Approved Patient Information Leaflet for Medicines for Human Use:

Note: The patient information leaflet conforms to Regulation 10 and the PIL guideline *2.14_PIL_Dec13_v4*

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM:

[PRODUCT NAME] BD S (Powder for suspension)

[PRODUCT NAME] BD SF (Powder for suspension)

Read all of this leaflet carefully before you are given [PRODUCT NAME] Keep this leaflet. You may need to read it again.

- If you have further questions, please ask your doctor or your pharmacist.
- **[PRODUCT NAME]** 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 [PRODUCT NAME] CONTAINS:

- **[PRODUCT NAME] BD S (Powder for suspension):**

  When reconstituted according to instructions each 5 ml contains amoxicillin trihydrate equivalent to 200 mg amoxicillin and potassium clavulanate equivalent to 28,5 mg clavulanic acid.

- **[PRODUCT NAME] BD SF (Powder for suspension):**

  When reconstituted according to instructions each 5 ml contains amoxicillin trihydrate equivalent to 400 mg amoxicillin and potassium clavulanate equivalent to 57,0 mg clavulanic acid.

  The other ingredients are:

Colloidal silicon dioxide (Aerosil 200), hydroxpropylmethylcellulose, (Metosel E-3(3 cps)), methyl paraben, orange flavour, silicon dioxide (Syloid AL-1-FP), sodium saccharin, succinic acid, golden syrup flavour, xanthan gum.

[PRODUCT NAME] contains an artificial sweetener called saccharin sodium and a preservative methyl paraben 0,5 % *m/m*.

2. WHAT [PRODUCT NAME] IS USED FOR:

[PRODUCT NAME] is:

- an antibiotic which contains two active ingredients: amoxicillin which is a penicillin and clavulanic acid.
- used to treat upper respiratory infections such as infections of the sinus, ears and tonsils
- used to treat lower respiratory infections such as bronchitis (infection of the lung)
- used for infections in the kidney and bladder
- used for infections of the skin
- when amoxicillin antibiotics alone are not effective

3. BEFORE YOU TAKE AUSTELL - CO-AMOXICLAV:

Do not take or give [PRODUCT NAME] to your child if:

- your child is hypersensitive (allergic) to amoxicillin, clavulanic acid, penicillin or to any of the other ingredients of **[PRODUCT NAME]**
- your child is allergic to amoxicillin or beta-lactam antibiotics (such as **[PRODUCT NAME]**. If he/she has had an allergic reaction (such as a rash) when taking an antibiotic, you should talk to your doctor before you give **[PRODUCT NAME]**
- your child has ever had jaundice (yellowing of the skin and/or eyes) or liver disease while taking antibiotics
- your child is under 2 months of age
- if your child has severe kidney problems

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist or healthcare professional.

Take special care with [PRODUCT NAME]:

The presence of other medical problems may affect the use of **[PRODUCT NAME]**. Talk to your doctor, or healthcare professional before taking or giving **[PRODUCT NAME]** to your child if:

- your child develops a skin rash fever, joint pain, swollen glands in the neck, armpit or groin, swelling of the face, lips, tongue, or other parts of the body (angioedema) while taking **[PRODUCT NAME]**. Do not give any more suspension and tell the doctor at once
- your child has glandular fever (mononucleosis)
- your child has liver or kidney problems. The dosage may need to be reduced or he/she may need to be given a different medicine
- your child has lymphatic leukaemia (a type of cancer which spreads quickly) since they may develop skin rashes
- your child is not passing water regularly
- your child develops diarrhoea while taking **[PRODUCT NAME] ES – 600**. If this becomes severe or persistent or you notice that your child's stools contains blood or mucus, consult your doctor or healthcare professional immediately. In this situation, you should not take medicines that stop or slow bowel movement your child develops thrush (white spots in the mouth or skin folds)

Taking [PRODUCT NAME] with food and drink:

- It is better to give **[PRODUCT NAME]** at the beginning of a meal, but **[PRODUCT NAME]** still works if it is given without food.
- Avoid taking alcohol whilst you are using **[PRODUCT NAME]** and for several days after treatment with **[PRODUCT NAME]** has stopped.

