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Medoject sterile hypodermic and blunt fill needles manufactured by Chirana T. Injecta – discontinue use

There is the potential for a black residue to be present on all Medoject hypodermic and blunt fill needles

From:
Medicines and Healthcare products Regulatory Agency (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency)
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Device safety information (https://www.gov.uk/drug-device-alerts?alert_type%5B%5D=device-safety-information)
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Some users of these needles have seen a black residue on the surface. The manufacturer issued a Field Safety Notice (FSN) (https://mhra-gov.filecamp.com/s/6NfvX51A6UfowTF8/d) recalling the 5 batches reported.

Further investigation by the MHRA has since revealed that the specific root cause of this issue is unknown, and it may affect all batches of the Medoject hypodermic and blunt fill needles.

Since the FSN was released, the black residue has been identified as amorphous carbon. The information currently available to the manufacturer suggests that the risk of harm to patients is low. There is a large number of alternative devices available on the UK market. Therefore, because the specific root cause of the problem is undetermined, the MHRA is advising the following actions:

Advice for healthcare professionals

- Identify all Medoject hypodermic and blunt fill needles in your organisation
- Stop using these needles and dispose of them
- Share this information with all those who may also have affected products
- Report any suspected or actual adverse incidents involving these devices through your healthcare institution’s local incident reporting system and your national incident reporting authority as appropriate: England (https://yellowcard.mhra.gov.uk/), Scotland (https://www.nss.nhs.scot/health-facilities/incidents-and-alerts/report-an-incident/), Northern Ireland (https://www.health-ni.gov.uk/articles/reporting-adverse-incident), Wales (https://yellowcard.mhra.gov.uk/).

If you have any queries about this information, please contact:

Manufacturer

Chirana T.Injecta Rastislav.Broska@t-injecta.sk +421 910 955 937

MHRA

aic@mhra.gov.uk quoting MHRA ref: 2020/010/001/487/002

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