

To: [redacted] 5.1.2e [redacted] 5.1.2e [redacted]@ema.europa.eu]
From: [redacted] 5.1.2e
Sent: Mon 2/21/2022 8:32:44 AM
Subject: RE: EMA SmPC Comirnaty 10 micrograms/dose concentrate for dispersion for injection
Received: Mon 2/21/2022 8:32:44 AM

Hi [redacted] 5.1.2e

You're completely right! Page 39 downwards has all the information I was looking for. I just had to scroll instead of looking for a separate SmPC... thank you for spending time on this and thanks for sending the contact page * .

See you soon!

Best wishes, [redacted] 5.1.2e

Van: [redacted] 5.1.2e <[redacted] 5.1.2e [redacted]@ema.europa.eu>
Verzonden: vrijdag 18 februari 2022 16:24
Aan: [redacted] 5.1.2e <[redacted] 5.1.2e [redacted]@rivm.nl>
Onderwerp: FW: EMA SmPC Comirnaty 10 micrograms/dose concentrate for dispersion for injection

Hi there,

I checked with one of my medical writer colleagues...

[redacted] buiten verzoek

[redacted] buiten verzoek

So, for you to know, so you can find what you're looking for, a lot of the information is *added* to the SmPC, rather than having a separate SmPC. As I said, **check page 39** and check also **page 98** of https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf

[redacted] buiten verzoek

[redacted] buiten verzoek

[redacted] buiten verzoek

please note that you can send your enquiries here:

<https://www.ema.europa.eu/en/about-us/contact/send-question-european-medicines-agency>.

Best wishes for this stormy weekend!

From: [redacted] 5.1.2e <[redacted] 5.1.2e [redacted]@ema.europa.eu>
Sent: Friday, 18 February 2022 15:58
To: [redacted] 5.1.2e <[redacted] 5.1.2e [redacted]@ema.europa.eu>; [redacted] 5.1.2e <[redacted] 5.1.2e [redacted]@ema.europa.eu>
Subject: RE: EMA SmPC Comirnaty 10 micrograms/dose concentrate for dispersion for injection

Hola [redacted] 5.1.2e

Yes it is page 39 of the link you have below. Page 98 is the package leaflet, which is also v useful.

[redacted] buiten verzoek

[redacted] buiten verzoek

the query should be entered here: <https://www.ema.europa.eu/en/about-us/contact/send-question-european-medicines-agency>

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[redacted] buiten verzoek

[redacted] buiten verzoek

Have a good weekend folks,

[redacted] 5.1.2e

Classified as internal/staff & contractors by the European Medicines Agency

From: [redacted] 5.1.2e <[redacted] 5.1.2e [redacted]@ema.europa.eu>
Sent: Friday, 18 February 2022 15:36
To: [redacted] 5.1.2e <[redacted] 5.1.2e [redacted]@ema.europa.eu>
Subject: FW: EMA SmPC Comirnaty 10 micrograms/dose concentrate for dispersion for injection

Hey [redacted] 5.1.2e

2 questions:

1. [redacted] buiten verzoek how should I channel this enquiry?
2. Is there an SmPC epar for Comirnaty 10 micrograms/dose concentrate for dispersion for injection that you can find?

I only found the page that [redacted] 5.1.2e found - [Comirnaty, INN-tozinameran \(europa.eu\)](https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf)

It looks like we should be sending her to page 39 of https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf

buiten verzoek

buiten verzoek

The world so needs ePI!!

buiten verzoek

From: [redacted] 5.1.2e <[redacted] 5.1.2e @rivm.nl>

Sent: Friday, 18 February 2022 13:45

To: [redacted] 5.1.2e <[redacted] 5.1.2e @ema.europa.eu>

Cc: [redacted] 5.1.2e <[redacted] 5.1.2e @rivm.nl>

Subject: EMA SmPC Comirnaty 10 micrograms/dose concentrate for dispersion for injection

Hi [redacted] 5.1.2e

buiten verzoek

Yesterday I received a question from a doctor working at one of the vaccination locations in the Netherlands and to address her question I needed the Comirnaty SmPC for 5-11 years old (Comirnaty 10 micrograms/dose concentrate for dispersion for injection). I went to the EMA website but could only find the regular Comirnaty SmPC 30 micrograms/dose concentrate for dispersion for injection. In the regular SmPC it says the following regarding the paediatric population: *"There is a paediatric formulation available for children 5 to 11 years of age (i.e. 5 to less than 12 years of age). For details, please refer to the Summary of Product Characteristics for Comirnaty 10 micrograms/dose concentrate for dispersion for injection"*.

So there should be a specific SmPC for 10mg but unfortunately I haven't been able to find the file of this specific SmPC. I looked at the [main Comirnaty page](#) but it is not included in the product information section. I did find it on this [website](#) but there is no link to the actual SmPC file. In our guideline we also refer to the Comirnaty 10 micrograms/dose concentrate for dispersion for injection but when you click on the link it directs you to the file of the regular SmPC 30 mg. Do you know where I can find the file of the SmPC Comirnaty 10 micrograms/dose concentrate for dispersion for injection? Or do you know who could direct me to the right EMA page that has it?

Thank you in advance for helping me with my question!

Kind regards,

[redacted] 5.1.2e

[redacted] 5.1.2e

**Landelijke Coördinatie Infectieziektebestrijding
Rijksinstituut voor Volksgezondheid en Milieu**

Antonie van Leeuwenhoeklaan 9 | 3721 MA Bilthoven
Postbus 1 | 3720 BA Bilthoven



[redacted] 5.1.2e

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[redacted] 5.1.2e



[redacted] 5.1.2e

[redacted] @rivm.nl

[redacted] www.rivm.nl

[redacted] 5.1.2e

Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is verzonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen. Het RIVM aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.

www.rivm.nl *De zorg voor morgen begint vandaag*

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