SCHEDULING STATUS: S4

Dapagliflozin 5 mg Adco, film-coated tablets
Dapagliflozin 10 mg Adco, film-coated tablets
Dapagliflozin
Sugar free.

DO NOT USE DAPAGLIFLOZIN ADCO IF YOU HAVE TYPE 1 DIABETES MELLITUS. DAPAGLIFLOZIN ADCO MUST NOT BE USED IN WEIGHT CONTROL PROGRAMMES. DAPAGLIFLOZIN ADCO MUST NOT BE USED FOR THE TREATMENT OF ANY OTHER CONDITIONS EXCEPTR FOR THE TREATMENT OF TYPE 2 DIABETES MELLITUS AND HEART FAILURE.

There have been reports of metabolic acidosis, including ketoacidosis, in patients taking Dapagliflozin Adco. These conditions are serious life-threatening or can be fatal.

Metabolic acidosis is a condition in which too much acid accumulates in the body. Risk factors for metabolic acidosis include sudden decrease of your insulin dose, prolonged fasting from food and drink, or increasing your insulin dose due to major surgery or serious illness, or alcohol abuse. Caution is advised when using Dapagliflozin Adco if you have these conditions.

Diabetic ketoacidosis is an increase of ketone bodies in your body, shown on blood or urine tests. Risk factors for diabetic ketoacidosis include pancreatic conditions, such as inflammation of the pancreas or previous pancreatic surgery. Do not use Dapagliflozin Adco if you have these conditions.

Contact a doctor or the nearest hospital straight away if you have the following symptoms even if your blood sugar levels are normal: nausea, vomiting, abdominal pain, fatigue, thirst, passing of large volumes of urine, shortness of breath and confusion. These symptoms could be a sign of metabolic or diabetic ketoacidosis.

Read all of this leaflet carefully before you start taking Dapagliflozin Adco

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist nurse or other healthcare provider.
- Dapagliflozin Adco 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 Dapagliflozin Adco is and what it is used for
2. What you need to know before you take Dapagliflozin Adco
3. How to take Dapagliflozin Adco
4. Possible side effects
5. How to store Dapagliflozin Adco
6. Contents of the pack and other information

1. What Dapagliflozin Adco is and what it is used for

Dapagliflozin Adco contains the active substance dapagliflozin. It belongs to a group of medicines called “sodium glucose co-transporter-2 (SGLT2) inhibitors”. They work by blocking the SGLT2 protein in your kidney. By blocking this protein, blood sugar (glucose), salt (sodium) and water are removed from your body via the urine.

What Dapagliflozin Adco is used for

Dapagliflozin Adco is used in adult patients aged 18 years and older to treat:

Type 2 diabetes

- together with diet and exercise.
- Dapagliflozin Adco can be used together with other medicines to treat diabetes.
- It is important to continue to follow the advice on diet and exercise given to you by your doctor, pharmacist or nurse.
- Dapagliflozin Adco can be used to reduce the risk of developing new or worsening existing heart failure if you already have established disease of the heart and blood vessels.

Heart failure

- in patients with symptoms due to a weak pump function of the heart.

2. What you need to know before you take Dapagliflozin Adco

Do not take Dapagliflozin Adco:

- if you are hypersensitive (allergic) to dapagliflozin or any of the other ingredients of Dapagliflozin Adco (listed in section 6).
- you have type 1 diabetes - the type that usually starts when you are young, and your body does not produce any insulin.
- if you have or have had problems with your pancreas.
- you are pregnant.
- you are breastfeeding your baby.

Warnings and precautions

Contact a doctor or go to the nearest hospital straight away, if any of the following occurs

1. Diabetic ketoacidosis:

- If you develop symptoms such as nausea, vomiting, anorexia, abdominal pain, excessive thirst, difficulty breathing, confusion, unusual fatigue or sleepiness, you may have a

condition called ketoacidosis.
- This is a serious, sometimes life-threatening problem you can get with diabetes because of increased levels of “ketone bodies” in your urine or blood, seen in tests.
- The risk of developing diabetic ketoacidosis may be increased with prolonged fasting, dehydration, sudden reductions in insulin dose, or a higher need of insulin due to major surgery or serious illness.

