

Updated 9 March 2017

## Pradaxa® (dabigatran etexilate)

### Pradaxa capsule colour change and removal of sunset yellow (E110)

Boehringer Ingelheim have changed the capsule colour for Pradaxa® (dabigatran etexilate) 75mg, 110mg and 150mg hard capsules in the UK and Ireland.


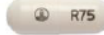




This change is part of a worldwide harmonisation of Pradaxa capsule colours according to dosage strength, so that the different strengths will be more clearly distinguishable by capsule colour. Currently, all three strengths of Pradaxa capsules have a light blue, opaque cap and cream-coloured, opaque body, and are differentiated only by capsule size and imprint.

We have also removed the colorant sunset yellow (E110), which may cause allergic reactions.

This colour change does not impact the efficacy and safety profile of dabigatran.

Table 1, below, shows the current (old) and new appearance of Pradaxa capsules.

**Table 1.** Current (old) and new appearance of Pradaxa capsules

Strength	Capsule Size	Old appearance	New appearance
75mg	2	 <p>Light blue, opaque cap and cream-coloured, opaque body. The cap is imprinted with the Boehringer Ingelheim company symbol, the body with "R75".</p>	 <p>White, opaque cap and body. The cap is imprinted with the Boehringer Ingelheim company symbol, the body with "R75".</p>
110mg	1	 <p>Light blue, opaque cap and cream-coloured, opaque body. The cap is imprinted with the Boehringer Ingelheim company symbol, the body with "R110".</p>	 <p>Light blue, opaque cap and body. The cap is imprinted with the Boehringer Ingelheim company symbol, the body with "R110".</p>
150mg	0	 <p>Light blue, opaque cap and cream-coloured, opaque body. The cap is imprinted with the Boehringer Ingelheim company symbol, the body with "R150".</p>	 <p>Light blue, opaque cap and white, opaque body. The cap is imprinted with the Boehringer Ingelheim company symbol, the body with "R150".</p>

Stock of the new formulation will be available from 7<sup>th</sup> March 2017.

Please be aware that as the old coloured capsules are phased out, patients may receive a combination of both the old and new colour capsules. Patients should continue to take their Pradaxa capsules as advised.

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A patient information card to help explain this change to patients is being prepared. A supply of these cards can be obtained from a Boehringer Ingelheim representative or by contacting Medical Information.

The Pradaxa Summary of Product Characteristics (SPC) are currently still in the process of being updated. However, the Patient Information Leaflet (PIL) provided in each pack of Pradaxa capsules has been updated to reflect the change in appearance and removal of the colorant sunset yellow (E110).