# Stop takingduo Flozina XR and see a doctor straight away if you notice any of the following serious or

botentially serious side effects:
 Lactic acidosis, seen very rarely (may affect up to 1 in 10,000 people) duo Flozina XR may cause a very rare, but very serious side effect called lactic acidosis (see section "Warnings and precautions"). If this happens you must stop taking duo Flozina XR and contact a doctor or the nearest hospital immediately, as lactic acidosis may lead to coma.

Contact a doctor or the nearest hospital straight away if you have any of the following side effects:

• Diabetic ketoacidosis, seen rarely (may affect up to 1 in 1,000 people)

These are the signs of diabetic ketoacidosis (see also section 2 Warnings and precautions):

-increased levels of "ketone bodies" in your urine or blood

- -rapid weight loss -feeling sick or being sick -stomach pain -excessive thirst
- -fast and deep breathing
- unusual sleepiness or tiredness
   a sweet smell to your breath, a sweet or metallic taste in your mouth or a different odour to your urine

This may occur regardless of blood glucose level. Your doctor may decide to temporarily or permanently stop your treatment with duo Flozina XR.

Necrotising fasciitis of the perineum or Fournier's gangrene, a serious soft tissue infection of the genitals or the area between the genitals and the anus, seen very rarely.

# $Stop\ taking\ duo\ Flozina\ XR\ and\ see\ a\ doctor\ as\ soon\ as\ possible\ if\ you\ notice\ any\ of\ the\ following\ serious$

or potentially serious effects:
Dehydration: loss of too much fluid from your body, seen uncommonly (may affect up to 1 in 100

- people). These are signs of dehydration: -very dry or sticky mouth, feeling very thirsty

feeling very sleepy or tired
passing little or no water (urine)
fast heartheat.

Urinary tract infection, seen commonly (may affect up to 1 in 10 people). These are signs of a severe infection of the urinary tract: -fever and/or chills

- pain in your back or side.

Although uncommon, if you see blood in your urine, tell your doctor immediately.

Contact your doctor as soon as possible if you have any of the following side effects:

Low blood sugar levels (hypoglycaemia), seen very commonly (may affect more than 1 in 10 people)when taking this medicine with a sulphonylurea or other medicines that lower the amount of sugar in

- your blood, such as insulin. These are the signs of low blood sugar: -shaking, sweating, feeling very anxious, fast heart beat -feeling hungry, headache, change in vision
- a change in your mood or feeling confused.

Your doctor will tell you how to treat low blood sugar levels and what to do if you get any of the signs above. If you have symptoms of low blood sugar, eat glucose tablets, a high sugar snack or drink fruit juice. Measure your blood sugar if possible and rest.

### Other side effects include:

- Very common
  Nausea, vomiting
- Diarrhoea or stomach ache
- Loss of appetite

- genital infection (thrush) of your penis or vagina (signs may include irritation, itching, unusual discharge or odour)
- back pain
- discomfort when passing water (urine), passing more water than usual or needing to pass water more
- changes in the amount of cholesterol or fats in your blood (shown in tests) 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
- changes in taste
- rash

- Constipation
- Awakening from sleep at night to pass urine
- Dry mouth
   Weight decreased
- Increases in creatinine (shown in laboratory blood tests) in the beginning of treatment

### Increases in urea (shown in laboratory blood tests)

### Decreased vitamin B12 levels in the blood

- Abnormalities in liver function tests, inflammation of the liver (hepatitis)
- · Redness of the skin (erythema), itching or an itchy rash (hives

Storage: Store below 30°C. Protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the blister or carton after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### Presentation: 28 Tablets

Marketed by:

# **PYXUS**

PYXUS PHARMACEUTICALS PVT. LTD.

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# Flozina R 10 mg / 1000 mg

Dapagliflozin and Metformin HCI extended-release Tablets

This medicine contains two different substances called Dapagliflozin and Metformin. Both belong to a group of medicines called oral anti-diabetics. These are medicines taken by mouth for diabetes

duo Flozina XR is used for a type of diabetes called "type 2 diabetes" in adult patients (aged 18 years and older) and usually occurs when you are older. If you have type 2 diabetes, your pancreas does not make enough insulin or your body is not able to use the insulin it produces properly. This leads to a high level of sugar (glucose) in your blood.

- Dapagliflozin works by removing excess sugar from your body via your urine and lowers the amount of sugar in your blood. It can also help prevent heart disease.
- Metformin works mainly by inhibiting glucose production in the liver.

- This medicine is taken in combination with diet and exercise.