2. Necrotising fasciitis of the perineum
- This is a serious bacterial infection that destroys tissue under the skin. The condition spreads quickly. Symptoms include blisters, fever, fatigue, swelling, tenderness and pain worse than a person would expect based on the wound's appearance. This is a serious and potentially life-threatening event that requires urgent surgical intervention and antibiotic treatment.

Talk to your doctor, pharmacist or nurse before taking Dapagliflozin Adco:
- If your blood pressure is lower than normal
- if you have a liver problem.
- if you are on high blood pressure medication, have a history of low blood pressure, or are an elderly patient
- if you have or develop nausea (feeling sick), vomiting or fever or if you are not able to eat or drink. These conditions can cause dehydration. Your doctor may ask you to stop taking Dapagliflozin Adco until you recover to prevent dehydration.
- if you often get infections of the urinary tract.
- elderly patients

If any of the above applies to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking Dapagliflozin Adco.

Kidney function
Your doctor will determine your kidney function prior to treatment and will monitor it on an ongoing basis.

Diabetes and foot care
If you have diabetes, it is important to check your feet regularly and adhere to any other advice regarding foot care given by your healthcare professional.

Urine glucose
Because of how Dapagliflozin Adco works, your urine will test positive for sugar while you are on this medicine.

Children and adolescents
Dapagliflozin Adco is not recommended for children and adolescents under 18 years of age, because it has not been studied in these patients.

Other medicines and Dapagliflozin Adco
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

- Tell your doctor if you are taking a medicine used to remove water from the body (diuretic), as Dapagliflozin Adco may increase the effect of the diuretic. You are more likely to become dehydrated or experience a drop in our blood pressure.
- if you have type 2 diabetes and are taking other medicines that lower the amount of sugar in your blood (such as insulin or a “sulphonylurea” medicine), your doctor may want to lower the dose of these other medicines, to prevent you from getting low blood sugar levels (hypoglycaemia).
- Tell your doctor if you are taking lithium, as you will need to monitor your lithium levels more regularly while on Dapagliflozin Adco.

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 healthcare provider for advice before taking Dapagliflozin Adco.

Do not take Dapagliflozin Adco if you are pregnant or breastfeeding your baby.

Driving and using machines
It is not always possible to predict to what extent Dapagliflozin Adco may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which Dapagliflozin Adco affects you.

Taking Dapagliflozin Adco with other medicines called sulphonylureas or with insulin can cause too low blood sugar levels (hypoglycaemia), which may cause symptoms such as shaking, sweating and change in vision, and may affect your ability to drive and use machines.
Do not drive or use any tools or machines, if you feel dizzy while taking Dapagliflozin Adco.

3. How to take Dapagliflozin Adco
Do not share medicines prescribed for you with any other person.
Always take Dapagliflozin Adco exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

If you are taking Dapagliflozin Adco for type 2 diabetes or for heart failure:
The recommended dose of Dapagliflozin Adco is 10 mg once daily.
Your doctor will prescribe the strength that is right for you.

Taking Dapagliflozin Adco
Swallow the tablet whole with half a glass of water.
You can take your tablet with or without food.
You can take the tablet at any time of the day. However, try to take it at the same time each day. This will help you to remember to take it.

Your doctor may prescribe Dapagliflozin Adco together with other medicine(s) to lower the amount of sugar in your blood. Remember to take these other medicine(s) as your doctor has told you. This will help get the best results for your health.

Diet and exercise can help your body use its blood sugar better. It is important to stay on any diet and exercise program recommended by your doctor while taking
Dapagliflozin Adco.

Your doctor will tell you how long your treatment with Dapagliflozin Adco will last. If you have the impression that the effect of Dapagliflozin Adco is too strong or too weak, tell your doctor or pharmacist.

