SANOFI

Direct Healthcare Professional Communication

Permanent discontinuation of supply of MODECATE® (fluphenazine decanoate) Injection by end of 2018.

31 May 2017

Dear Healthcare Professional

In agreement with the Medicines and Healthcare products Regulatory Agency (MHRA), Sanofi is providing you advanced notification of the permanent discontinuation of supply of Modecate (fluphenazine decanoate) Injection. Production will cease in mid-2018, and the product is expected to remain available in the United Kingdom up until the end of 2018 (assuming that the rate of use does not change significantly at that time).

A further communication will be sent before production ends to provide a more accurate estimate of the end of availability of Modecate Injection in the UK.

Why is the product being withdrawn?

Modecate Injection is provided by Bristol-Myers Squibb (BMS) and distributed by Sanofi in the UK. BMS have notified the end of production of Modecate Injection due to the unpredictability of supply of fluphenazine decanoate, the active pharmaceutical ingredient (API), from the third party manufacturer, Fine Chemicals of South Africa. There are no other manufacturers of API worldwide. Even if a new manufacturer were identified, there would be a gap of 2-4 years before a new pharmaceutical preparation would become available for clinical use.

As there are several comparable therapeutic equivalent drugs, it has been decided that permanent discontinuation is the best option for patients who require a depot antipsychotic treatment. This would avoid the need for patients to switch from Modecate and then switch back to a new fluphenazine preparation at some point in the future.

It is important to make clear that the shortage has arisen due to manufacturing and supply problems and is **not due to any safety issue.** Modecate Injection currently on the market can continue to be used.

Which presentations are affected?

All presentations will be withdrawn:

MODECATE® Injection 25mg/ml
MODECATE® Concentrate Injection 100mg/ml]

What are the implications for patients?

Firstly we apologise for the inconvenience and difficulty that this issue may cause. Sanofi remains committed to providing high-quality medicines for the benefit of patients, although for reasons outside of Sanofi's control this is not always possible.

This early notification of the planned withdrawal of Modecate Injection at the end of 2018 is intended to give healthcare providers sufficient time to identify and begin administering alternative therapies to their patients.

It is recommended that no patient commence treatment with Modecate Injection where it is expected that treatment will be required to continue beyond the end of 2018.

For patients currently treated with Modecate Injection and expected to continue beyond 2018, you should make plans to switch patients to a suitable alternative. This should always be under medical supervision, and occur at the most appropriate point in time considering the patients clinical condition and the care provider's capacity to identify and mange any risks associated with the change in treatment. The choice of antipsychotic should be made by the service user and healthcare professional together, taking into account previous response to other treatments and the adverse effects of available alternatives.

The British National Formulary (BNF) suggests the following dose equivalents for depot antipsychotics:

Equivalent doses of depot antipsychotics		
These equivalences are intended only as an approximate guide; individual dosage instructions should also be checked; patients should be carefully monitored after any change in medication		
Antipsychotic drug	Dose (mg)	Interval
Flupentixol decanoate	40	2 weeks
Fluphenazine decanoate	25	2 weeks
Haloperidol (as decanoate)	100	4 weeks
Zuclopenthixol decanoate	200	2 weeks
Important These equivalences must not be extrapolated beyond the maximum dose for the drug		

BNF February 2017
http://dx.doi.org/10.18578/BNF.850676554

Call for reporting

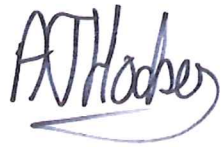
Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

Adverse events arising from the use of medicines manufactured by Sanofi may also be reported to the **Sanofi UK Pharmacovigilance** department at: Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS, UK. - Tel: 01483 554242, Fax: 01483 554806, Email: uk-drugsafety@sanofi.com

Company contact point

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: Sanofi Customer Services – 0800 854 430, (9am – 5.15pm Monday-Thursday, 9am – 4pm Friday).
Yours faithfully,



Dr Andrew Hockey FFPM
Medical Head - General Medicines
Sanofi UK