Pregnancy and Breastfeeding*:*

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before you take AUSTELL CO- AMOXICLAV.

- **[PRODUCT NAME]** should not be used if you are pregnant or breastfeeding since safety has not been established.
- If you are taking a contraceptive pill, could be pregnant, or are breast-feeding a baby, you should talk to the doctor before using **[PRODUCT NAME]**.

Driving and using machinery:

- You should not drive or operate machinery until you are sure how **[PRODUCT NAME]** affects you.

Taking other medicines with [PRODUCT NAME]. Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

It is particularly important that the doctor knows if your child is taking the following medicines:

- Allopurinol and probenecid (used for the treatment of gout)
- Oral contraceptives (pill for the prevention of pregnancy) since **[PRODUCT NAME]** may affect how the well the oral contraceptive works.
- Tetracyclines (antibiotics)
- Medicines to prevent blood clotting such as warfarin.

HOW TO TAKE [PRODUCT NAME]:

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

Always take [PRODUCT NAME] exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

- It is better to give **[PRODUCT NAME]** at the same time as a meal, but **[PRODUCT NAME]** still works if it is given without food. Make sure the whole dose is swallowed every time.
- **[PRODUCT NAME]** is available in powder form. Your doctor or pharmacist will reconstitute it as required before dispensing it to you.
- Shake the bottle well before each dose.

The usual dose is:

- The dose will be determined by your doctor depending on the weight of the child and must be given in two divided doses at 12 hourly intervals.

Your doctor will tell you how long your treatment with **[PRODUCT NAME]** will last. Do not stop treatment early because your child is feeling better.

If you have the impression that the effect **[PRODUCT NAME]** is too strong or too weak, tell your doctor or pharmacist.

If your child has taken more [PRODUCT NAME] than he/she should:

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

- Symptoms that may occur are nausea, vomiting and diarrhoea.

Treatment of overdosage is usually symptomatic:

- Give plenty of water to drink and contact a doctor. Show the doctor the container of **[PRODUCT NAME].**

If you forget to give [PRODUCT NAME]:

- Give it as soon as you remember, then carry on as before, but do not give two doses within an hour of each other.
- Do not give a double dose to make up for the forgotten dose.

Effects when treatment with [PRODUCT NAME] is stopped

Keep giving the medicine until the complete course has been finished. Do not stop when your child feels better.

5. POSSIBLE SIDE EFFECTS

[PRODUCT NAME] can have side effects.

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

If any of the following happens, stop taking **[PRODUCT NAME]** and tell your doctor immediately or go the casualty department of the nearest hospital:

***Less frequent*:**

- sudden wheeziness, shortness of breath, or chest tightness
- swelling of the face, lips, tongue, or other parts of the body (angioedema).
- suddenly feeling faint, especially upon standing up
- convulsions (fits or seizures)
- yellowing of the skin and/or eyes, or dark urine. These symptoms may be accompanied by itching, fever, nausea, vomiting, loss of appetite and feeling generally unwell. These symptoms may not occur until several weeks after the end of treatment and can be severe
- blood in the urine which may be associated with rash, fever, joint pain, or a reduction in passing water (urine)
- severe diarrhoea, which may be bloody, or contain mucus, and which may be accompanied by stomach cramps
- a rash with blisters that may cause the skin to peel, flake, or bleed
- unusual tiredness, headaches, being short of breath when exercising, dizziness, looking pale, and yellowing of the skin and/or eyes

These are very serious side effects. If you have them, you may have had a serious reaction to **[PRODUCT NAME].** 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:

Less frequent:

- fever, severe chills, sore throat or mouth ulcers. Unusual joint pains especially if accompanied by a rash
- the tongue may change colour to yellow, brown or black, and it may have a hairy appearance
- bleeding, or bruising, more easily than usual.
- a rash where the spots (usually 0,5 cm to 2 cm in size) have a pink/red ring around the edge and a darker centre
- mild rash, itching or hives (itchy lumps)
- indigestion
- headache and dizziness

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

Tell your doctor if you notice any of the following:

Frequent:

- diarrhoea (loose, or watery bowel movements)
- nausea (feeling sick)
- vomiting (being sick)
- thrush (a fungal infection). In babies this can look like a severe nappy rash. Older children may experience itching and burning around the genital area (private parts) with the presence of a thick, white discharge. Babies and children can also develop thrush in their mouth. This appears as painful white patches on the inside of their mouth and on their tongue.

