

Ms Liz Ryburn

8th July 2020

Ref: 01787519

risdiplam

Dear Ms Ryburn,

Thank you for taking the time to contact us in relation to our product in development risdiplam for spinal muscular atrophy (SMA). Your request was forwarded to the Roche Medical Information team by my colleague Jack Robinson. I understand you requested information on risdiplam and its affect on female fertility and menstruation.

Female fertility

- Effects of risdiplam on female fertility have not been assessed in clinical studies in patients.
- A non-clinical rat study showed that risdiplam did not affect female fertility or the number and structure of oocytes (premature egg cells).

Menstruation

- Approximately 20% (n=90) of the patients in clinical studies were of childbearing potential. Adverse events relating to the menstrual cycle were reported in some patients:
 - dysmenorrhea (menstrual pain and cramps; n=35), metrorrhagia (irregular menstrual bleeding; n=3), menstrual disorder (n=1) and amenorrhea (absent menstruation; n=1).
- As determined by the investigators, there was no indication that these events were related to any risdiplam-related safety issues on the menstrual cycle.¹
 - Adverse events resolved with ongoing treatment with risdiplam except for one patient with metrorrhagia, which had not resolved 2 months after onset but was reported as unrelated to risdiplam.
- Risdiplam did not affect menstruation in a non-clinical rat study.

Roche recommends that a healthcare professional should be consulted regarding the medical care of a patient.

Should the doctor require any further information we can provide this to them, on request, if they contact us. Please ask them to contact the Medical Information Team.

Please be advised that Roche cannot provide medical advice for individual cases and the responsibility for prescribing or treatment decisions always resides with the healthcare professional.

Roche is providing this information in response to your enquiry and to assist you in making your own decisions about patient care. We cannot recommend the use of our products for any indication, dosage, or route of administration not covered in the product's licence.

I hope that this information is useful. If you require any further assistance please contact me or a member of the Medical Information team on Freephone 0800 328 1629 or by e-mailing medinfo.uk@roche.com.