

PATIENT INFORMATION LEAFLET

Dapagliflozin and Metformin Hydrochloride Extended-Release Tablets
(5/500, 5/1000, 10/500 and 10/1000 mg)

OZIN M XR 5/500, 5/1000, 10/500 and 10/1000

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What OZIN M XR is and what it is used for
2. What you need to know before you take OZIN M XR
3. How to take OZIN M XR
4. Possible side effects
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6. Contents of the pack and other information

1. What OZIN M XR is and what it is used for

OZIN M XR contains active substances Dapagliflozin and Metformin Hydrochloride. OZIN M XR is used in the treatment of Type 2 diabetes when treatment with either Dapagliflozin and Metformin has not controlled your blood sugar.

2. What you need to know before you take OZIN M XR

Do not take OZIN M 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 OZIN M XR.

Warnings and Precautions

Lactic Acidosis: Metformin, one of the medicines in OZIN M XR, can cause a rare but serious condition called lactic acidosis that can cause death.

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

Pregnancy and lactation: There are no data from the use of OZIN M XR similar product in pregnant women. Studies in rats treated with dapagliflozin have shown toxicity to the developing kidney in the time period corresponding to the second and third trimesters of human pregnancy. Therefore, the use of this OZIN M XR is not recommended during the second and third trimesters of pregnancy.

When the patient plans to become pregnant, and during pregnancy, it is

recommended that diabetes is not treated with this medicinal product due to the risk of malformations of the foetus associated with abnormal blood glucose levels.

OZIN M XR is not recommended to be used while breast-feeding.

Other medicines with OZIN M XR

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)

Effects on ability to drive and use machines

OZIN M XR has no or negligible influence on the ability to drive and use machines. Patients should be alerted to the risk of hypoglycemia when this medicinal product is used in combination with other glucose-lowering medicinal products known to cause hypoglycemia.

3. How to take OZIN M XR

- ❖ Take OZIN M XR exactly as your doctor tells you to take it.
- ❖ Your doctor will tell you how much OZIN M XR tablets to take and when to take it. Your doctor may change your dose if needed.
- ❖ Do not change your dose of OZIN M XR without talking to your healthcare provider.
- ❖ Take OZIN M XR by mouth 1 time each day with meals to lower your chance of an upset stomach. If you miss a dose, take it as soon as you remember. If it is close to your next dose, do not take the missed dose. Take the next dose at your regular time.
- ❖ Swallow OZIN M XR whole. Do not crush, cut, or chew OZIN M XR. You may sometimes pass a soft mass in your stools (bowel movement) that looks like OZIN M XR tablets.
- ❖ If you take too much OZIN M XR, call your doctor or go to the nearest hospital emergency room right away.

4. Possible side effects

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

Elderly patients may experience more side effects due to a reduced immune defense.

Dehydration: OZIN M XR can cause some people to become dehydrated. Dehydration may cause you to feel dizzy, faint, lightheaded, or weak, or orthostatic hypotension.

Ketoacidosis: Ketoacidosis can happen with OZIN M XR even if your blood sugar is less than 250 mg/dL. Stop taking OZIN M XR and call your doctor right away if you get any of the following symptoms:

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

Kidney problems: Sudden kidney injury has happened to people taking OZIN M 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 OZIN M XR.

Low blood sugar (hypoglycemia). If you take OZIN M 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 OZIN M XR.

Vaginal yeast infection: Women who take OZIN M XR may get vaginal yeast infections.

Vitamin B12 Deficiency: Metformin may lower vitamin B12 levels.

Yeast infection of the penis (balanitis): Men who take OZIN M 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.

These are not all the possible side effects of OZIN M XR. Tell your doctor if you have any side effect that bothers you or that does not go away.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

If you forget to take OZIN M XR

It is advisable to take your medicine at the same time each day. However, if you forget to take a dose, you should simply take the next one at the scheduled time. Do not take a double dose to make up for a forgotten dose.

If you stop taking OZIN M XR

Stopping your treatment with OZIN M XR may cause your condition to get worse. Do not stop taking your medicine unless your doctor tells you to. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

5. How to store OZIN M XR

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

Do not use OZIN M XR after the expiry date stated on the strip and the carton after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture. Store below 30°C.

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 OZIN M XR contains

The active substances of OZIN M XR are Dapagliflozin and Metformin Hydrochloride.

OZIN M XR 5/500

Each film coated tablet contains:

Dapagliflozin Propanediol Monohydrate equivalent to Dapagliflozin 5 mg

Metformin Hydrochloride IP (Extended Release) 500 mg

Colours: Sunset Yellow Lake & Titanium Dioxide

OZIN M XR 5/1000

Each film coated tablet contains:

Dapagliflozin Propanediol Monohydrate equivalent to Dapagliflozin 5 mg

Metformin Hydrochloride IP (Extended Release) 1000 mg

Colours: Black & Titanium Dioxide

OZIN M XR 10/500

Each film coated tablet contains:

Dapagliflozin Propanediol Monohydrate equivalent to Dapagliflozin 10 mg

Metformin Hydrochloride IP (Extended Release) 500 mg

Colours: Iron Oxide Red & Titanium Dioxide

OZIN M XR 10/1000

Each film coated tablet contains:

Dapagliflozin Propanediol Monohydrate equivalent to Dapagliflozin 10 mg

Metformin Hydrochloride IP (Extended Release) 1000 mg

Colours: Iron Oxide Yellow & Titanium Dioxide

What OZIN M XR looks like and contents of the pack

OZIN M XR 5/500 tablets are orange colored, oval, biconvex, film coated tablets. Tablets are packed into Alu-Alu Blister. The pack size is 10 X 10 tablets in a printed paper carton with packing insert.

OZIN M XR 5/1000 tablets are gray colored, oval, biconvex, film coated tablets. Tablets are packed into Alu-Alu Blister. The pack size is 10 X 10 tablets in a printed paper carton with packing insert.

OZIN M XR 10/500 tablets are red colored, oval, biconvex, film coated tablets. Tablets are packed into Alu-Alu Blister. The pack size is 10 X 10 tablets in a printed paper carton with packing insert.

OZIN M XR 10/1000 tablets are yellow colored, oval, biconvex, film coated tablets. Tablets are packed into Alu-Alu Blister. The pack size is 10 X 10 tablets in a printed paper carton with packing insert.



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