If you take more Dapagliflozin Adco than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take the medicine pack with you.

If you forget to take Dapagliflozin Adco
- Do not take a double dose to make up for forgotten individual doses.

If you stop taking Dapagliflozin Adco
Do not stop taking Dapagliflozin Adco without talking to your doctor first. Your blood sugar may increase without Dapagliflozin Adco.

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

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

These are signs of angioedema
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- hives, rash or itching,
- fainting.

These are the signs of diabetic ketoacidosis
- nausea, vomiting, extreme weight loss, stomach pain, excessive thirst, fast and deep breathing, confusion, unusual sleepiness or tiredness

This may occur regardless of blood sugar level. Your doctor may decide to temporarily or permanently stop your treatment with Dapagliflozin Adco.

- necrotising fasciitis of the perineum or Fournier's gangrene

This is a serious soft tissue infection of the genitals or the area between the genitals and the anus.

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

Tell your doctor if you notice any of the following:
Frequent side effects:
- genital infection (thrush) of your penis or vagina (signs may include irritation, itching, unusual discharge or odour)
- urinary tract infections (UTI) characterised by back pain, strong, persistent urge to urinate, burning sensation when urinating, blood in the urine.
- low blood sugar (confusion, heart palpitations, shakiness and anxiety are symptoms)
- dizziness
- rash
- excessive urination
- Positive test for glucose in the urine
- increases in the amount of red blood cells in your blood (shown in tests)
- decreases in creatinine renal clearance (shown in tests) in the beginning of treatment

Less frequent side-effects:
- Fungal infection, you may experience a red, itchy rash
- loss of too much fluid from your body (dehydration, signs may include very dry or sticky mouth, passing little or no water (urine) or fast heartbeat)
- thirst
- constipation
- dry mouth
- awakening from sleep at night to pass urine
- itchy genitals
- increases in creatinine (shown in laboratory blood tests) in the beginning of treatment
- increases in urea (shown in laboratory blood tests)

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 Dapagliflozin Adco.

5. How to store Dapagliflozin Adco
Store all medicines out of reach of children.
Store at or below 25 °C.
Store in the original packaging until required for use, in order to protect from light.
Do not use after the expiry date stated on the label, carton and bottle.
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 Dapagliflozin Adco contains
- The active substance is dapagliflozin.
- The other ingredients are:
- tablet core: microcrystalline cellulose, sodium lauryl sulphate, crospovidone, colloidal silicon dioxide, magnesium stearate
- film-coating: Opadry II 85F42129 Yellow consisting of polyvinyl alcohol - part hydrolysed (E1203), titanium dioxide (E171), macrogol/PEG (E1521), talc (E553b) and iron oxide yellow (E172).

What Dapagliflozin Adco looks like and contents of the pack
Dapagliflozin 5 mg Adco: Yellow coloured, round, biconvex, film-coated tablets debossed with "D1" on one side and "M" on other side.
Dapagliflozin 10 mg Adco: Yellow coloured, diamond, biconvex, film-coated tablets debossed with "D2" on one side and "M" on other side.

The film-coated tablets are packed in:
White HDPE containers with white PP closure and silica gel canister. Pack sizes 30 or 500 tablets.
Alu-Alu blister pack with 10 tablets per blister strip. Three blister strips in an outer cardboard carton. Pack size: 30 tablets.
Not all pack sizes may be marketed.

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Customer Care: 0860 ADCOCK / 232625

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Dapagliflozin 5 mg Adco, filmbedekte tablette
Dapagliflozin 10 mg Adco, filmbedekte tablette
Dapagliflosien
Suikervry.

