June 22, 2015

Anakinra, Kineret 100 mg and 100 mg/0.67 ml solution for injection in a pre-filled syringe: product complaints regarding presence of solid material visible on the surface of the needle

Dear Healthcare Professional,
Swedish Orphan Biovitrum (Sobi) in agreement with the Health Products Regulatory Authority (HPRA) and the European Medicines Agency (EMA) would like to inform you of the following:

Summary

- Sobi has received product complaints regarding presence of solid material visible on the surface of the needle of Kineret prefilled syringes from different batches.
- The currently observed frequency of complaints is low relative to the number of syringes manufactured and distributed.
- The syringes and needles have been analyzed and the material on the needle has been identified as anakinra, the active protein in Kineret
- If present, the solid material can be seen on the needle when the rubber needle shield is removed prior to injection. Additional analysis of affected syringes has confirmed the integrity of the syringe and rubber needle shield, indicating that sterility is not compromised.
- Sobi has not yet identified the root cause; an investigation is ongoing.
- No serious adverse events related to the Kineret complaints have been reported. The benefit/risk balance for Kineret remains positive.
- Syringes, **including the needle**, should be thoroughly inspected before administration. Syringes with presence of solid material on the outer surface of the needle should not be used. Unaffected syringes can be used. However, all unused syringes (affected and unaffected) from an affected pack can be returned to the pharmacy through the standard routes and will be replaced by Sobi.

Further information on the safety concern and the recommendations

The safety of patients is our main priority and we are treating this quality issue with the highest priority. During the past 4 months there have been 16 product complaints, as described above.

There have been no serious adverse events and there are no reports indicating an increased risk for other events in connection with these complaints.

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Registered No. 4369760 Registered in England & Wales

The solid material on the needle of the affected syringes is identified as anakinra, the active protein in Kineret. Additional analysis of affected syringes has confirmed the integrity of the syringe and rubber needle shield, indicating that sterility is not compromised. Sobi has not yet identified the root cause, investigation is ongoing.

The benefit/risk balance for Kineret remains positive.

While quality investigations are ongoing and until further clarity is obtained and the quality issue is resolved patients, physicians and nurses should not use the affected syringes.

Therefore, we recommend additional awareness on visual inspection of the syringe AND the needle before administration and to report such findings to complaints@sobi.com. In addition, we recommend the relevant health care professionals should instruct their patients to do so.

In any case of visible solid material on the needle or the syringe, the syringe should not be used. Packages with affected syringes will be replaced upon request through the standard routes.

For assistance with complaints please contact your pharmacy or Sobi UK Ltd, tel +44 1638 722 380.

Further information

Kineret is indicated in adults for treatment of the signs and symptoms of rheumatoid arthritis (RA) in combination with methotrexate, with an inadequate response to methotrexate alone.

Kineret is also indicated in adults, adolescents, children and infants aged 8 months and older with a body weight of 10 kg or above for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including:

- Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA)
- Muckle-Wells Syndrome (MWS)
- Familial Cold Autoinflammatory Syndrome (FCAS)

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Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the HPRA using a Yellow Card obtained either from the HPRA, or electronically via the website at www.hpra.ie. Adverse reactions can also be reported to the HPRA by calling (01) 676 4971. The company email address for reporting of adverse events is drugsafety@sobi.com, and for complaints complaints@sobi.com. Alternatively, they can be reported to Sobi UK Ltd, telephone number +44 1638 722 380.

Company contact point

For further information, please contact Kristina Timdahl, Therapeutic Area Head and Global Medical Director, Torbjörn Kullenberg, Drug Safety Physician, Carina Carlsson, Qualified Person, telephone number +46 8 697 20 00, or the Medical Director in your local Sobi office, telephone number +44 1638 722 380. You can also send an email to medical.info@sobi.com.
The address to Swedish Orphan Biovitrum in Sweden is SE-112 76 Stockholm, Sweden. Our website is www.sobi.com.

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