

MICRO LABS LIMITED, INDIA

MODULE:1 Pharmaceutical Products Registration Administrative Requirements

DAPZIN 10-M PLUS (DAPAGLIFLOZIN 10mg AND EXTENDED RELEASE

METFORMIN HYDROCHLORIDE 1000mg TABLETS)



1.4.3 Patient Information Leaflet (PIL)

Enclosed



WHAT IS IN THIS LEAFLET

- What DAPZIN 10-M PLUS is and what it is used for?
- What you need to know before you take DAPZIN 10-M PLUS
- How to take DAPZIN 10-M PLUS
- Possible side effects
- How to store DAPZIN 10-M PLUS
- Contents of the pack and other information

WHAT DAPZIN 10-M PLUS IS AND WHAT IT IS USED FOR

It contains 2 prescription medicines called Dapagliflozin and Metformin HCl XR. It is used along with diet and exercise to improve blood sugar (glucose) control in adults with type 2 diabetes when treatment with either dapagliflozin or metformin has not controlled your blood sugar.

Dapagliflozin and Metformin are not for people with type 1 diabetes.

Dapagliflozin and Metformin are not for people with diabetic ketoacidosis (increased ketones in your blood or urine).

It is not known if Dapagliflozin and Metformin are safe and effective in children younger than 18 years of age.

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WHAT YOU NEED TO KNOW BEFORE YOU TAKE DAPZIN10-M PLUS

Do not take Dapagliflozin and Metformin XR if you: have moderate to severe kidney problems or are on dialysis are allergic to dapagliflozin, metformin HCl, or any of the ingredients in Dapagliflozin And Metformin XR. See the end of this Medication Guide for a list of ingredients in Dapagliflozin and Metformin XR. Symptoms of a serious allergic reaction to Dapagliflozin and Metformin XR may include: skin rash raised red patches on your skin (hives) swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing

If you have any of these symptoms, stop taking Dapagliflozin and Metformin XR and contact your healthcare provider or go to the nearest hospital emergency room right away. Have conditions called metabolic acidosis or diabetic ketoacidosis (increased ketones in your blood or urine).

Warning and precaution

Lactic Acidosis. Metformin, one of the medicines in Dapagliflozin and Metformin XR, can cause a rare but serious condition called lactic acidosis (a build-up of an acid in the blood) that can cause death. Lactic acidosis is a medical emergency and must be treated in the hospital.

Call your doctor right away if you have any of the following symptoms, which could be signs of lactic acidosis:

- you feel cold in your hands or feet
- you feel dizzy or lightheaded
- you have a slow or irregular heartbeat
- you feel very weak or tired
- you have unusual (not normal) muscle pain
- you have trouble breathing
- you feel unusual sleepiness or sleep longer than usual
- you have stomach pains, nausea or vomiting

Other medicines with Dapagliflozin and Metformin XR

Dapagliflozin and Metformin XR may affect the way other medicines work and other medicines may affect the way Dapagliflozin and Metformin XR works. Especially tell your healthcare provider if you take:

- Water pills (diuretics)
- Rifampin (used to treat or prevent tuberculosis)
- Phenytoin or phenobarbital (used to control seizures)
- Ritonavir (used to treat HIV infections)
- Digoxin (used to treat heart problems)

Ask your healthcare provider for a list of these medicines if you are not sure if your medicine is listed above.

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

3. HOW TO TAKE DAPZIN 10-M PLUS

Take Dapagliflozin and Metformin XR exactly as your healthcare provider tells you to take it.

Do not change your dose of Dapagliflozin And Metformin XR without talking to your healthcare provider.

Take Dapagliflozin and Metformin XR by mouth 1 time each day with meals to lower your chance of an upset stomach. Talk to your healthcare provider about the best time of day for you.

Swallow Dapagliflozin and Metformin XR whole. Do not crush, cut, or chew Dapagliflozin and Metformin XR.

You may sometimes pass a soft mass in your stools (bowel movement) that looks like Dapagliflozin and Metformin XR tablets.

When your body is under some types of stress, such as fever, trauma (such as a car accident), infection, or surgery, the amount of diabetes medicine you need may change. Tell your healthcare provider right away if you have any of these conditions and follow your healthcare provider's instructions.

Stay on your prescribed diet and exercise program while taking Dapagliflozin and Metformin XR.

Your healthcare provider may do certain blood tests before you start Dapagliflozin and Metformin XR and during your treatment.

Your healthcare provider will check your diabetes with regular blood tests, including your blood sugar levels and your A1C.

Follow your healthcare provider's instructions for treating low blood sugar (Hypoglycemia). Talk to your healthcare provider if low blood sugar is a problem for you.

If you miss a dose of Dapagliflozin and Metformin XR, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at the next regularly scheduled time.

If you take too much Dapagliflozin and Metformin XR, call your healthcare provider or go to the nearest hospital emergency room right away.

4. POSSIBLE SIDE EFFECTS

Dapagliflozin and Metformin XR may cause serious side effects including:

See "What is the most important information I should know about Dapagliflozin and Metformin XR?"

- Dehydration. Dapagliflozin and metformin XR can cause some people to become dehydrated (the loss of body water and salt). Dehydration may cause you to feel dizzy, faint, lightheaded, or weak, especially when you stand up (orthostatic hypotension).
- You may be at a higher risk of dehydration if you:
 - Have low blood pressure
 - Take medicines to lower your blood pressure, including water pills (diuretics)
 - Are 65 years of age or older
 - Are on a low salt diet
 - Have kidney problems

Talk to your doctor about what you can do to prevent dehydration including how much fluid you should drink on a daily basis.

