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Organon Announces MHRA Approval Extending Duration of Use of NEXPLANON® (etonogestrel implant) 68 mg Radiopaque to Five Years

London, United Kingdom. – 21 May 2026 – Global women’s healthcare company, Organon, announced today that the UK’s Medical Healthcare products Regulatory Agency (MHRA) has approved an extension of the labelled duration of use for NEXPLANON® (etonogestrel). The contraceptive implant, indicated for prevention of pregnancy in women of reproductive potential, is now approved for up to five years, extending its previous three-year indication. The updated license also confirms efficacy across a broader range of body mass index (BMI) values (17.4 to 63.9 kg/m²).¹

During the clinical trial to assess the contraceptive efficacy and safety of extended use (years 4 and 5), no pregnancies were reported and there were no new safety findings.¹ Additionally, the study enrolled women with a range of body mass index (BMI) values (17.4 to 63.9 kg/m²), with 42.1% of them having a BMI ≥30 kg/m².^{1,2}

In the UK, there are over 15 million women of reproductive age (ages 16-49 years)³ and 31% of women aged 16 and over are living with obesity, including severe obesity, defined as a BMI ≥30 kg/m².⁴

The MHRA decision is supported by data from a multicentre, single-arm, open-label clinical trial (NCT04626596) evaluating contraceptive efficacy and safety of continued etonogestrel implant use into years 4 and 5. No pregnancies were reported during the extended-use period, and no new safety were identified.¹ The clinical trial enrolled women across a broad range of BMI values (17.4 to 63.9 kg/m²), with 42.1% having classified as having a BMI ≥30 kg/m². By contrast, earlier clinical trials supporting the three-year indication excluded women weighing more than 130% of their ideal body weight.

“With this label update, we are helping make women’s healthcare more inclusive and comprehensive,” said **Sofia Ferreira, Organon’s Country Lead for UK, Ireland, Portugal and the Nordics**. “This approval reinforces our dedication to ensuring women have access to contraceptive choices that support diverse needs and circumstances. We are proud to deliver innovations that give women greater agency over their reproductive health.”

About the extended-use trial for etonogestrel implant (68 mg Radiopaque)

The contraceptive efficacy of the etonogestrel implant (68 mg Radiopaque) during use from 3 to 5 years was evaluated in a multicentre, single-arm, open-label study (NCT04626596) conducted in the United States. A total of 498 women were evaluated, having a mean age of 27 years, ranging from 18 to 35 years, and having been using the etonogestrel implant for 36 months (± 2 weeks) from the date of insertion at the time of enrolment. Participants were 74.2% White, 16.8% Black/African American, 3.8% Asian, 1.3% American Indian or Alaska Native, 0.5% Native Hawaiian or Other Pacific Islander, and 3.5% multiple or missing races. The mean BMI was 29.6 kg/m² (range: 17.2-64.3 kg/m²), and the mean weight was 79.0 kg (range: 40.8-180.8 kg). One hundred ninety-eight participants (38.1%) had a BMI ≥30 kg/m², including 51 participants (10.2%) with a BMI ≥40 kg/m².

The primary efficacy endpoint was the Pearl Index (PI) at years 4 and 5. No pregnancies were reported during this period, resulting in a PI of 0.0 (95% CI: 0.00, 0.69) pregnancies per 100 women-years of use, and there were no new safety findings.¹

For UK medical and pharmaceutical trade media only

About NEXPLANON® (etonogestrel implant 68 mg Radiopaque)

In the UK, NEXPLANON® (etonogestrel implant 68mg Radiopaque) is indicated for contraception for up to 5 years. Safety and efficacy have been established in women between 18 and 40 years of age.

Before prescribing the etonogestrel implant 68 mg Radiopaque, please read the [Summary of Product Characteristics \(SmPC\)](#). The [Patient Information Leaflet](#) also is available.

About Organon

Organon (NYSE: OGN) is a global healthcare company with a mission to deliver impactful medicines and solutions for a healthier every day. With a portfolio of over 70 products across Women's Health and General Medicines, which includes biosimilars, Organon focuses on addressing health needs that uniquely, disproportionately or differently affect women, while expanding access to essential treatments in over 140 markets.

Headquartered in Jersey City, New Jersey, Organon is committed to advancing access, affordability, and innovation in healthcare. Learn more at www.organon.com/uk.

References

¹ Medicines and Healthcare Products Regulatory Agency. NEXPLANON, 68mg implant for subdermal use. Summary of Product Characteristics. Available at <https://www.medicines.org.uk/emc/product/5720/smpc>. Last accessed May 2026.

² Data available on request from Organon Professional Services-DAP (Marketing Operations), 30 Hudson St., Jersey City, NJ 07302. Please specify information package US-XPL-117854.

³ Office for National Statistics. Estimates of the population for the UK, England, Wales, Scotland, and Northern Ireland. <https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/datasets/populationestimatesforukenglandandwalesscotlandandnorthernireland> Accessed May 2026

⁴ NHS England. Health Survey for England, 2024. <https://digital.nhs.uk/data-and-information/publications/statistical/health-survey-for-england/2024/adults-overweight-and-obesity> Accessed May 2026