PATIENT INFORMATION LEAFLET for

SYNGLUTRA 5/500; 5/1 000; 10/500; 10/1 000 mg

Extended Release Tablets

SCHEDULING STATUS

S4

SYNGLUTRA 5/500 Extended Release Tablets

SYNGLUTRA 5/1 000 Extended Release Tablets

SYNGLUTRA 10/500 Extended Release Tablets

SYNGLUTRA 10/1 000 Extended Release Tablets

Dapagliflozin / metformin hydrochloride

Contains sugar (Mannitol 84 mg per tablet).

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

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

SYNGLUTRA SHOULD ONLY BE USED IN THE TREATMENT OF TYPE 2 DIABETES. DO NOT TAKE SYNGLUTRA FOR TYPE 1 DIABETES OR AS PART OF WEIGHT CONTROL PROGRAMMES.

Metabolic acidosis (when the body produces too much acid or the kidneys are not removing enough acid from the body), including ketoacidosis (high levels of acids, called ketones, in the blood), has occurred in patients taking SYNGLUTRA, which may be serious and/or life-threatening.

If you experience nausea, vomiting, stomach pain, a general feeling of discomfort or illness, and shortness of breath, you should report to your doctor promptly, even if your blood sugar levels are below 11 mmol/L, as you may have metabolic acidosis. Your doctor will evaluate and manage your condition appropriately.

You may develop metabolic acidosis more easily if your insulin dose is reduced, your caloric/food intake is reduced, your intake of fluids is reduced or if you require more insulin due to infections, illness, surgery or with alcohol abuse. You should discuss these situations with your doctor while taking SYNGLUTRA.

Do not take SYNGLUTRA if you have disorders of the pancreas, e.g. a history of pancreatitis (inflammation in the pancreas) or pancreatic surgery, as you may develop ketoacidosis more easily.

Lactic acidosis (high levels of acid, called lactate, in the blood) is a rare, but serious complication that may occur with SYNGLUTRA. Tell your doctor if you have sepsis (an extreme reaction to an infection that can be life-threatening), if you are dehydrated, have high alcohol intake, liver function impairment, kidney function impairment or heart problems.

Report to your doctor if you experience a general feeling of discomfort or illness, muscle pain, difficult breathing, increasing sleepiness and stomach pain, as you may have lactic acidosis. Your doctor may conduct blood tests and may decide to stop your treatment with SYNGLUTRA.

Acidosis is a serious condition that may require you to be hospitalised (see Warnings and precautions).

What is in this leaflet:

1. What SYNGLUTRA is and what it is used for
2. What you need to know before you take SYNGLUTRA
3. How to take SYNGLUTRA
4. Possible side effects

5. How to store SYNGLUTRA
6. Contents of the pack and other information

1. What SYNGLUTRA is and what it is used for

SYNGLUTRA contains dapagliflozin and metformin, which belong to a group of medicines called oral anti-diabetic medicines.

SYNGLUTRA is used to treat type 2 diabetes mellitus in adults, when treatment with both dapagliflozin and metformin is suitable, together with diet and exercise:

- If you have, or is at risk of developing a condition called heart failure (pain in the chest, fast breathing, shortness of breath, extreme fatigue and weakness) and if you suffer from Type 2 diabetes mellitus with heart disease or heart risk factors such as high blood pressure, high cholesterol or being overweight.

2. What you need to know before you take SYNGLUTRA

Do NOT take SYNGLUTRA:

- If you are allergic (hypersensitive) to dapagliflozin, metformin hydrochloride or to any of the inactive ingredients of SYNGLUTRA.
- If you have any type of metabolic acidosis (increased levels of acid in the blood), such as lactic acidosis or diabetic ketoacidosis.
- If you have diabetic pre-coma (extremely high blood sugar levels with dehydration).
- If you have severe kidney function impairment.
- If you are dehydrated, suffer from severe infection or shock.
- If you are planning to undergo a medical procedure where iodinated contrast media will be used to enhance visibility of your blood vessels.
- If you have any disease that may cause hypoxia (where your tissues are deprived of oxygen), such as heart or lung failure, pancreatitis (inflammation of the pancreas), heart

attack or shock.

- If you have liver function impairment (see **Warnings and precautions**).
- If you have alcohol poisoning, or suffer from excessive use of alcohol or alcoholism.
- If you have diabetes mellitus type 1.
- If you are pregnant or breastfeeding your baby (see **Pregnancy, breastfeeding and fertility**).

