



SK PHARMA LTD

Debi 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: Dabigatran 75mg

Therapeutic class: Direct thrombin inhibitor. Oral anticoagulant.

Uses: Prevention of stroke in eligible patients with atrial fibrillation.

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.

Do not use with active significant bleeding. Tell your doctor about kidney or liver problems, ulcers, recent surgery or a mechanical heart valve. Do not stop treatment without advice.

Other medicines: Other anticoagulants, antiplatelets, anti-inflammatory painkillers and some antifungal or antiviral medicines can increase bleeding 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

Swallow the capsule whole with water. Do not open, chew or crush a dabigatran capsule; this can increase exposure and bleeding risk. Follow the individualized prescription.

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: Bruising, bleeding and stomach upset.

When to get help: Uncontrolled bleeding, black stools, vomiting blood, severe headache or a head injury need urgent assessment.

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: Debi. Presentation: 2x10 Capsules.

Active ingredients: Dabigatran 75mg.

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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