

**PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

**Dippo 5 MG
Film-coated Tablets**

**Dippo 10 MG
Film-coated Tablets**

Composition:

Each tablet contains:
Dapagliflozin 5 mg

Each tablet contains:
Dapagliflozin 10 mg

For the list of inactive and allergenic ingredients in the preparation, see in section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Type 2 diabetes mellitus

Dippo is administered to adults aged 18 years and older for the treatment of insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise

- as monotherapy in case of metformin intolerance.
- in addition to other medicines for the treatment of type 2 diabetes.

Heart failure

Dippo is administered for the treatment of adults with symptomatic chronic heart failure.

Chronic kidney disease

Dippo is administered for the treatment of adults with chronic kidney disease.

Therapeutic group

SGLT2 (sodium-glucose co-transporter 2) inhibitors

2. BEFORE USING THE MEDICINE

Do not use Dippo if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (see in section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information").

Special warnings regarding use of the medicine

Refer to the doctor or to the closest hospital immediately

Diabetic ketoacidosis

- If you suffer from diabetes and experience nausea or vomiting, stomach pains, increased thirst, fast and deep breathing, confusion, unusual sleepiness or tiredness, a sweet smell to your breath, a sweet or metallic taste in the mouth, a different odor to your urine or sweat or rapid weight loss.
- The above symptoms could be a sign of diabetic ketoacidosis – a rare but serious, sometimes life-threatening problem you can get with diabetes due to increased levels of ketones 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 dosage, or a higher need for insulin due to serious illness or surgery.
- When you are treated with **Dippo**, diabetic ketoacidosis may occur even if your blood sugar level is normal.

If you suspect that you have diabetic ketoacidosis, contact a doctor or the nearest hospital immediately and stop using the medicine.

Necrotising fasciitis of the perineum

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

Before treatment with Dippo, tell the doctor, pharmacist or nurse if:

- you suffer from "type 1 diabetes" – the type that usually starts when you are young, and your body does not produce insulin. Do not use **Dippo** to treat this condition.
- you suffer from diabetes and a kidney problem – the doctor may tell you to take a different or additional medicine to treat your blood sugar level.
- you suffer from a liver function problem – the doctor may tell you to start with a lower dosage.
- you are receiving medicinal treatment to lower your blood pressure and you have a history of low blood pressure. Additional information is given below in section "Drug interactions".
- you suffer from very high levels of blood glucose, which may lead to dehydration (too much body fluid loss). Possible signs of dehydration are listed in section 4 "Side effects". Before starting treatment with **Dippo**, please tell your doctor if you have any of these signs.
- you suffer from or developed nausea, vomiting or fever, or you are unable to eat or drink. These conditions can cause dehydration. To prevent dehydration, the doctor may instruct you to stop taking **Dippo** until you recover.
- you often suffer from urinary tract infections.

If any of the above apply to you or you are unsure, refer to the doctor, pharmacist or nurse before taking **Dippo**.

Diabetes and foot care

If you suffer from diabetes, it is important to check your feet regularly and adhere to the additional medical recommendations given regarding foot care.

Urine sugar (glucose)

Because of how **Dippo** works, urine tests will show a positive result for sugar (glucose) while you are taking the medicine.

Children and adolescents

There is no information regarding the safety and efficacy of use of this preparation in children and adolescents.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:

- a diuretic, to remove fluids from the body.
- other medicines to lower the blood sugar level, such as insulin or a sulphonylurea medicine. The doctor may instruct you to lower the dosage of these medicines, to prevent you from reaching low blood sugar levels (hypoglycemia).
- lithium, because **Dippo** may lower the amount of lithium in your blood.

Use of the medicine and food

The medicine can be taken with or without food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, refer to the doctor or pharmacist before taking **Dippo**.

Stop taking the medicine if you are pregnant, since the medicine is not recommended during the second and third trimesters of pregnancy. Consult the doctor about the best way to treat and control your blood sugar level during pregnancy.

If you are breastfeeding or plan to breastfeed, consult the doctor before taking **Dippo**.

Do not use **Dippo** if you are breastfeeding. It is not known if the medicine passes into breast milk.

Driving and operating machinery

Dippo has no or a negligible influence on the ability to drive or operate machinery. Taking the medicine with other medicines – sulphonylureas or insulin – might cause blood sugar levels to be too low (hypoglycemia), which may cause symptoms such as shaking, sweating and changes in vision, and

may affect the ability to drive and operate machinery. If you feel dizzy while taking **Dippo**, do not drive or operate any machinery or tools.

Important information about some of the ingredients of the medicine

Dippo contains lactose. If you have been told by the doctor that you have an intolerance to certain types of sugar, consult the doctor before taking this medicine.

3. HOW SHOULD THE MEDICINE BE USED?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage

- The recommended dosage is usually one 10 mg tablet per day.
- If you have impaired liver function, the doctor may prescribe a 5 mg tablet.
- The doctor will prescribe the dosage that is right for you.

Do not exceed the recommended dose.

Method of administration

- Swallow the tablet with half a glass of water.
- If needed, to make swallowing easier, the tablet can be halved for immediate use. Swallow the two halves together immediately after halving.
- There is no information regarding crushing and chewing the tablet.
- The tablet can be taken with or without food.
- The tablet can be taken at any time of the day; however, try to take it at the same time each day. This will help you remember to take the medicine.

The doctor can prescribe **Dippo** together with other medicines. Remember to take the other medicines that the doctor has prescribed. This will help get the best results for your health.

