[Insert sending date]

Modecate (fluphenazine decanoate) injection: Permanent discontinuation –end of supply in 2019 and 2020.

Dear Healthcare Professional

Sanofi would like to inform you of the following:

Summary

- **Manufacture of Modecate (fluphenazine decanoate) injection has ceased**
- **Existing stock of Modecate Injection (25 mg/ml) will expire in August 2019 – supplies should be ordered now to treat any patients who have yet to be switched to an alternative treatment.**
- **Existing stock of Modecate Concentrate Injection (100 mg/ml) will expire in August 2020 – stock will not be released after 29 February 2020.**
- **Prescribers should complete arrangements to transfer patients on Modecate to therapeutic alternatives under medical supervision**

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

Background

Sanofi notified you in March 2017 of the permanent discontinuation of supply of Modecate (fluphenazine decanoate) Injection. Production of Modecate Injection has now ceased; this letter is to confirm the last dates of supply within the UK.

Patients should be permanently transferred to another therapeutic option, under medical supervision. 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.

What are the final dates for supply?

Modecate Injection 25mg/ml

The last batch of this preparation has an expiry date of 31 August 2019. There are sufficient quantities in the UK to last until this date based on normal patterns of use.

At this point you should place your final order to ensure that you have sufficient supply to treat any patients who have yet to be switched to an alternative treatment. Orders will not be able to be fulfilled after August 2019.

Modecate Concentrate Injection 100mg/ml

The last batch of this preparation has an expiry date of 31 August 2020. There are sufficient quantities in the UK to last until this date based on normal patterns of use.

Sanofi will no longer release stock to their distributors after 29 February 2020.

What are the implications for patients?

For patients still being treated with Modecate Injection, plans should be finalised to switch to a suitable alternative in the coming months. 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 patient 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

Antipsychotic drug/interval	Dosage (mg)
Flupentixol decanoate / 2 weeks	40
Fluphenazine decanoate / 2 weeks	25
Haloperidol (as decanoate) / 4 weeks	100
Zuclopenthixol decanoate / 2 weeks	200
Important: These equivalences must **not** be extrapolated beyond the maximum dose for the drug	

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.

BNF December 2018
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 to the Yellow Card Scheme.

It is easiest and quickest to report ADRs online via the Yellow Cards website - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store.

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 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: 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

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