Warnings and precautions

Take special care with SYNGLUTRA

Lactic acidosis

Lactic acidosis (high levels of acid, called lactate, in the blood), is a rare, but serious complication that may occur with SYNGLUTRA. It may also occur if your kidney function is impaired.

If you experience dehydration due to severe diarrhoea/loose stools or vomiting, fever or have reduced intake of fluids, you should report to your doctor, as SYNGLUTRA may need to be stopped temporarily.

Report to your doctor if you experience a general feeling of discomfort or illness, muscle pain, difficult breathing, increasing sleepiness and stomach pain, as you may have lactic acidosis. Your doctor may decide to stop your treatment with SYNGLUTRA. Lactic acidosis is a serious condition that may require you to be hospitalised, therefore your doctor may need to monitor your kidney function regularly.

Medicines that may impair your kidney function, such as medicines used for high blood pressure, diuretics (water tablets) and medicines used for pain and inflammation, called non-steroidal anti-inflammatory medicines (NSAIDs), should be used with caution while taking SYNGLUTRA (see **Other medicines and SYNGLUTRA**).

Excessive amounts of alcohol should be avoided as it may lead to lactic acidosis. You should tell your doctor if you suffer from liver function impairment, diabetes that is not well controlled, ketosis (raised levels of ketones), if you are fasting, and of any conditions associated with hypoxia (decreased oxygen levels in the tissues), as well as any other medicines you are using concomitantly (see **Do NOT take SYNGLUTRA** and **Other medicines and SYNGLUTRA).**
Whether you are the patient or a caregiver, you should be aware that lactic acidosis is a life-threatening condition.

Kidney function
Do not take SYNGLUTRA if you have moderate to severe kidney function impairment (see **Do NOT take SYNGLUTRA**).

Your doctor may monitor your kidney function before you start taking SYNGLUTRA and periodically thereafter (see **How to take SYNGLUTRA**). Your kidney function will be monitored at least yearly while you are taking SYNGLUTRA, but may be tested more frequently if you have mild kidney function impairment, if you are over the age of 65 years, or if you need to start taking other medicines, including blood pressure lowering medicines or water tablets, and medicines used to treat pain and inflammation (NSAIDs). If your kidney function deteriorates, your doctor may decide to stop SYNGLUTRA.

Liver function impairment
If you have impaired liver function, please discuss this with your doctor .

Fluid loss/dehydration, low blood pressure or electrolyte imbalances
SYNGLUTRA may cause a decrease in your blood pressure, which may be more pronounced if you have very high blood sugar levels. This may be a concern if you have lost fluids/are dehydrated.

Tell your doctor if you are taking furosemide for high blood pressure (see **Other medicines and** SYNGLUTRA), or if you have lost fluids due to diarrhoea/loose stools or vomiting. Your doctor may stop your treatment with SYNGLUTRA if you have lost too much fluids (see **Possible side effects**).

Tell your doctor if you have heart problems, are taking blood pressure lowering medicines, if you have a history of low blood pressure or are over 65 years of age. Your doctor may need to monitor your fluid and electrolyte levels, your blood pressure and conduct blood tests while you are taking SYNGLUTRA.

SYNGLUTRA is not recommended if you are suffering from serious infections, have suffered an injury or are on a low calorie diet.

Your doctor may monitor your vitamin B_{12} levels if you are taking SYNGLUTRA long-term.

Diabetic ketoacidosis

Do not take SYNGLUTRA if you have diabetic ketoacidosis (high levels of acids, called ketones, in the blood) (see **Do NOT take SYNGLUTRA**).

Ketoacidosis and diabetic ketoacidosis (DKA), which may be life-threatening, have occurred with SYNGLUTRA.

Report to your doctor immediately if you experience nausea, vomiting, loss of appetite, stomach pain, a general feeling of discomfort or illness, excessive thirst, difficult breathing, confusion and unusual fatigue or sleepiness, regardless of your blood sugar level, as you may have diabetic ketoacidosis. Your doctor may decide to stop your treatment with SYNGLUTRA.

Inform your doctor if you are scheduled to undergo surgery or if you suffer from any serious

illness, as your doctor may temporarily stop your treatment with SYNGLUTRA.

Tell your doctor if you have a history of type 2 diabetes with low C-peptide (a certain protein) or latent autoimmune diabetes (LADA) (a form of diabetes) before starting SYNGLUTRA.

Do not take SYNGLUTRA if you have disorders of the pancreas, e.g. a history of pancreatitis (inflammation in the pancreas) or pancreatic surgery, as you may develop ketoacidosis more easily.