Diet and exercise

Diet and exercise can help your body balance blood sugar levels. If you have diabetes, it is important to stay on any diet and exercise program recommended by your doctor while taking **Dippo**.

If you accidentally took a higher dosage of Dippo

If you took an overdose of **Dippo**, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forgot to take Dippo

If you forgot to take a tablet at the scheduled time, it depends how much time is left until the next dose.

- If it is 12 hours or more until the next dose, take a dose of **Dippo** soon after you remember and then take the next dose at the usual time.

- If it is less than 12 hours until the next dose, do not take the forgotten dose. Take the next dose at the usual time.
- Do not take a double dose of **Dippo** to make up for a forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

If you stop taking Dippo

Do not stop treatment with **Dippo** without consulting the doctor. If you have diabetes, your blood sugar level may increase without the medicine.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Dippo** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Refer to a doctor or the nearest hospital immediately if you notice any of the following side effects:

- **Angioedema** – a very rare side effect (an effect that occurs in less than one user in 10,000). Signs of angioedema:
 - swelling of the face, tongue or throat
 - difficulties swallowing
 - hives and breathing difficulties
- **Diabetic ketoacidosis** – occurs rarely **in patients with type 2 diabetes mellitus** (occurs in 1-10 in 10,000 users). These are the signs of diabetic ketoacidosis (see in section 2 “Special warnings regarding use of the medicine”):
 - high levels of ketones in your urine or blood
 - nausea or vomiting
 - stomach pains
 - increased thirst
 - fast and deep breathing
 - confusion
 - unusual sleepiness or tiredness
 - a sweet smell to your breath, a sweet or metallic taste in the mouth or a different odor to your urine or sweat
 - rapid weight loss

This effect may occur regardless of your blood sugar (glucose) levels. The doctor may decide to temporarily or permanently stop your treatment with **Dippo**.

- **Infections of the genital area (Fournier’s gangrene/necrotising fasciitis of the perineum)**

A serious soft tissue infection of the genitals or the area between the genitals and the anus – a very rare effect.

Stop treatment with Dippo and refer to a doctor as soon as possible if you notice any of the following serious side effects:

- **Urinary tract infection**, common effect (an effect that occurs in 1-10 in 100 users).

Signs of a severe infection of the urinary tract:

- fever and/or chills
- burning sensation when urinating
- pain in the back or sides

Although the effect is uncommon, if you notice blood in the urine, please report to the doctor immediately.

Refer to the doctor as soon as possible if you notice any of the following side effects:

- **Low blood sugar level (hypoglycemia)** – a side effect that occurs very often (effect that occurs in more than one user in ten) in patients with diabetes taking **Dippo** with another drug from the sulphonylurea group or with insulin.

Signs of low blood sugar level:

- shaking, sweating, feeling very anxious, fast heart rate
- feeling hungry, headache, changes in vision
- mood change or feeling confused

The doctor will tell you how to treat low blood sugar levels (hypoglycemia) and what to do if you get any of the signs listed above.

Other side effects when taking Dippo:

Common side effects – effects that occur in 1-10 in 100 users:

- genital infection (thrush) of the vagina or penis (signs may include irritation, itching, unusual discharge or odor)
- back pain
- passing more urine than usual or needing to pass urine more often
- change in the level of cholesterol or fats in the blood (seen in tests)
- increase in the amount of red blood cells in the blood (seen in tests)
- decrease in renal creatinine clearance (seen in tests) in the beginning of treatment
- dizziness
- rash

Uncommon side effects – effects that occur in 1-10 in 1,000 users:

- excessive loss of body fluids (dehydration; signs may include: very dry mouth or stickiness in the mouth, passing little or no urine, fast heart rate)
- thirst
- constipation
- nocturia
- dry mouth
- weight loss
- increase in creatinine (seen in blood tests) in the beginning of the treatment
- increase in urea levels (seen in blood tests)

Very rare side effects – effects that occur in less than 1 in 10,000 users:

- inflammation of the kidneys (tubulointerstitial nephritis)

If a side effect occurs, if one of the side effects worsens, or if you suffer from side effects not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "[Report Side Effects of Drug Treatment](#)" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>. Additionally, you can report to "[Unipharm Ltd.](#)".

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C, in a place protected from light.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Dippo 5 MG:

Microcrystalline cellulose, Lactose anhydrous, Crospovidone, White coating blend (Hypromellose, Titanium dioxide, Polyethylene glycol), Colloidal silicon dioxide, Magnesium stearate.

Dippo 10 MG:

Microcrystalline cellulose, Lactose anhydrous, Crospovidone, Orange coating blend (Hypromellose, Titanium dioxide, Polyethylene glycol, Sunset yellow FCF aluminum lake), Colloidal silicon dioxide, Magnesium stearate.

Each **Dippo 5 MG** tablet contains 25 mg lactose.

Each **Dippo 10 MG** tablet contains 50 mg lactose.

What does the medicine look like and what are the contents of the package?

Dippo 5 MG: Round, film-coated, biconvex, white tablets with a break line.

Dippo 10 MG : Round, film-coated, biconvex, orange tablets with a break line.

Dippo is packaged in trays (blister) which are inserted in a carton package. There are package sizes of 28, 30, 56 and 60 tablets. Not all package sizes may be marketed.

Registration holder and address: Unipharm Ltd., P.O. Box 16545, Tel Aviv, 6116401.

Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Dippo 5 MG: 180 31 37708 99

Dippo 10 MG: 180 32 37709 99

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