MEDICAL INFORMATION

7-January-2021

[redacted]

Your medical information enquiry concerning COMIRNATY▼ (COVID-19 mRNA vaccine (BNT162))

Dear [redacted]

Thank you for your enquiry regarding our medicine COMIRNATY▼. You were requesting data from the fertility trials in rats.

▼ Relevant to Switzerland: This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

Comirnaty is temporarily authorised. The Prescribing Information will be updated on a regular basis as further data and safety reports become available.

Local Prescribing Information

Fertility
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. [1]

Preclinical data
Non-clinical data reveal no special hazard for humans based on conventional studies of repeat dose toxicity and reproductive and developmental toxicity.[1]

Developmental toxicity
Reproductive and developmental toxicity were investigated in rats in a combined fertility and developmental toxicity study where female rats were exposed to Comirnaty prior to mating and during gestation. There were no vaccine-related effects on female fertility, pregnancy, or embryo-foetal or offspring development.[1]

For further information regarding this vaccine, please refer to the COMIRNATY Local Prescribing Information.[1]

Additional Information from European Public Assessment Report

The **European** Public Assessment Report (EPAR) provides further detailed information regarding the *reproduction toxicity* which may be pertinent to your question: [2]

Reproduction Toxicity

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[1] Comirnaty (COVID-19 mRNA Vaccine). Local Prescribing Information (Switzerland) [V: Date of revision of text 12/2020; LC].
[2] Comirnaty (COVID-19 mRNA Vaccine). European Public Assessment Report (EPAR). Available online at: Comirnaty, INN-COVID-19 mRNA Vaccine (nucleoside-modified) (europa.eu) (Accessed on January 07, 2021)

In the DART study, the test substances used were BNT162b1, BNT162b2 and BNT162b3, which were given to female rats twice before the start of mating and twice during gestation at the human clinical dose (30 µg RNA/dosing day). The test substances were administered intramuscularly (IM) to F0 female Wistar rats 21 and 14 days before the start of mating (M-21 and M-14, respectively) and then on Gestation Day (GD) 9 and GD20, for a total of 4 doses. A subgroup was terminated at GD21 and another (litter) group was terminated at PND21. SARS-CoV-2 neutralizing antibody titers were found in the majority of females just prior to mating (M-14), in most females and foetuses at the end of gestation (GD21), and in most offspring at the end of lactation (PND21). There was transient reduced body weight gain and food consumption after each dose. No effects on the estrous cycle or fertility index were observed. There was an increase (~2x) of pre-implantation loss (9.77%, compared to control 4.09%) although this was within historical control data range (5.1%-11.5%). Among foetuses (from a total of n=21 dams/litters), there was a very low incidence of gastroschisis, mouth/jaw malformations, right sided aortic arch, and cervical vertebrae abnormalities, although these findings were within historical control data. Regarding skeletal findings, the exposed group had comparable to control group levels of presacral vertebral arches supernumerary lumbar ribs, supernumerary lumbar short ribs, caudal vertebrae number < 5). There were no signs of adverse effects on the postnatal pups (terminated at PND21). It is noted that there is currently no available data on the placental transfer of BNT162b2. This information is reflected in section 5.3 of the (European) SmPC (correspondent of section "preclinical data" in the Swiss LPI).[2]

(...)
Finally, the combined fertility and developmental toxicity study showed that SARS-CoV-2 neutralising antibody responses were present in maternal animals from prior to mating to the end of the study on postnatal day 21 as well as in foetuses and offspring. There were no vaccine-related effects on female fertility, gestation, or embryo-foetal or offspring development up to weaning. [2]

Are there official recommendations on the COVID-19 vaccination programme?

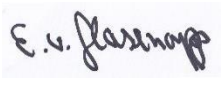
The use of Comirnaty vaccine should be in accordance with official recommendations.[1]

For official recommendations on the COVID-19 vaccination programme in Switzerland, please refer to the following website*: https://www.bag.admin.ch/bag/en/home/krankheiten/ausbrueche-epidemien-pandemien/aktuelle-ausbrueche-epidemien/novel-cov/impfen.html*

Please note that Pfizer is independent of these recommendations.

I hope the information enclosed proves to be of help and interest. Please do not hesitate to contact us if you require anything further.

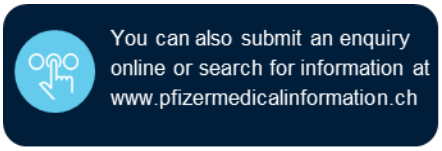
Yours sincerely



Elisabeth v. Glasenapp

Ref: 00053661

To help us serve you better in the future, please take a few minutes to complete our survey which is found on the following link:
https://pfizermi.qualtrics.com/SE/?SID=SV_7TLsDr25NMfzRnT&Q_lang=EN&CaseID=00053661&Product=COMIRNATY▼



▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions online via the ElViS portal (Electronic Vigilance System). You can obtain information about this at www.swissmedic.ch. If you are not a HealthCare Professional you can help by reporting any side effects you may get. Please refer to the Package Leaflet for your medicine, for information on reporting side effects.

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