

MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-102249-PIP01-25-M01

Scope of the Application

Active Substance(s)

ESTETROL MONOHYDRATE; DROSPIRENONE

Condition(s)

Prevention of pregnancy

Pharmaceutical Form(s)

Film-coated tablet

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Gedeon Richter Plc

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Gedeon Richter Plc submitted to the licensing authority on 09/04/2026 18:11 BST an application for a Modification

The procedure started on 22/04/2026 19:10 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-102249-PIP01-25-M01

Of 02/06/2026 14:05 BST

On the adopted decision for ESTETROL MONOHYDRATE; DROSPIRENONE (MHRA-102249-PIP01-25-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for ESTETROL MONOHYDRATE; DROSPIRENONE, Film-coated tablet , ORAL USE .

This decision is addressed to Gedeon Richter Plc, Gyömrői út 19-21, Budapest, HUNGARY, 1103

ANNEX I

1. Waiver

1.1 Condition:

Prevention of pregnancy. The waiver applies / applied to: Paediatric Subset(s): All male paediatric population from birth to less than 18 years of age and pre-menarche female population. Pharmaceutical form(s): Film-coated tablet Route(s) of administration: ORAL USE Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of pregnancy.

2.2 Indication(s) targeted by the PIP:

Prevention of pregnancy.

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

Girls from menarche to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Film-coated tablet

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	1	Study 1 (MIT-Es001-C303) Open-label, single-arm study to evaluate the safety and pharmacokinetics of the combined oral contraceptive (COC) containing estetrol and drospirenone for 6 cycles of 28 days in post-menarcheal female adolescents from 12 to less than 18 years of age.
Extrapolation, Modeling & Simulation Studies	0	Not applicable
Other Studies	0	Not applicable
Other Measures	0	Not applicable

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	30/03/2024
Deferral of one or more studies contained in the paediatric investigation plan:	Yes