  This medicine is used if your diabetes cannot be controlled with other medicines used to treat
- Your doctor may ask you to take this medicine on its own or together with other medicines to treat diabetes. This may be another medicine taken by mouth and/or a medicine given by injection, such as insulin or a GLP-1 receptor agonist (helps your body to increase the production of insulin when your
- blood sugar is high).
  If you are already taking both dapagliflozin and metformin as single tablets, your doctor may ask you to switch to this medicine. To avoid overdose, do not continue taking dapagliflozin and metformin tablets, if you are taking duo Flozina XR.

It is important to continue to follow the advice on diet and exercise given to you by your doctor,

### 2. What you need to know before you takeduo Flozina XR

- Do not take duo Flozina XR

   if you are allergic to dapagliflozin, metformin or any of the other ingredients of this medicine (listed
- if you have ever had a diabetic coma.

  If you have uncontrolled diabetes, with, for example severe hyperglycaemia (high blood glucose),
  nausea, vomiting, diarrhoea, rapid weight loss, lactic acidosis (see "Risk of lactic acidosis" below) or ketoacidosis. Ketoacidosis is a condition in which substances called 'ketone bodies' accumulate in the blood and which can lead to a diabetic pre-coma. Symptoms include stomach pain, fast and deep breathing, sleepiness or your breath developing an unusual fruity smell.

  if you have severely reduced kidney function.
- if you have a severe infection.
- if you have lost a lot of water from your body (dehydration), e.g. due to long-lasting or severe diarrhoea, if you have recently had a heart attack or if you have heart failure or serious problems with your
- blood circulation or difficulties in breathing
- if you have problems with your liver.

if you drink large amounts of alcohol, either every day or only from time to time (please see section "duo Flozina XR with alcohol").

Do not take this medicine if any of the above apply to you.

# Warnings and precautions

Risk of lactic acidosis

isk or I actic acidosis duo Flozina XR may cause a very rare, but very serious side effect called lactic acidosis, particularly if your kidneys are not working properly. The risk of developing lactic acidosis is also increased with uncontrolled diabetes, serious infections, prolonged fasting or alcohol intake, dehydration (see further information below), liver problems and any medical conditions in which a part of the body has a reduced supply of oxygen (such as acute severe heart disease).

If any of the above apply to you, talk to your doctor for further instructions.

# Stop takingduo Flozina XR for a short time if you have a condition that may be associated with

dehydration
(significant loss of body fluids) such as severe vomiting, diarrhoea, fever, exposure to heat or if you drink less fluid than normal. Talk to your doctor for further instructions.

Stop takingduo Flozina XR and contact a doctor or the nearest hospital immediately if you experience some of the symptoms of lactic acidosis, as this condition may lead to coma. Symptoms of lactic acidosis include:

- · Stomach ache (abdominal pain)
- Muscle cramps
  A general feeling of not being well with severe tiredness
  Difficulty in breathing
- Reduced body temperature and heartbeat

Lactic acidosis is a medical emergency and must be treated in a hospital.

### $Talk \ to \ your \ doctor, pharmacist \ or \ nurse \ before \ taking \ duo \ Flozina \ XR \ , \ and \ during \ treatmagnetic \ during \ during \ treatmagnetic \ during \ treatmagnetic \ during \ treatmagnetic \ during \ treatmagnetic \ during \ du$ if you have "type 1 diabetes" – the type that usually starts when you are young, and your body does not produce any insulin. duo Flozina XR should not be used to treat this condition.

- in you experience rapid weight loss, feeling sick or being sick, stomach pain, excessive thirst, fast and deep breathing, confusion, unusual sleepiness or tiredness, a sweet smell to your breath, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat, contact a doctor the nearest hospital straight away. These symptoms could be a sign of "diabetic ketoacidosis" – a rare but 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, excessive alcohol consumption, dehydration,
- sudden reductions in insulin dose, or a higher need of insulin due to major surgery or serious illness. if you have problems with your kidneys. Your doctor will check your kidney function. if you have very high levels of glucose in your blood which may make you dehydrated (lose too much body fluid). Possible signs of dehydration are listed at the top of section 4. Tell your doctor before you start taking this medicine if you have any of these signs.
- fyou are taking medicines to lower blood pressure (anti-hypertensives) and have a history of low blood pressure (hypotension). More information is given below under 'Other medicines a if you often get infections of the urinary tract. This medicine may cause urinary tract infections and
- your doctor may want to monitor you more closely. Your doctor may consider temporarily changing your treatment if you develop a serious infection. If you need to have major surgery, you must stop taking duo Flozina XR during and for some time after the procedure. Your doctor will decide when you must stop and when to restart your treatment with
- t is important to check your feet regularly and adhere to any other advice regarding foot care given

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

Talk to your doctor immediately if you develop a combination of symptoms of pain, tenderness. redness, or swelling of the genitals or the area between the genitals and the anus with fever or feeling generally unwell. These symptoms could be a sign of a rare but serious or even life-threatening infection, called necrotising fasciitis of the perineum or Fournier's gangrene which destroys the tissue under the skin. Fournier's gangrene has to be treated immediately

During treatment withduo Flozina XR , your doctor will check your kidney function at least once every year or more frequently if you are elderly and/or if you have worsening kidney function.

