

1 July 2020

Product update: Chromium (Cr-51) EDTA injection

As part of our continuous product enhancements, ANSTO, through the Therapeutic Goods Administration (TGA) approval process, has refreshed our Chromium (Cr-51) EDTA injection offering.

You will notice the following changes from 1 August 2020:

- An increase in the Chromium specific activity in the product from 30GBq/gram to new 50GBq/gram (range of 36 – 200GBq/gram Chromium; pr).
- An updated Product Information (PI) leaflet, refreshed to meet TGA's PI reformat requirements.
- The stated amount of Chromium content in the formulation will match the maximum amount specified in the latest version of the British Pharmacopoeia monograph of $\leq 1\text{mg/mL}$ (the actual chromium content will be $\leq 0.25\text{mg/mL}$). EDTA content in the formulation will be the specification limit of $\leq 15\text{mg}$ (actual EDTA content will be $\sim 10\text{mg/mL}$). Each mL of 8MBq Chromium (51Cr) supplied in 0.9 w/v% sodium chloride solution. These changes are noted in Section 2 of the updated PI.
- Data for absorbed dose per unit activity administered (mGy MBq^{-1}) updated in Section 4.2 of the PI; this is in line with the data published in International Commission on Radiological Protection (ICRP) publication 128.

There has been no change to the radioactive content specification, which remains at 8MBq/mL in a 3mL vial.

[Take a look at the latest PI here.](#)

If you have any questions, our Customer Service team are here to help

Phone: 1800 251 572 or +61 2 9717 9992

Email: health@ansto.gov.au



Graham Mori
Sales and Marketing Manager
Customer Advocacy and Value Chain