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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

13 July 2023

Dear Healthcare Professional,

DRUG ALERT CLASS 2 DRUG ALERT 25 2023 – CLASS 2 MEDICINES RECALL – ACTION WITHIN 48 HOURS – AVENTIS PHARMA LTD (T/A SANOFI UK) SABRIL 500MG FILM-COATED TABLETS

Please see drug alert for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Medicines Policy Team

Medicines & Healthcare products Regulatory Agency

MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Patient/Pharmacy/Wholesaler Level Recall

Date: 13 July 2023 EL (23)A/25 Our Ref: MDR 009-06/23

Dear Healthcare Professional

Aventis Pharma Limited (t/a Sanofi UK)

Sabril 500 mg film-coated tablets PL 04425/0171

SNOMED Code: 184311000001104

Batch Number	Expiry Date	Pack Size	First Distributed
2989A	April 2025	100	02/08/22
2988D	April 2025	100	15/07/22
2006B	November 2025	100	15/03/23

Sabril 500 mg granules for oral solution PL 04425/0170

SNOMED Code: 3711611000001107

Batch Number	Expiry Date	Pack Size	First Distributed
1994A	May 2024	50	15/09/21
2028B	March 2025	50	30/08/22

Active Pharmaceutical Ingredient: Vigabatrin

Brief description of the problem
Sanofi UK is recalling the listed batches of Sabril tablets and Sabril granules as a precautionary measure due to the detection of traces of tiapride in the batches of the source material of manufacturer for vigabatrin. Sabril (vigabatrin) is indicated for adjunctive treatment of focal seizures with or without secondary generalisation not satisfactorily controlled with other antiepileptics (under expert supervision) and monotherapy in the treatment of infantile spasms (West's syndrome). All patients should be advised **not to discontinue Sabril tablets or Sabril granules without consulting with their prescriber.** The risks of suddenly stopping medication for seizures/epilepsy is higher than the potential risk presented by the presence of tiapride. Sanofi UK have confirmed that no other batches are impacted, and other stock remains available.

There are no licenced products that contain tiapride in the UK and to date, tiapride use has not been thoroughly investigated in children. Tiapride is indicated for the treatment of a variety of neurological and psychiatric disorders including dyskinesia, alcohol withdrawal syndrome, negative symptoms of psychosis, and agitation and aggression in the elderly.

Although Sanofi UK has confirmed the presence of tiapride by carrying out analytical testing of impacted batches, the trace amounts of tiapride observed in the source material are significantly lower than permitted daily exposure to tiapride in adults. **However, there is a potential risk to children who may have or are taking the impacted batches of Sabril tablets or Sabril granules.** This is a theoretical risk as the calculation is based on the amount of tiapride detected in the source material. A precautionary recall is undertaken in view of the potential for serious adverse events in children.

Advice for healthcare professionals
Stop supplying the above batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

Based on the distribution dates most of the stock of these batches will have been used already, however healthcare professionals should note the specific advice for adults and children, who may have been or are taking the impacted batches of Sabril tablets or Sabril granules in the sections below. The information for children who have been prescribed/dispensed Sabril tablets or granules includes a direct action to contact patients/parents/carers/guardians and consider recall, where appropriate.

- **Advice for healthcare professionals to give to children (17 years and below) and their parents/carers/guardians**

    - Pharmacists involved in dispensing this product should immediately contact all patients who have been dispensed the impacted batches and ask them to confirm if they have remaining stock of the impacted batches within their possession. If batch traceability information is not available, all patients dispensed Sabril 500 mg granules for oral solution since September 2021 and/or Sabril 500 mg film-coated tablets since July 2022 should be contacted. This information is based on the first distribution dates as indicated in the product details within this notification.

    - **If the pharmacist identifies any child patients with an impacted batch, they should, in the first instance, contact the patient/parents/carers/guardians and inform them of the information in this recall. They should be advised to seek a review from their GP, specialist prescriber or other relevant prescriber responsible for their care. If the patient has an impacted batch then an alternative batch should be provided and the impacted batch recalled. Patients may need to obtain additional prescriptions for further supply, however this should not cause any interruptions to treatment.**

    - Healthcare professionals should advise all patients/parents/carers/guardians undergoing treatment **not to discontinue Sabril tablets or Sabril granules without consulting with their prescriber.** The risks of suddenly stopping medication for seizures/epilepsy is higher than the potential risk presented by the presence of tiapride.

    - Sabril treatment is usually only initiated by a specialist in epileptology, neurology or paediatric neurology. Patients are routinely monitored and any follow-ups are normally arranged under supervision of a specialist in epileptology, neurology or paediatric neurology, therefore patients may already be undergoing suitable monitoring.

    - If patients/parents/carers/guardians have any concerns or experience any adverse events, they should be advised to seek medical attention immediately.

- **Advice for healthcare professionals to give to adults (18 years and above)**

    - Based on the information that trace amounts of tiapride observed in the source material are significantly lower than permitted daily exposure to tiapride in adults, this product is not specifically being recalled from adults.

    - Healthcare professionals should advise all patients undergoing treatment **not to discontinue Sabril tablets or Sabril granules without consulting with their prescriber.** The risks of suddenly stopping medication for seizures/epilepsy is higher than the potential risk presented by the presence of tiapride.

    - If patients have any concerns or experience any adverse events, they should be advised to seek medical attention immediately.

Advice for patients
Continue taking your medication. Do not stop Sabril tablets or Sabril granules without talking to a relevant healthcare professional first, such as your GP or pharmacist. Remember the risks of suddenly stopping medication for seizures/epilepsy are higher than the potential risk presented by the presence of tiapride.

- People over 18 years with these batches of affected medicines do not need to return them for a replacement. The trace amounts of tiapride are significantly lower than the safe exposure limits in adults.

- **People aged 17 years or below, confirm whether the batches you have recently consumed or are consuming are affected (affected batches are in the table above). If they are, immediately inform a healthcare professional and don't stop your medication until you have an alternative batch, where possible.**

Patients who experience adverse reactions or have any questions about the medication should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Further Information
For stock control enquiries please contact GB-CustomerServices@sanofi.com or via telephone: 0800 854 430. For more information or medical information at uk-medicalinformation@sanofi.com or via telephone: 0800 035 25 25.

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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