MOENIE DAPAGLIFLOZIN ADCO GEBRUIK INDIEN U TIPE 1 DIABETES MELLITUS HET NIE. DAPAGLIFLOZIN ADCO MOET NIE IN GEWIGSBEHEERPROGRAMME GEBRUIK WORD NIE. DAPAGLIFLOZIN ADCO MAG NIE GEBRUIK WORD VIR DIE BEHANDELING VAN ENIGE ANDER TOESTANDE NIE, BEHALWE VIR DIE BEHANDELING VAN TIPE 2 DIABETES MELLITUS EN HARTVERSAKING.

Daar was aanmeldings van metaboliese asidose, insluitend ketoasidose, by pasiënte wat Dapagliflozin Adco neem. Hierdie toestande is ernstig, lewensgevaarlik of kan dodelik wees.

Metaboliese asidose is 'n toestand waarin te veel suur in die liggaam ophoop. Risikofaktore vir metaboliese asidose sluit in skielike verlaging van u insuliendosis, langdurige vas van kos en drank, of die verhoging van u insuliendosis as gevolg van 'n groot operasie of ernstige siekte, of alkoholmisbruik. Wees versigtig met die gebruik van Dapagliflozin Adco indien u hierdie toestande het.

Diabetiese ketoasidose is 'n toename van ketoonliggame in u liggaam, getoon op bloed- of urientoetse. Risikofaktore vir diabetiese ketoasidose sluit in pankreastoestande, soos inflammasie van die pankreas of vorige pankreas-chirurgie. Moenie Dapagliflozin Adco gebruik indien u hierdie toestande het nie.

Kontak dadelik 'n dokter of die naaste hospitaal indien u die volgende simptome het, selfs al is u bloedsuikervlakke normaal: naarheid, braking, buikpyn, moegheid, dors, skei groot hoeveelhede urien uit, kortasem en verwarring. Hierdie simptome kan 'n teken wees van metaboliese of diabetiese ketoasidose.

Lees hierdie hele biljet noukeurig deur voordat u Dapagliflozin Adco begin neem

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- Dapagliflozin Adco is aan u persoonlik voorgeskryf en u moenie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.

Wat is in hierdie biljet

1. Wat Dapagliflozin Adco is en waarvoor dit gebruik word
2. Wat u moet weet voordat u Dapagliflozin Adco neem
3. Hoe om Dapagliflozin Adco te neem
4. Moontlike newe-effekte
5. Hoe om Dapagliflozin Adco te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat Dapagliflozin Adco is en waarvoor dit gebruik word

Dapagliflozin Adco bevat die aktiewe bestanddeel dapagliflosien. Dit behoort tot 'n groep medisyne genaamd "natriumglukose ko-transport-2 (SGLT2) inhibeerders". Hulle werk deur die SGLT2-proteïen in u nier te blok. Deur hierdie proteïen te blok, word bloedsuiker (glukose), sout (natrium) en water via die urien uit u liggaam verwyder.

Waarvoor Dapagliflozin Adco gebruik word

Dapagliflozin Adco word by volwasse pasiënte van 18 jaar en ouer gebruik om die volgende te behandel:

Tipe 2-diabetes

- saam met dieet en oefening.
- Dapagliflozin Adco kan saam met ander medisyne gebruik word om diabetes te behandel.
- Dit is belangrik om voort te gaan om die advies oor dieet en oefening wat u dokter, apteker of verpleegkundige aan u gegee het, te volg.
- Dapagliflozin Adco kan gebruik word om die risiko van nuwe, of bestaande hartversaking wat kan vererger, te verminder, indien u reeds 'n siekte van die hart en bloedvate het.

Hartversaking

- by pasiënte met simptome as gevolg van 'n swak pompfunksie van die hart.

2. Wat u moet weet voordat u Dapagliflozin Adco neem

Moenie Dapagliflozin Adco neem nie:

- indien u hipersensitief (allergies) is vir dapagliflosien of enige van die ander bestanddele van Dapagliflozin Adco (gelys in afdeling 6).
- u tipe 1 diabetes het - die tipe wat gewoonlik begin wanneer u jonk is, en u liggaam produseer geen insulien nie.
- indien u probleme met u pankreas het, of gehad het.
- u swanger is.
- u u baba borsvoed.

