10 June 2019

Myocrisin (Sodium aurothiomalate) injection: Permanent discontinuation – end of supply in 2019.

Dear Healthcare Professional

This letter has been sent with the agreement of the Medicines and Healthcare products Regulatory Agency (MHRA).

Sanofi is providing you with advanced notification of the permanent discontinuation of Myocrisin (Sodium aurothiomalate) Solution for Injection, also known as gold injections. This discontinuation is due to a shortage of Active Pharmaceutical Ingredient (API) and not due to any safety issue with the product therefore product already in the supply chain can continue to be used.

Summary

- **Manufacture of Myocrisin (Sodium aurothiomalate) injection has ceased**
- **Existing stock of Myocrisin Solution for injection (100 mg/ml) will last until the end of June 2019 – (based on current pattern of use)**
- **Existing stock of Myocrisin Solution for injection (20 mg/ml) are likely to last until end of July 2019 – (based on projected pattern of use)**
- **No new patient should commence treatment with Myocrisin injection**
- **Prescribers should complete arrangements to transfer patients on Myocrisin to suitable therapeutic alternatives under medical supervision**

Background

Due to a long-term shortage of Active Pharmaceutical Ingredient (API), it is not currently possible to manufacture Myocrisin Solution for injection and Sanofi have therefore taken the decision to permanently discontinue this product.

Patients should be permanently transferred to another therapeutic option, under medical supervision. This discontinuation is **not due to any safety issue and** Myocrisin Solution for Injection currently on the market can continue to be used.

Which presentations are affected?

All presentations will be discontinued:

- **MYOCRISIN** Solution for Injection 100mg/ml
- **MYOCRISIN** Solution for Injection 20mg/ml

What are the final dates for supply?

Myocrisin Solution for Injection 100mg/ml

Based on current patterns of use stocks are expected to last until the end of June 2019.

Myocrisin Solution for Injection 20mg/ml

Based on projected patterns of use stocks are expected to last until the end of July 2019.

What are the implications for patients?

This notification of the discontinuation of Myocrisin Injection is given so healthcare professionals can identify and begin administering suitable alternative therapies to their patients.

It is recommended that no new patient commence treatment with Myocrisin Injection as the current stocks are likely to last no longer than June 2019 (for 100mg/ml solution for inj) and July 2019 (for 20mg/ml solution for inj).

For patients currently being treated with Myocrisin Injection, plans should be finalised to switch to a suitable alternative treatment *as soon as possible*. This should always be under medical supervision and occur at the most appropriate point in time considering the patients clinical condition and the health care professional's capacity to identify and manage any risks associated with the change in treatment.

The choice of alternative treatment should be made by the patient and healthcare professional together, taking into account previous response to other treatments and benefit-risk profile of available alternatives.

Call for reporting

Reporting of suspected adverse reactions

Reporting suspected adverse drug reactions to medicines is important. It allows continued monitoring of the benefit/risk balance of the medicinal product, even after discontinuation.

Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store.

Suspected adverse reactions to Myocrisin should also be reported to Sanofi:

Tel: 0800 0902314. Email: UK-drugsafety@sanofi.com

Company contact points

Should you have any question or require additional information, please call **Medical Information** at Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS, UK - Tel: 0845 372 7101, Email: uk-medicalinformation@sanofi.com. For questions relating to order of product, please contact your first line Agents (AAH/ Phoenix).

Yours faithfully,

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