You may also develop DKA more easily if your insulin dose is reduced, your caloric/food intake is reduced, your intake of fluids is reduced or if you require more insulin due to infections, illness, surgery or with alcohol abuse. You should discuss these situations with your doctor while taking SYNGLUTRA.

Do not take SYNGLUTRA if you have type 1 diabetes mellitus (see **Do NOT take SYNGLUTRA**).

Fournier's gangrene

If you experience symptoms of pain, tenderness, redness or swelling in the genital and surrounding area, with fever and tiredness, you should report to your doctor as it may be signs of a rare and potentially life threatening inflammation.

Urinary tract infections

Urinary tract infections, including serious urinary tract infections (pyelonephritis) requiring hospitalisation, may occur with SYNGLUTRA (see **Possible side effects**). Report to your doctor if you develop signs and symptoms of urinary tract infections, such as increased urge to urinate, pain with urination or blood in the urine.

Use in the elderly (65 years and older)

People 65 years and older are more likely to have impaired kidney function, to develop fluid loss/dehydration, or to be treated with medicines for high blood pressure, such as enalapril, lisinopril, perindopril, losartan, irbesartan or valsartan, that may cause changes in kidney function. Tell your doctor if you are 65 years and older. Refer to **Kidney function** and **Fluid loss/dehydration, low blood pressure or electrolyte imbalances** above (also see **Do NOT take SYNGLUTRA** and **Possible side effects**).

Heart failure

Tell your doctor if you have heart failure (see **Do NOT take SYNGLUTRA**).

Use with medicines known to cause low blood sugar levels

Other medicines used for high blood sugar, including insulin and sulphonylureas (such as glimepiride, glibenclamide or tolbutamide), may cause low blood sugar when used with SYNGLUTRA. Therefore, your doctor may decrease your dose of insulin or sulphonylurea if prescribed in combination with SYNGLUTRA (see **Possible side effects**).

You may experience low blood sugar levels if your caloric/food intake is insufficient, with strenuous exercise, or with the use of alcohol. If you are elderly, debilitated or undernourished, or if you have adrenal or pituitary insufficiency (a condition in which the adrenal or pituitary glands do not produce enough hormones) or alcohol intoxication, you may develop low blood sugar levels more easily. Low blood sugar levels may be difficult to recognise if you are elderly or are taking beta-adrenergic blocking medicines (such as bisoprolol, atenolol or acebutolol).

Lower limb amputations

It is important to maintain preventative foot care to prevent the occurrence of lower limb amputation (such as the toe).

Urine laboratory tests

Please note that you will test positive for glucose/sugar in your urine while you are taking SYNGLUTRA.

Medical procedures with iodinated contrast media

Tell your doctor if you are planning to undergo a medical procedure where iodinated contrast media (radiographic dye) will be used to enhance visibility of your veins (such as intravenous urography or intravenous angiography), as it may cause kidney damage or failure, which may also lead to lactic acidosis. Your doctor may decide to stop your treatment with SYNGLUTRA before, or at the time of the medical procedure, and may only re-start your treatment 48 hours afterwards, and only after your kidney function has been found to be normal (see **Do NOT take SYNGLUTRA** and **Other medicines and SYNGLUTRA).**

Surgery

Inform your doctor if you are scheduled to undergo surgery with anaesthesia, as your doctor may stop your treatment with SYNGLUTRA 48 hours before the surgery. Your treatment will be restarted 48 hours afterwards, or when you are able to resume eating and provided that your kidney function and circulation are stable.

If you are also taking a sulphonylurea (such as glimepiride, glibenclamide or tolbutamide), your blood sugar will be monitored because combination treatment with SYNGLUTRA may cause low blood sugar levels. If you are also using insulin, your sugar levels will be stabilised in hospital (see **Do NOT take SYNGLUTRA**).

Change in sugar control if you were previously well-controlled

If your sugar levels were previously well-controlled with SYNGLUTRA and you suddenly develop blood test abnormalities or signs of illness, you should report to your doctor promptly to be evaluated for ketoacidosis or lactic acidosis. Your doctor may decide to stop treatment with

SYNGLUTRA if acidosis occurs (see **Do NOT take SYNGLUTRA**).

Use in children

Do not use SYNGLUTRA if you are younger than 18 years of age, as safety and efficacy has not been established.

