



### PATIENT ALERT CARD

Dabigatran Etexilate hard capsules  
Dabigatran Etexilate

- This card should be with you / the caregiver at all times
- Make sure to use the latest version

October 2024

**Dear Patient/Caregiver of a paediatric patient,**

Your / your child's doctor has initiated treatment with Dabigatran Etexilate hard capsules. In order to use Dabigatran Etexilate hard capsules safely, please consider the important information in the package leaflet.

As this patient alert card contains important information about your / your child's treatment, this card should be with you or your child at all times to inform healthcare professionals about your / your child's intake of Dabigatran Etexilate hard capsules.

## Dabigatran Etexilate hard capsules Information for Patients / Caregivers of paediatric patients

About your / your child's treatment

- Dabigatran Etexilate hard capsules thin the blood. It is used to treat existing blood clots or to prevent the formation of dangerous blood clots.
- Follow your/ your child's doctor's instructions when taking Dabigatran Etexilate hard capsules. Never skip a dose or stop the intake of Dabigatran Etexilate hard capsules without talking to your / your child's doctor.
- Inform your / your child's doctor about all medicines you / your child is currently taking.
- Inform your / your child's doctor about the intake of Dabigatran Etexilate hard capsules before any surgery / invasive procedure.
- Dabigatran Etexilate hard capsules can be taken with or without food. The capsule should be swallowed whole with a glass of water. The capsule must not be broken or chewed, and the pellets must not be emptied from the capsule.

### When to seek medical advice

- Taking Dabigatran Etexilate hard capsules may increase the risk of bleeding. Speak to your / your child's doctor immediately if you / your child experiences any signs and symptoms of bleeding such as: swelling, discomfort, unusual pain or headache, dizziness, paleness, weakness, unusual bruising, nosebleeds, bleeding of gums, unusually long bleeding cuts, abnormal menstrual flow or vaginal bleeding, blood in the urine which may be pink or brown, red/black stools, coughing up blood, vomiting blood or coffee ground like material.
- In case of fall or injury, especially if the head is hit, urgently seek medical advice.
- Do not stop intake of Dabigatran Etexilate hard capsules without talking to your/your child's doctor, if you / your child experience(s) heartburn, nausea, vomiting, stomach discomfort, bloating or upper abdominal pain.

**Dabigatran Etexilate hard capsules**  
**Information for Healthcare Professionals**

- Dabigatran Etexilate hard capsules is an oral anticoagulant (direct thrombin inhibitor).
- Dabigatran Etexilate hard capsules may need to be stopped in advance of surgical or other invasive procedures.
- In case of major bleeding events, Dabigatran Etexilate hard capsules must be stopped immediately.
- A specific reversal agent (idarucizumab) is available for adult patients. The efficacy and safety of the specific reversal agent idarucizumab have not been established in paediatric patients.

- For details and more advice to antagonise the anticoagulant effect of Dabigatran Etexilate hard capsules please refer to the Summary of Product Characteristics of Dabigatran Etexilate hard capsules and idarucizumab.
- Dabigatran Etexilate hard capsules is mainly eliminated by the kidneys; adequate diuresis must be maintained. Dabigatran Etexilate hard capsule is dialyzable.

**Please complete this section or ask your/  
your child's doctor to do it.**

## Patient Information

**Name of the patient**

**Date of Birth**

### Indication of anticoagulation

### **Dose of Dabigatran Etxilate hard capsules**

418754  
BPCM0294/01

## ARTWORK DETAILS

NAME OF THE PRODUCT		Dabigatran Etxelilate Hard Capsules		COMPONENT		Patient Alert Card	
MFG. SITE		Galenicum Health, S.L.U.		DIMENSIONS		85 x 440 mm	
CUSTOMER / PARTNER		Biocon Pharma UK Limited		DESIGN / STYLE		NA	
COUNTRY		UK		PANTONE COLOURS		<div style="display: inline-block; width: 20px; height: 10px; background-color: black; vertical-align: middle;"></div> Black	
PACK		NA		FONTS		Times New Roman	
ARTWORK CODE		BPCM0294/01		MINIMUM FONT SIZE		12 Points	
PHARMA CODE		1601		BAR CODE		NA	
SPECIFICATIONS		As per CMO site requirement.					
CHANGE CONTROL REFERENCE NO.		83843					
SPECIAL INSTRUCTIONS (IF ANY)		Magenta color to be referred for DIE key line, instructions are not to be considered for printing					
Artwork Reviewed and Approved by							
	Artwork Designed by	Packaging Development	Marketing	PV / Medical	Regulatory	QA	
(Sign. & Date)							
NAME							