Ketoacidosis (increased ketones in your blood or urine). Ketoacidosis has happened in people who have type 1 diabetes or type 2 diabetes, during treatment with dapagliflozin, one of the medicines in Dapagliflozin And Metformin XR. Ketoacidosis is a serious condition, which may need to be treated in a hospital. Ketoacidosis may lead to death. Ketoacidosis can happen with Dapagliflozin and Metformin XR even if your blood sugar is less than 250 mg/dL. Stop taking Dapagliflozin and Metformin XR and call your doctor right away if you get any of the following symptoms:

- Nausea
- Vomiting
- Stomach area (abdominal) pain
- Tiredness
- Trouble breathing

If you get any of these symptoms during treatment with Dapagliflozin and Metformin XR, if possible check for ketones in your urine, even if your blood sugar is less than 250 mg/dL. Kidney problems. Sudden kidney injury has happened to people taking Dapagliflozin and Metformin XR. Talk to your doctor right away if you: reduce the amount of food or liquid you drink for example, if you are sick and cannot eat or you start to lose liquids from your body for example, from vomiting, diarrhea or being in the sun too long. Serious urinary tract infections. Serious urinary tract infections that may lead to hospitalization have happened in people who are taking dapagliflozin, one of the medicines in Dapagliflozin and Metformin XR. Tell your doctor if you have any signs or symptoms of a urinary tract infection such as a burning feeling when passing urine, a need to urinate often, the need to urinate right away, pain in the lower part of your stomach (pelvis), or blood in the urine. Sometimes people also may have a fever, back pain, nausea or vomiting.

Low blood sugar (hypoglycemia). If you take Dapagliflozin And Metformin XR with another medicine that can cause low blood sugar, such as sulfonylureas or insulin, your risk of getting low blood sugar is higher. The dose of your sulfonylurea medicine or insulin may need to be lowered while you take dapagliflozin and metformin XR. Signs and symptoms of low blood sugar may include:

- Headache
- Shaking or feeling jittery
- Dizziness
- Weakness
- Sweating
- Fast heartbeat
- Confusion
- Drowsiness
- Irritability
- Hunger

Low vitamin B12 (vitamin B12 deficiency). Using metformin for long periods of time may cause a decrease in the amount of vitamin B 12 in your blood, especially if you have had low vitamin B 12 levels before. Your healthcare provider may do blood tests to check your vitamin B 12 levels.

Vaginal yeast infection. Women who take Dapagliflozin and Metformin XR may get vaginal yeast infections. Symptoms of a vaginal yeast infection include:

Vaginal odor

White or yellowish vaginal discharge (discharge may be lumpy or look like cottage cheese)

Vaginal itching

Yeast infection of the penis (balanitis). Men who take Dapagliflozin and Metformin XR may get a yeast infection of the skin around the penis. Certain men who are not circumcised may have swelling of the penis that makes it difficult to pull back the skin around the tip of the penis. Other symptoms of yeast infection of the penis include:

- Redness, itching, or swelling of the penis
- Rash of the penis
- Foul smelling discharge from the penis
- Pain in the skin around the penis

Talk to your healthcare provider about what to do if you get symptoms of a yeast infection of the vagina or penis. Your healthcare provider may suggest you use an over-the-counter antifungal medicine. Talk to your healthcare provider right away if you use an over-the-counter antifungal medication and your symptoms do not go away.

Increased fats in your blood (bad cholesterol or LDL) Bladder cancer. In studies of dapagliflozin in people with diabetes, bladder cancer occurred in a few more people who were taking dapagliflozin than in people who were taking other diabetes medications. There were too few cases to know if bladder cancer was related to dapagliflozin. You should not take Dapagliflozin and Metformin XR if you have bladder cancer. Tell your healthcare provider right away if you have any of the following symptoms:

Blood or a red color in your urine

Pain while you urinate

The most common side effects of Dapagliflozin and Metformin XR include:

- Vaginal yeast infections and yeast infections of the penis
- Stuffy or runny nose and sore throat
- Diarrhea
- Nausea and vomiting
- Headache

5. HOW TO STORE DAPZIN 10-M PLUS

Keep this medicine out of the sight and reach of children.

Does not use after the expiry date, which is stated on the carton. The expiry date refers to the last day of that month.

This medicinal product 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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What DAPZIN 10-M PLUS contains

Active ingredients: Dapagliflozin and metformin hydrochloride

Inactive ingredients: Microcrystal line Cellulose; Anhydrous Lactose; Crospovidone; Polysorbate 80; Microcrystalline Cellulose; Colloidal silicon dioxide; Ferric Oxide Yellow/ Yellow Iron Oxide; Povidone K-30; Glyceryl Behenate; Hydroxy Propyl Methyl Cellulose 100 M Premium; Hydroxy Propyl Methyl Cellulose 200M Premium; Magnesium Stearate; Talc; Polyethylene glycol; Opadry Yellow 85F520254.

What DAPZIN M 10 PLUS looks like and contents of the pack

Yellow to dark yellow colored oval shaped, beveled edge, biconvex, film coated tablets debossed with "DM4" on one face and plain on other face.

Blister pack of 10's

Manufacturer

MICRO LABS LIMITED

92, Sipcot Industrial Complex.

Hosur – 635 126

India

Marketing Authorisation Holder

MICRO LABS LIMITED

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Bangalore-560001

INDIA

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