Waarskuwings en voorsorgmaatreëls

Kontak 'n dokter of gaan dadelik na die naaste hospitaal, indien enige van die volgende voorkom

1. Diabetiese ketoasidose:

- Indien u simptome ontwikkel soos naarheid, braking, anoreksie, buikpyn, oormatige dors,

moeilike asemhaling, verwarring, ongewone moegheid of slaperigheid; u kan 'n toestand hê wat ketoasidose genoem word.
- Dit is 'n ernstige, soms lewensgevaarlike probleem wat u met diabetes kan kry as gevolg van verhoogde vlakke van "ketoonliggame" in u urien of bloed, gesien in toetse.
- Die risiko om diabetiese ketoasidose te ontwikkel, kan verhoog word met langdurige vas, dehidrasie, skielike verlaging in insuliendosis, of 'n groter behoefte aan insulien as gevolg van groot chirurgie of ernstige siekte.

2. Nekrotiserende fasciïtis van die perineum
- Dit is 'n ernstige bakteriële infeksie wat weefsel onder die vel vernietig. Die toestand versprei vinnig. Simptome sluit in blase, koors, moegheid, swelling, sensitiwiteit en pyn erger as wat 'n persoon sou verwag op grond van die wond se voorkoms. Dit is 'n ernstige en potensieel lewensgevaarlike gebeurtenis wat dringende chirurgiese ingryping en antibiotiese behandeling vereis.

Raadpleeg u dokter, apteker of verpleegkundige voordat u Dapagliflozin Adco neem:
- Indien u bloeddruk laer is as normaal.
- indien u 'n lewerprobleem het.
- indien u op hoë bloeddrukmedikasie is, 'n geskiedenis van lae bloeddruk het, of 'n bejaarde pasiënt is.
- indien u naar is, of naarheid ontwikkel (naar voel), braking of koors, of indien u nie kan eet of drink nie. Hierdie toestande kan dehidrasie veroorsaak. U dokter kan u vra om Dapagliflozin Adco te staak totdat u herstel, om dehidrasie te voorkom.
- indien u dikwels infeksies van die urienweg kry.
- bejaarde pasiënte.

Indien enige van die bogenoemde op u van toepassing is (of u is nie seker nie), raadpleeg u dokter, apteker of verpleegkundige voordat u Dapagliflozin Adco neem.

Nierfunksie
U dokter sal u nierfunksie voor behandeling bepaal en sal dit deurlopend monitor.

Diabetes en voetversorging
Indien u diabetes het, is dit belangrik om u voete gereeld na te gaan, en te voldoen aan enige ander advies rakende voetversorging wat deur u gesondheidsorg kundige gegee word.

Urinêre glukose
As gevolg van hoe Dapagliflozin Adco werk, sal u urien positief toets vir suiker terwyl u op hierdie medisyne is.

Kinders en adolessente
Dapagliflozin Adco word nie aanbeveel vir kinders en adolessente jonger as 18 jaar nie, omdat dit nie by hierdie pasiënte bestudeer is nie.

Ander medisyne en Dapagliflozin Adco
Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

- Lig u dokter in indien u 'n medisyne gebruik om water uit die liggaam te verwyder (diuretikum), aangesien Dapagliflozin Adco die effek van die diuretikum kan verhoog. U is meer geneig om gedehidreer te raak of 'n daling in u bloeddruk te ervaar.
- Indien u tipe 2 diabetes het en ander medisyne gebruik wat die hoeveelheid suiker in u bloed verlaag (soos insulien of 'n "sulfonielureum"-medisyne), sal u dokter dalk die dosis van hierdie ander medisyne wil verlaag, om te verhoed dat u lae bloedsuikervlakke (hipoglukemie) kry.
- Lig u dokter in indien u litium neem, aangesien u u litiumvlakke meer gereeld sal moet monitor terwyl u Dapagliflozin Adco neem.