Other medicines and SYNGLUTRA

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

Please inform your doctor or pharmacist if you are taking any of the following medicines, as you may require special precautions:

- Diuretics (water tablets) for the treatment of high blood pressure, such as hydrochlorothiazide, indapamide, bumetanide or furosemide.
- Insulin, sulphonylureas (such as glimepiride, glibenclamide or tolbutamide), pioglitazone, sitagliptin or voglibose, used for high blood sugar levels.
- Ketoconazole, a medicine used for the treatment of fungal infections.
- Valsartan, used for high blood pressure or heart problems.
- Simvastatin or nicotinic acid (vitamin B3), for the treatment of high blood cholesterol levels.
- Rifampicin or isoniazid, used for the treatment of tuberculosis (TB).
- Mefenamic acid, used for the treatment of pain.
- Digoxin, used for heart problems.
- Warfarin, a blood thinner.
- If you are monitoring the sugar in your urine, the 1,5-anhydroglucitol (1,5-AG) assay should not be used, as SYNGLUTRA may interfere with the results.
- Medicines used to treat high blood pressure, such as amiloride, triamterene, or calcium

channel blockers, including amlodipine, diltiazem, nifedipine or verapamil.

- Cimetidine or ranitidine, for treatment of stomach ulcers or acid reflux.
- Morphine, for treatment of severe pain.
- Procainamide or quinidine for the treatment of irregular heartbeat.
- Quinine, for treatment of malaria.
- Trimethoprim or vancomycin, antibiotics used to treat bacterial infections.
- Alcohol or medicines containing alcohol, as it may increase your risk of developing lactic acidosis, especially if you are also fasting, are malnourished or have liver function impairment (see **Warnings and precautions**).
- Iodinated contrast media (radiographic dye), used to enhance visibility of your veins or organs during certain medical procedures.
- Oral or inhaled glucocorticoids, used for inflammation or to suppress the immune system, such as beclomethasone, budesonide, cortisone, dexamethasone, hydrocortisone or prednisolone.
- Medicines used to treat asthma called beta-2-agonists, such as salbutamol, fenoterol, salmeterol or formoterol.
- Phenothiazines, used to treat psychiatric disorders, such as thioridazine, fluphenazine or prochlorperazine.
- Medicines used to treat disorders of the thyroid gland, e.g. levothyroxine.
- Medicines containing oestrogens, including hormone replacement therapy and oral contraceptives (“the pill”).
- Phenytoin, used to treat epilepsy.
- Non-steroidal anti-inflammatory medicines (NSAIDs), such as aspirin, diclofenac or ibuprofen, and selective cyclo-oxygenase (COX) II inhibitors, such as celecoxib, used to treat pain and inflammation.
- Angiotensin-converting-enzyme (ACE) inhibitors, such as captopril, enalapril or lisinopril, and angiotensin II receptor antagonists (ARBs), such as candesartan, irbesartan or

losartan, used for high blood pressure or heart problems.

- Long-term treatment with SYNGLUTRA may cause vitamin B_{12} deficiency.

SYNGLUTRA with food, drink and alcohol

You should avoid excessive alcohol while taking SYNGLUTRA since it may increase your risk of lactic acidosis (see **Warnings and precautions**).

Pregnancy, breastfeeding and fertility

Do not take SYNGLUTRA while you are pregnant or breastfeeding your baby (see **Do NOT take SYNGLUTRA**).

SYNGLUTRA is present in breast milk.

If you plan to become pregnant or if you become pregnant while taking SYNGLUTRA, report to your doctor as SYNGLUTRA should not be taken while you are pregnant. Your doctor will prescribe different medicines to manage your blood sugar levels.

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

Driving and using machines

SYNGLUTRA has no or negligible influence on your ability to drive or use machines. You should take care when using SYNGLUTRA in combination with other medicines that may lead to low blood sugar levels.

It is not always possible to predict to what extent SYNGLUTRA may interfere with your daily activities, including driving, riding, flying, sailing, or operating machines/equipment. Do not engage in the above activities until you know how SYNGLUTRA affects you.

3. How to take SYNGLUTRA

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

Always take SYNGLUTRA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Take SYNGLUTRA once daily in the morning with food. Based on your current treatment, your doctor will decide upon the appropriate starting dose of SYNGLUTRA and will gradually increase your dosage to the correct level.

SYNGLUTRA tablets must be swallowed whole and never crushed, cut, or chewed. Occasionally, the inactive ingredients of SYNGLUTRA may be found in your stool as a soft mass that looks like the original tablet. Do not fear, as this is normal.

Your doctor will prescribe the correct dose for you according to your condition.

