<Contact information>
<Address>

cc :

<Date>

Evrysdi® (risdiplam) 0,75 mg/ml pulver til oral opløsning

Kære farmaceut,
Roche vil, efter aftale med Det Europæiske Lægemiddelagentur og Lægemiddelstyrelsen, informere om følgende:

Sammenfatning

- **Der er indrapporteret klager fra et apotek i Tyskland vedrørende uopløselige fremmede partikler i rekonstitueret Evrysdi® 0,75 mg/ml oral opløsning for batches B2033B03 og B2035B09.**
  Den potentielle tilstedeværelse af partikler i andre batches kan ikke udelukkes. Dette inkluderer batches mærket med batchnumre, der starter med et af følgende numre: B2033, B2034, B2035, B2036, B2037, B2038 og B2039. Andre batches er ikke omfattet.
- **Undersøgelse fra markedsføringstilladelsesindehaveren har vist, at disse partikler består af hvid polytetrafluorethylen (PTFE-Teflon). PTFE er et kemisk inaktivt, ikke-toksisk materiale, der forventes at passere uændret gennem mave-tarm-kanalen uden systemisk absorption. Baseret på identifikationen af PTFE partikler, der måler 0,3 mm til 2,7 mm, er den vurderede kliniske risiko for patientpopulationen lav, da tilstedeværelsen af disse små partikler ikke udgør en specific eller forhøjet risiko for patienter med spinal muskelatrofi (SMA), sammenlignet med den generelle risiko forbundet med administration af væske eller mad.**
- **Ingen af de modtagne klager var i denne kontekst forbundet med bivirkninger eller andre uønskede hændelser.**
- **En gennemgang af relevante spontant indberettede bivirkningsdata efter markedsføring viste ingen evidens for kausalitet i forhold til sikkerhedssignaler relateret til denne produktklage. Bivirkningerne, der blev gennemgået, var typiske for denne patientpopulation og svarende til progression af den underliggende sygdom.**

- **En gennemgang af virksomhedens sikkerhedsdatabase i rapporteringsintervallet efter frigivelsen af de omfattede batches samt rutinemæssig signalhåndtering identificerede ingen nye signaler vedrørende gastrointestinal obstruktion, respirationsbesvær, respirationssvigt eller dødelighed.**

Baggrund for sikkerhedsbekymringen

Evrysdi® (risdiplam) er indiceret til behandlingen af 5q spinal muskelatrofi (SMA) i patienter med en klinisk diagnose af SMA type 1, type 2 eller type 3 eller med en til fire SMN2-kopier. Evrysdi® pulver til oral opløsning skal rekonstitueres med renset vand eller vand til injektionsvæsker af en sundhedsperson (f.eks. farmaceut) før udleveringen. Et apotek i Tyskland har identificeret fremmede partikler ved rekonstitution af opløsningen.

De identificerede partikler består af et kemisk inaktivt, ikke-toksisk materiale, der forventes at passere uændret gennem mave-tarm-kanalen uden systemisk absorption.
Under SMA-sygdommens progression er dysfagi en velkendt potentiel tilstand, som kan udgøre kritiske risici for patienterne. Dysfagi håndteres traditionelt proaktivt ved indsættelse af en ernæringssonde for at sikre sikker ernæring og reducere respirationsrisici. I en sådan situation bør lejlighedsvis tilstedeværelse af partikler ikke øge risikoen for patienterne ud over de eksisterende risici ved administration af væsker eller mad.
Alligevel ønsker markedsføringstilladelsesindehaveren, i samarbejde med relevante sundhedsmyndigheder, at give farmaceuter instruktioner med yderligere forholdsregler.

Korrigerende og forebyggende handlinger

Som en forsigtighedsforanstaltning bør farmaceuter gøre følgende:

- Tjek om opløsningen i flasken er klar i henhold til *Vejledning til rekonstitution* trin 5, eller om den indeholder synlige uopløselige fremmede partikler efter rekonstitution af opløsningen.
- Den brune glasflaske og klarheden af den rekonstituerede lægemiddelopløsning muliggør at de relevante hvide PTFE-partikler kan ses med det blotte øje i normalt omgivende lys.
- Udlever ikke Evrysdi® 0,75 mg/ml pulver til oral opløsning, hvis der er identificeret synlige fremmede partikler i flasken efter at det rekonstituerede produkt er rystet to gange i 15 sekunder, i henhold til *Vejledning til rekonstitution*.
- Erstat straks det påvirkede lægemiddel med en ny, upåvirket flaske for at sikre behandlingskontinuitet.
- Produktklager kan indberettes døgnet rundt via webformularen https://medinfo.roche.com/dk/da.html. Alternativt, kan Patient Safety afdelingen kontaktes på telefon: 36 39 99 99.

Opfordring til rapportering

Farmaceuter bedes rapportere alle formodede bivirkninger relateret til anvendelsen af Evrysdi® til Lægemiddelstyrelsen via en e-blanket på styrelsens hjemmeside www.meldenbivirkning.dk. Inkluder venligst batch-/lotnummer.

Hvis du har spørgsmål til indberetning af formodede bivirkninger, kan du kontakte:

Lægemiddelstyrelsen
Axel Heides Gade 1
DK-2300 København S
Telefon: +45 44 88 95 95

Virksomhedens kontaktoplysninger

For yderligere information eller spørgsmål vedrørende Evrysdi®, kontakt venligst:

Roche Pharmaceuticals A/S
Flaskehalsen 17, 4. sal
1799 København V
Tlf.: 36 39 99 99
Emailadresse: denmark.medinfo@roche.com
Webformular: https://medinfo.roche.com/dk/da.html
Website: www.roche.dk

Med venlig hilsen

Signed by:
Karin Madsen
9B922FE78B6D4A6...

Karin Madsen, Country Medical Director

Roche Pharmaceuticals A/S

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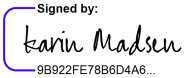
Karin Madsen karin.madsen@roche.com Country Medical Director Roche Pharmaceuticals A/S Security Level: Email, Account Authentication (None)	Signed by:  9B922FE78B6D4A6... Signature Adoption: Pre-selected Style Using IP Address: 196.3.50.247	Sent: 6/1/2026 11:02:32 AM Viewed: 6/1/2026 11:02:43 AM Signed: 6/1/2026 11:02:52 AM

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