Symptoms such as indigestion, feeling sick and being sick can often be avoided by giving **[PRODUCT NAME]** at the beginning of a meal.

Less frequent:

- teeth can become discoloured while using **[PRODUCT NAME]**. If you notice any side effects mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF [PRODUCT NAME]:

- Store in the original packaging until required for use.
- Do not store your medicine in the bathroom.
- Store at or below 25 °C.
- Keep tightly closed.
- After reconstitution, store the suspension in a refrigerator between 2 °C - 8 °C and use within 7 days. Do not freeze.
- Do not use after the expiry date stated on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINE OUT OF REACH OF CHILDREN

7. PRESENTATION OF AUSTELL CO- AMOXICLAV:

- **[PRODUCT NAME] BD S 70 ml** (Powder for suspension)**:** is packed in a Type III amber coloured, 100 ml glass bottle (marked to 70 ml), with a 31 PP neck that is closed with a white polypropylene cap with a safety strap. The bottle and transparent spoon (marked to 1,25 ml; 2,5 ml and 5 ml) are placed together with a patient information leaflet in a carton box.
- **[PRODUCT NAME] BD SF 35 ml** (Powder for suspension forte)**:** is packed in a Type III amber coloured, 100 ml glass bottle (marked to 70 ml), with a 31 PP neck that is closed

with a white polypropylene cap with a safety strap. The bottle and 4, 5 ml pipette are placed together with a patient information leaflet in a carton box.

- **[PRODUCT NAME] BD SF 70 ml** (Powder for suspension forte)**:** is packed in a Type III amber coloured, 100 ml glass bottle (marked to 70 ml), with a 31 PP neck that is closed with a white polypropylene cap with a safety strap. The bottle and transparent spoon (marked to 1, 25 ml; 2, 5 ml and 5 ml) are placed together with a patient information leaflet in a carton box.

8. IDENTIFICATION OF [PRODUCT NAME] BD:

- **[PRODUCT NAME] BD S 70 ml** (Powder for suspension)**:**

Before reconstitution: White to cream coloured, orange – golden syrup odoured, homogeneous powder mixture.

After reconstitution: When diluted according to label white to cream coloured homogeneous suspension with aromatic odour (orange-golden syrup).

- **[PRODUCT NAME] BD SF 35 ml** (Powder for suspension)**:**

Before reconstitution: White to cream coloured, orange – golden syrup odoured, homogeneous powder mixture.

After reconstitution: When diluted according to label white to cream coloured homogeneous suspension with aromatic odour (orange-golden syrup).

- **[PRODUCT NAME] BD SF 70 ml** (Powder for suspension)**:**

Before reconstitution: White to cream coloured, orange – golden syrup odoured, homogeneous powder mixture.

After reconstitution: When diluted according to label white to cream coloured homogeneous suspension with aromatic odour (orange-golden syrup).

9. REGISTRATION NUMBER:

~~[AUSTELL CO AMOXICLAV BD S]~~ CO AMOXICLAV BD S AUSTELL : 48/20.1.2/1175

~~[AUSTELL CO AMOXICLAV BD SF]~~ CO AMOXICLAV BD SF AUSTELL : 48/20.1.2/1176

AVUTAN BD S : 48/20.1.2/1177

AVUTAN BD SF : 48/20.1.2/1178

~~[APEX CO AMOXICLAV BD S]~~ CO AMOXICLAV BD S APEX : 48/20.1.2/1179

~~[APEX CO AMOXICLAV BD SF]~~ CO AMOXICLAV BD SF APEX 48/20.1.2/1180

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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11. DATE OF PUBLICATION:

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