Children and adolescents

SYNGLUTRA is not recommended in children and adolescents as safety has not been established.

Your doctor will tell you how long your treatment with SYNGLUTRA will last. Do not stop treatment early because your blood sugar levels will not be controlled. If you have the impression that the effect of SYNGLUTRA is too strong or too weak, tell your doctor or pharmacist.

If you take more SYNGLUTRA than you should

In the event of an overdosage, or if someone else has taken your medicine by mistake, you, or this other person, may experience any of the side effects listed below (see **Possible side effects**). Lactic acidosis may occur and is a medical emergency that must be treated in hospital.

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 SYNGLUTRA

Always take SYNGLUTRA as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next dose is due, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

SYNGLUTRA can have side effects.

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

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

- Allergic reactions, which may include a skin rash, fever, difficult breathing, wheezing, hives, itching, or swelling of the face, lips, or tongue (which may be life-threatening).
- Diabetic ketoacidosis, which may cause nausea, vomiting, loss of appetite, stomach pain, a general feeling of discomfort or illness, excessive thirst, difficult breathing, confusion and unusual fatigue or sleepiness (see **Warnings and precautions**).
- Lactic acidosis, which may cause a general feeling of discomfort or illness, muscle pain, difficult breathing, increasing sleepiness and stomach pain (see **Warnings and precautions**).
- Inflammation of the liver (hepatitis), which may cause yellow skin or eyes (jaundice), dark urine, pale stools, stomach pain and loss of appetite.

- Skin rash (macular, maculopapular), including itchy (pruritic), blistering (pustular, vesicular) or red (erythematous) rash.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to SYNGLUTRA. 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:

- Female genital infection or inflammation (vulvovaginitis, vaginal infection, vulvitis, bacterial vaginitis, vulval abscess), or yeast infection (vulvovaginal mycotic infection, vulvovaginal candidiasis), which may cause irritation, redness, itching, discharge, unpleasant odour/smell, burning and discomfort while urinating, swelling and rash.
- Male genital infection or inflammation (balanitis, penile infection, balanoposthitis, penile abscess, posthitis), or yeast infection of the penis (balanitis candida), which may cause irritation, redness, itching, discharge, unpleasant odour/smell, burning and discomfort while urinating, swollen glands and soreness.
- Urinary tract infection, including inflammation of the kidney (pyelonephritis), inflammation of the urethra (urethritis), bladder infection (cystitis, trigonitis) and inflammation of the prostate gland (prostatitis), which may cause fever, back pain, nausea, vomiting, cloudy, dark urine or blood in the urine, burning urine and frequent urination.
- Low blood sugar (hypoglycaemia), when used with other medicines to treat high blood sugar levels, which may cause you to feel shaky, dizzy, hungry, or tired.
- Dehydration, decreased blood volume (hypovolaemia), or low blood pressure (hypotension), and thirst, which may cause a rapid heartbeat, decreased or no urination, shallow breathing, weakness, dizziness or fainting.

- Kidney function impairment (including decreased creatinine clearance, increased blood creatinine levels), which may cause back or flank pain, swelling of your lower legs or feet and nausea, muscle cramps and high blood pressure.

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

Tell your doctor if you notice any of the following:

- Those that occur frequently:
  - Taste disturbance, dizziness, headache.
  - Cough.
  - Gastrointestinal symptoms, including nausea, vomiting, diarrhoea / loose stools, stomach pain and loss of appetite.
  - Back pain.
  - Sugar in the urine (glucosuria), painful or difficult urination (dysuria), frequent / increased urination or large volumes of urine (polyuria, pollakiuria, osmotic diuresis).
  - Increased or decreased blood cholesterol levels (dyslipidaemia).
  - Increased red blood cell counts (haematocrit), which may cause heavy bleeding from small cuts or bruises.
  - Increased blood phosphate levels (hyperphosphatemia), which may cause muscle cramps, numbness or tingling.
- Those that occur less frequently:
  - Fungal infection, which may cause an itchy red rash that may form a circular / ring shape, or flaking skin.
  - Inflammation of the throat and/or the nasal passages (pharyngitis, nasopharyngitis), or the flu (influenza), that may cause runny nose, sneezing, coughing, sore throat, headache, fatigue, and sore muscles.

