



SK PHARMA LTD

ORA-5 Patient Information Leaflet

Read this leaflet before using this product. Keep it for reference and ask your doctor or pharmacist if you have questions. Do not share a prescribed medicine with another person.

1 What this product contains and is used for

Composition: Dapagliflozin 5mg

Therapeutic class: SGLT2 inhibitor. Oral glucose-lowering medicine.

Uses: Type 2 diabetes mellitus.

2 Before using this product

Do not use if you are allergic to an active ingredient or any other ingredient. Get emergency help for difficulty breathing, collapse or swelling of the face, lips, tongue or throat.

Tell your doctor about kidney problems, dehydration or repeated genital infections. Ask for a sick-day and surgery plan. This medicine is not a substitute for insulin.

Other medicines: Diuretics can increase dehydration. Insulin or sulfonylureas may increase low-blood-sugar risk.

Pregnancy and breastfeeding: ask a clinician before use if you are pregnant, planning pregnancy or breastfeeding. The advice depends on this product and your condition.

3 How to use this product

Use exactly as directed by your doctor or pharmacist. The prescribed amount, frequency and treatment duration depend on the diagnosis, age, kidney or liver function and other medicines.

Missed dose: ask your pharmacist for the product-specific rule. Do not take an extra dose automatically; some medicines have special missed-dose instructions.

Too much: seek urgent medical advice or emergency care and take the container with you. Do not wait for symptoms or induce vomiting.



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4 Possible side effects

Not everyone develops side effects. Effects listed here are a concise selection; the final product label must include the complete medicine-specific information.

Possible effects: Genital fungal infections, increased urination and dehydration.

When to get help: Nausea, abdominal pain, rapid breathing or unusual sleepiness may indicate ketoacidosis, even without very high blood sugar. Seek urgent care. Severe pain or swelling around the genitals also needs urgent care.

Get emergency help for a severe allergic reaction. Contact your doctor or pharmacist for troublesome or persistent symptoms. Report suspected reactions to SK Pharma with the product name, batch number, dates of use and symptoms.

5 Storage and safe disposal

Keep out of the sight and reach of children. Store in the original closed container and follow the temperature and light-protection conditions printed on the pack. Do not use after the expiry date or if the seal is damaged.

An expiry date on a label does not establish the period allowed after opening. Ask your pharmacist about the approved after-opening period and disposal of unused product. Do not discard medicines in household wastewater.

6 Presentation and ingredients

Brand: ORA-5. Presentation: 1x10 Tablets.

Active ingredients: Dapagliflozin 5mg.

Other ingredients: the full excipient list, including any sugar, alcohol, allergens, preservatives and capsule-shell components, must be completed from the approved SK Pharma formula.

7 Manufacturer and contact details

SK Pharma Ltd

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