough, sore throat.
- Fast heart rate, muscle weakness.
- Swelling below the skin surface, usually around the eyes and lips, but also may occur around the hands, feet, and throat.

- Purple or brownish-red spots mainly on the legs, buttocks, or trunk.
- Scaling and thickening of skin.
- Reversible hyperactivity.
- Sensitivity to light, loss of appetite.
- Discolouration of the teeth (reversible).

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 or pharmacist. 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 or to Cipla Medpro (Pty) Ltd. by email: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of BINDOCLAV.

5. How to store BINDOCLAV

- Store all medicines out of the reach of children.
- Store at or below 30 °C.
- Do not remove blister strip from carton until required for use.
- Do not take the tablets after the expiry date printed on the 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 BINDOCLAV contains

The active substances are amoxicillin and clavulanic acid.

BINDOCLAV 375 mg: Each film-coated tablet contains amoxicillin trihydrate equivalent to 250 mg amoxicillin, and potassium clavulanate equivalent to 125 mg clavulanic acid.

BINDOCLAV 625 mg: Each film-coated tablet contains amoxicillin trihydrate equivalent to 500 mg amoxicillin, and potassium clavulanate equivalent to 125 mg clavulanic acid.

BINDOCLAV 1 000 mg: Each film-coated tablet contains amoxicillin trihydrate equivalent to 875 mg amoxicillin, and potassium clavulanate equivalent to 125 mg clavulanic acid.
The other ingredients are colloidal silicon dioxide, isopropyl alcohol, magnesium stearate, methylene chloride, microcrystalline cellulose, Opadry white (which consists of Hypromellose 5cP, Hypromellose 15cP, macrogol and titanium dioxide (E171)) and sodium starch glycolate.

What BINDOCLAV looks like and contents of the pack

BINDOCLAV 375 mg: White oval shaped film coated tablets, debossed with 'A' on one side and '63' on the other side.

BINDOCLAV 625 mg: White oval shaped film coated tablets, debossed with 'A' on one side and '64' on the other side.

BINDOCLAV 1 000 mg: White coloured, capsule shaped, film coated tablets, debossed with 'A' on one side and with a score line in between '6' and '5' on the other side.

BINDOCLAV 375 mg:

Tablets are packed in 25-micron polyamide / 45-micron aluminium foil/ 60-micron PVC film (width 138 mm) as the forming material and 25-micron printed aluminium foil (width 138 mm) as the lidding material.

Each blister strip contains 5 tablets.

Pack size: 15's: Each carton contains 3 blister strips of 5 tablets each.

Pack size: 100's: Each carton contains 20 blister strips of 5 tablets each.

BINDOCLAV 625 mg:

Tablets are packed in 25-micron polyamide / 45-micron aluminium foil/ 60-micron PVC film (width 138 mm) as the forming material and 25-micron printed aluminium foil (width 138 mm) as the lidding material.

Each blister strip contains 5 tablets.

Pack size: 15's: Each carton contains 3 blister strips of 5 tablets each.

BINDOCLAV 1 000 mg:

- Tablets are packed in 25-micron polyamide / 45-micron aluminium foil / 60-micron PVC film (width 138 mm) as the forming material and 25-micron printed aluminium foil (width 138 mm) as the lidding material.

  Each blister strip contains 5 tablets.

  Pack size: 10's: Each carton contains 2 blister strips of 5 tablets each.
- Tablets are packed in printed 40-micron aluminium foil laminated with 150-gauge poly on one side and plain 40-micron aluminium foil laminated with 150-gauge poly on other side.

  Each blister strip contains 10 tablets.

  Pack size: 10's: One blister strip pack containing tablets.

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

Building 9, Parc du Cap

Mispel Street,

Bellville,

7530

Customer care: 080 222 6662

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