Swangerskap, borsvoeding en vrugbaarheid
Indien u swanger is of borsvoed, dink u kan swanger wees, of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u Dapagliflozin Adco neem.

Moenie Dapagliflozin Adco neem indien u swanger is of u baba borsvoed nie.

Bestuur en gebruik van masjinerie
Dit is nie altyd moontlik om te voorspel in watter mate Dapagliflozin Adco met u daaglikse aktiwiteite kan inmeng nie. U moet seker maak dat u nie bestuur of masjinerie hanteer voordat u bewus is van die mate waartoe Dapagliflozin Adco u beïnvloed nie.

Die gebruik van Dapagliflozin Adco saam met ander medisyne genaamd sulfonielureum-middels of met insulien, kan té lae bloedsuikervlakke (hipoglukemie) veroorsaak, wat simptome soos bewerasies, sweet en verandering in visie kan veroorsaak, en u vermoë om te bestuur en masjiene te hanteer, kan beïnvloed.
Moenie bestuur of enige gereedskap of masjiene hanteer indien u duiselig voel terwyl u Dapagliflozin Adco neem nie.

3. Hoe om Dapagliflozin Adco te neem
Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.
Neem altyd Dapagliflozin Adco presies soos u dokter of apteker u vertel het. Raadpleeg u dokter of apteker indien u nie seker is nie.

Indien u Dapagliflozin Adco neem vir tipe 2 diabetes of vir hartversaking:
Die aanbevole dosis Dapagliflozin Adco is 10 mg een keer per dag.
U dokter sal die sterkte voorskryf wat reg is vir u.

Die neem van Dapagliflozin Adco
Sluk die tablet heel met 'n halwe glas water.
U kan u tablet met of sonder kos neem.
U kan die tablet enige tyd van die dag neem. Probeer egter om dit elke dag op dieselfde tyd te neem. Dit sal u help om te onthou om dit te neem.

U dokter kan Dapagliflozin Adco saam met ander medisyne voorskryf om die hoeveelheid suiker in u bloed te verlaag. Onthou om hierdie ander medisyne te neem soos u dokter vir u gesê het. Dit sal help om die beste resultate vir u gesondheid te kry.

Dieet en oefening kan u liggaam help om u bloedsuiker beter te gebruik. Dit is belangrik om op enige dieet en oefenprogram te bly wat deur u dokter aanbeveel word terwyl u Dapagliflozin Adco neem.

U dokter sal u vertel hoe lank u behandeling met Dapagliflozin Adco sal duur. Indien u die indruk het dat die effek van Dapagliflozin Adco te sterk of te swak is, lig u dokter of apteker in.

Indien u meer Dapagliflozin Adco neem as wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum. Neem die medisyneverpakking saam.

Indien u vergeet om Dapagliflozin Adco te neem
Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

Indien u ophou om Dapagliflozin Adco te neem
Moenie ophou om Dapagliflozin Adco te neem sonder om eers met u dokter te praat nie. U bloedsuiker kan styg sonder die neem van Dapagliflozin Adco.

4. Moontlike newe-effekte
Dapagliflozin Adco kan newe-effekte hê.
Nie alle newe-effekte wat vir Dapagliflozin Adco aangemeld is, word in hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of u enige ongewenste gevolge ervaar terwyl u Dapagliflozin Adco neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak Dapagliflozin Adco en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- Hierdie is tekens van angio-edeem
  - swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal,
  - galbulte, veluitslag of jeukerigheid,
  - floute.

- Hierdie is die tekens van diabetiese ketoasidose
  - naarheid, braking, uiterste gewigsverlies, maagpyn, oormatige dors, vinnige en diep asemhaling, verwarring, ongewone slaperigheid of moegheid

Dit kan voorkom ongeag die bloedsuikervlak. U dokter kan besluit om u behandeling met Dapagliflozin Adco tydelik, of permanent te staak.