Because of how this medicine works, your urine will test positive for sugar while you are on this

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

Other medicines and duo Flozina XR If you need to have an injection of a contrast medium that contains iodine into your bloodstream, for example in the context of an X-ray or scan, you must stop takingduo Flozina XR before or at the time of the injection. Your doctor will decide when you must stop and when to restart your treatment with

Tell your doctor if you are taking, have recently taken or might take any other medicines. You may need more frequent blood glucose and kidney function tests, or your doctor may adjust the dosage of duo Flozina XR. It is especially important to mention the following: if you are taking medicines which increase urine production (diuretics). Your doctor may ask you to stop taking this medicine. Possible signs of losing too much fluid from your body are listed at the

- if you 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 blood sugar levels that are too low (hypoglycaemia).
- if you are taking cimetidine, a medicine used to treat stomach problems. if you are using bronchodilators (beta-2 agonists) which are used to treat asthma. if you are using corticosteroids (used to treat inflammation in diseases like asthma and arthritis)
- that are given by mouth, as an injection, or inhaled. if you are using medicines used to treat pain and inflammation (NSAID and COX-2-inhibitors, such s ibuprofen and celecoxib). if you are using certain medicines for the treatment of high blood pressure (ACE inhibitors and

### angiotensin II receptor antagonists). duo Flozina XR with alcohol

Avoid excessive alcohol intake while taking duo Flozina XR since this may increase the risk of lactic acidosis (see "Warnings and precautions")

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should stop taking this medicine if you become pregnant, since it is not recommended during the second and third trimesters (the last six months) of pregnancy. Talk to your doctor about the best way to control your

Talk to your doctor if you would like to or are breast-feeding before taking this medicine. You should not use this medicine if you are breast-feeding. Metformin passes into human milk in small amounts. It is not known if dapagliflozin passes into human breast milk.

This medicine has no or negligible influence on the ability to drive and use machines. Taking it with other medicines that lower the amount of sugar in your blood, such as insulin or a "sulphonylurea" medicine, can cause too low blood sugar levels (hypoglycaemia), which may cause symptoms such as weakness, dizziness, increased sweating, fast heart beat, change in vision or difficulties concentrating, and may affect your ability to drive and use machines. Do not drive or use any tools or machines, if you start to feel these symptoms.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say it is essentially 'sodium-free'.

# 3. How to takeduo Flozina XR

ine exactly as your doctor has told you. Check with your doctor or pharmacist

# How much to take

The amount of this medicine that you will take varies depending on your condition and the doses you currently take of metformin and/or individual tablets of dapagliflozin and metformin. Your doctor will tell you exactly which strength of this medicine to take.

The recommended dose is one tablet twice a day.

Taking this medicine

• Swallow the tablet whole with half a glass of water.

Take your tablet with food. This is to reduce the risk of side effects in the stomach. Take your tablet twice daily, once in the morning (breakfast) and once in the evening (dinner).

Your doctor may prescribe this medicine together with other medicine(s) to lower the amount of sugar in your blood. These may be medicine(s) by mouth or given by injection, such as insulin or a GLP-1 receptor agonist. Remember to take these other medicine(s) as your doctor has told you. This will help get the best results for your health.

To control your diabetes, you still need to keep to diet and exercise, even when you are taking this medicine. So it is important to keep following the advice about diet and exercise from your doctor, pharmacist or nurse. In particular, if you are following a diabetic weight control diet, continue to follow it while you are taking this medicine.

rou take more duo Flozina XR than you should If you take moreduo Flozina XR tablets than you should, you may experience lactic acidosis. Symptoms of lactic acidosis include feeling or being very sick, vomiting, stomach ache, muscular cramps, severe tiredness or difficulty breathing. If this happens to you, you may need immediate hospital treatment, as lactic acidosis may lead to coma. Stop taking this medicine immediately and contact a doctor or the nearest hospital straight away (see section 2). Take the medicine pack with you.

### If you forget to take duo Flozina XR If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not take a double dose of this medicine to make up for a forgotten dose

4. Possible side effects

If you stop taking duo Flozina XR Do not stop taking this medicine without talking to your doctor first. Your blood sugar may increase

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

Like all medicines, this medicine can cause side effects, although not everybody gets them.