24 January 2023
EMA/660805/2022
EMEA/H/C/004891

Public statement

Darunavir Krka d.d. (darunavir)

Expiry of the marketing authorisation in the European Union

The marketing authorisation for Darunavir Krka d.d. (darunavir) expired on 22 January 2023 following the decision of the marketing authorisation holder, KRKA, d.d., Novo mesto, not to apply for a renewal of the marketing authorisation.

KRKA, d.d., Novo mesto confirmed that it did not apply for renewal of the authorisation due to commercial reasons.

Darunavir Krka d.d. was granted marketing authorisation in the European Union (EU) on 18 January 2018 for use with other human immunodeficiency virus (HIV) medicines to treat patients with HIV-1, a virus that causes acquired immune deficiency syndrome (AIDS). It was given with low-dose ritonavir or, in adults, with cobicistat. Darunavir Krka d.d. could be given to adults or children from 3 years of age and weighing at least 15 kg.

The marketing authorisation was valid for a 5-year period.

Darunavir Krka d.d. is a generic medicine of Prezista.

The European Public Assessment Report (EPAR) for Darunavir Krka d.d. will be updated to indicate that the marketing authorisation is no longer valid.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union