- Vitamin B_{12} deficiency (or megaloblastic anaemia) may occur with long-term treatment, and may cause you to feel nauseous, weakness, tiredness, numbness, tingling or muscle weakness.
- Constipation, dry mouth.
- Liver function test abnormalities.
- Increased sweating (hyperhidrosis).
- Skin reactions such as redness (erythema), itchiness (pruritus) and hives (urticaria).
- Excessive urination at night (nocturia).
- Itchiness of the genital area (vulvovaginal pruritus, genital pruritus).
- Increased blood urea levels, which may cause weakness, nausea and vomiting.
- Decreased weight.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 or drugsafetysa@cipla.com. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store SYNGLUTRA

Store at or below 25 °C.

Keep bottle tightly closed.

Store in the original package.

Store all medicines out of reach of children.

Keep the container in the outer carton until required for use.

Do not use after the expiry date stated on the packaging material.

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 SYNGLUTRA contains:

The active ingredients in SYNGLUTRA are dapagliflozin and metformin hydrochloride.

SYNGLUTRA 5 /500: Each film coated tablet contains the equivalent of 5 mg dapagliflozin as dapagliflozin propanediol and 500 mg of metformin hydrochloride.

Inactive ingredients are carboxymethylcellulose sodium, copovidone, crospovidone, ferric oxide red, hypromellose, magnesium stearate, mannitol, microcrystalline cellulose, silicon dioxide and Opadry II 85F17424 Beige film coating (containing ferrosoferric oxide, iron oxide red, iron oxide yellow, macrogol, part hydrolysed polyvinyl alcohol, talc, titanium dioxide).

Contains mannitol (84 mg/tablet).

SYNGLUTRA 5/1 000: Each film coated tablet contains the equivalent of 5 mg dapagliflozin as dapagliflozin propanediol and 1 000 mg of metformin hydrochloride.

Inactive ingredients are carboxymethylcellulose sodium, copovidone, crospovidone, ferric oxide red, hypromellose, magnesium stearate, mannitol, microcrystalline cellulose, silicon dioxide and Opadry II 85F565267 Brown film coating (containing iron oxide red, iron oxide yellow, macrogol, part hydrolysed polyvinyl alcohol, talc, titanium dioxide).

Contains mannitol (84 mg/tablet).

SYNGLUTRA 10/500: Each film coated tablet contains the equivalent of 10 mg dapagliflozin as dapagliflozin propanediol and 500 mg of metformin hydrochloride.

Inactive ingredients are carboxymethylcellulose sodium, copovidone, crospovidone, ferric oxide

yellow, hypromellose, magnesium stearate, mannitol, microcrystalline cellulose, silicon dioxide and Opadry II 85F510122 Green film coating (containing FD&C Blue #2/Indigo carmine, iron oxide yellow, macrogol, part hydrolysed polyvinyl alcohol, talc, titanium dioxide).
Contains mannitol (84 mg/tablet).

SYNGLUTRA 10/1 000: Each film coated tablet contains the equivalent of 10 mg dapagliflozin as dapagliflozin propanediol and 1 000 mg of metformin hydrochloride.
Inactive ingredients are carboxymethylcellulose sodium, copovidone, crospovidone, ferric oxide yellow, hypromellose, magnesium stearate, mannitol, microcrystalline cellulose, silicon dioxide and Opadry II 85F94245 Pink film coating (containing iron oxide red, macrogol, part hydrolysed polyvinyl alcohol, talc, titanium dioxide).
Contains mannitol (84 mg/tablet).

What SYNGLUTRA looks like and contents of the pack
SYNGLUTRA 5/500: Beige, biconvex, capsule-shaped, film coated tablets, “C394" debossed on one side and plain on the reverse side.
Packed in a 100 cc white HDPE container of 30 tablets with a 38 mm blue child-resistant cap and three 1 g silica gel bags.

SYNGLUTRA 5/1 000: Brown, biconvex, oval shaped, film coated tablets, "C396" debossed on one side and plain on the reverse side.
Packed in a 100 cc white HDPE container of 30 tablets with a 38 mm blue child-resistant cap and one 2 g silica gel bag.

SYNGLUTRA 10/500: Green, biconvex, capsule-shaped, film coated tablets, "C395" debossed on one side and plain on the reverse side.
Packed in a 100 cc white HDPE container of 30 tablets with a 38 mm blue child-resistant cap and three 1 g silica gel bags.

SYNGLUTRA 10/1 000**:** Pink, biconvex, oval-shaped, film coated tablets, "C397" debossed on one side and plain on the reverse side.

Packed in a 100 cc white HDPE container of 30 tablets with a 38 mm blue child-resistant cap and one 2 g silica gel bag.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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Customer care number: 080 2226662

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