- Nekrotiserende fasciïtis van die perineum of Fournier se gangreen

Dit is 'n ernstige sagteweefsel-infeksie van die geslagsdele of die area tussen die geslagsdele en die anus.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige reaksie op Dapagliflozin Adco gehad. U sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Lig u dokter in indien u enige van die volgende opmerk:
Gereelde newe-effekte:

- genitale infeksie (sproei) van u penis of vagina (tekens kan irritasie, jeukerigheid, ongewone afskeiding of reuk insluit).
- urienweginfeksies (UWI) wat gekenmerk word deur rugpyn, sterk, aanhoudende drang om te urineer, brandende sensasie tydens urinering, bloed in die urien.
- lae bloedsuiker (simptome is verwarring, hartkloppings, bewerigheid en angs).
- duiseligheid.
- veluitslag.
- oormatige urinering.
- positiewe toets vir glukose in die urien.
- toename in die hoeveelheid rooibloedselle in u bloed (getoon in toetse).
- afname in kreatinien nieropruiming (getoon in toetse) aan die begin van die behandeling.

Minder gereelde newe-effekte:

- Swaminfeksie; u kan 'n rooi, jeukerige veluitslag ervaar.
- verlies van te veel vloeistof uit u liggaam (dehidrasie, tekens kan baie droë of taai mond insluit, min of geen water (urien) uitskei, of vinnige hartklop.
- dors.
- hardlywigheid.
- droë mond.
- snags uit die slaap wakker word om urien uit te skei.
- jeukerige geslagsdele.
- verhoging in kreatinien (getoon in laboratoriumbloedtoetse) aan die begin van behandeling.
- verhoging in ureum (getoon in laboratoriumbloedtoetse).

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief

u dokter of apteker in kennis.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, raadpleeg u dokter, apteker of verpleegkundige. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en eAanmeldingsplatform (who-umc.org) wat op SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van Dapagliflozin Adco te verskaf.

5. Hoe om Dapagliflozin Adco te bêre

Bêre alle medisyne buite bereik van kinders.
Bêre teen of benede 25 °C.
Bêre in die oorspronklike verpakking totdat dit benodig word vir gebruik, om teen lig te beskerm.
Moenie gebruik ná die vervaldatum wat op die etiket, kartonboksie en bottel vermeld word nie.
Neem alle ongebruikte medisyne terug na u apteker.
Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat Dapagliflozin Adco bevat

- Die aktiewe bestanddeel is dapagliflosien.
- Die ander bestanddele is:

- tabletkern: mikrokristallyne sellulose, natriumlourielsulfaat, kruispovidoon, kolloïdale silikondioksied, magnesiumstearaat
- filmbedekking: “Opadry” II 85F42129 Geel, bestaande uit polivinielalkohol - deels gehidroliseer (E1203), titaandioksied (E171), makrogol/PEG (E1521), talk (E553b) en ysteroksiedgeel (E172).

Hoe Dapagliflozin Adco lyk en die inhoud van die verpakking

Dapagliflozin 5 mg Adco: Geel-gekleurde, ronde, bikonvekse, filmbedekte tablette met "D1" aan die een kant gegraveer, en "M" aan die ander kant.
Dapagliflozin 10 mg Adco: Geel-gekleurde, diamant-vormige, bikonvekse, filmbedekte tablette met "D2" aan die een kant gegraveer, en "M" aan die ander kant.

Die filmbedekte tablette is verpak in:
Wit HDPE-houers met wit PP-prop en silikajel-houer. Verpakkingsgroottes 30 of 500 tablette.
Alu-Alu-stulpstrookverpakking met 10 tablette per stulpstrook. Drie stulpstroke in 'n buitenste kartonboksie. Verpakkingsgrootte: 30 tablette.
Nie alle verpakkingsgroottes mag dalk bemark word nie.

Houer van Sertifikaat van Registrasie
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Dapagliflozin 5 mg Adco: 57/21.2/0222
Dapagliflozin 10 mg Adco: 57/21.2/0223

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