Medicines & Healthcare products Regulatory Agency

M E D I C I N E S N O T I F I C A T I O N

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 06 December 2023 EL(23)A/41 Our Ref: MDR 055-11/23

Dear Healthcare Professional,

Strandhaven Ltd t/a Somex Pharma

Tramadol Hydrochloride 50mg Capsules, Hard **PL 15764/0138**

SNOMED Code N/A

Batch Number	Expiry Date	Pack Size	First Distributed
SMI2201	Mar-2024	100	27/10/2022
SMI2202	Apr-2024	100	27/10/2022
SMI2203	Apr-2024	100	27/10/2022
SMI2204	Apr-2024	100	27/10/2022
SMI2205	Sep-2025	100	08/02/2023
SMI2206	Sep-2025	100	01/02/2023
SMI2207	Sep-2025	100	01/02/2023
SMI2208	Nov-2025	100	03/04/2023
SMI2209	Nov-2025	100	03/04/2023
SMI2210	Nov-2025	100	13/04/2023
SMI2211	Nov-2025	100	13/04/2023
SMI2212	Nov-2025	100	15/04/2023
SMI2301	Dec-2025	100	15/04/2023
SMI2302	Dec-2025	100	15/04/2023
SMI2303	Dec-2025	100	03/04/2023
SMI2304	Dec-2025	100	03/04/2023
SMI2305	Dec-2025	100	03/04/2023
SMI2306	Jan-2026	100	13/06/2023
SMI2307	Jan-2026	100	13/06/2023
SMI2308	Jan-2026	100	13/06/2023
SMI2309	Jan-2026	100	13/06/2023
SMI2310	Jan-2026	100	13/06/2023
SMI2311	Jan-2026	100	13/06/2023
SMI2312	Feb-2026	100	15/06/2023
SMI2313	Feb-2026	100	15/06/2023
SMI2314	Feb-2026	100	15/06/2023
SMI2315	Feb-2026	100	15/06/2023
SMI2316	Feb-2026	100	15/06/2023
SMI2317	Feb-2026	100	15/06/2023
SMI2318	Feb-2026	100	15/06/2023
SMI2319	Feb-2026	100	15/06/2023

Batch Number	Expiry Date	Pack Size	First Distributed
SMH2301	Dec-2025	30	15/04/2023
SMH2303	Feb-2026	30	15/06/2023

Active Pharmaceutical Ingredient: Tramadol Hydrochloride

Brief description of the problem
Strandhaven Limited t/a Somex Pharma has informed the MHRA regarding an error with the Patient Information Leaflets (PILs) that have been packed in the listed batches of Tramadol Hydrochloride 50mg Capsules, Hard. The PIL does not include the most up to date safety information for drug interaction of antidepressants with Tramadol, sleep-related breathing disorders, adrenal insufficiency, hiccups, and serotonin syndrome, and the need to seek medical advice if they occur. The information missing from the PILs is included below:

2. What you need to know before you take Tramadol

Warnings and precautions

- If you suffer from depression and you are taking antidepressants as some of them may interact with tramadol

Sleep-related breathing disorders
Tramadol can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep-related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

There is a small risk that you may experience a so-called serotonin syndrome that can occur after having taken tramadol in combination with certain antidepressants or tramadol alone. Seek medical advice immediately if you have any of the symptoms related to this serious syndrome (see section 4 ‘Possible side effects’).

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Talk to your doctor or pharmacist or nurse if you experience any of the following symptoms while taking Tramadol:

- Extreme fatigue, lack of appetite, severe abdominal pain, nausea, vomiting or low blood pressure. This may indicate that you have adrenal insufficiency (low cortisol levels).

If you have these symptoms, contact your doctor, who will decide if you need to take hormone supplement.

4. Possible side effects

Not known: frequency cannot be estimated from the available data

- hiccups
- Serotonin syndrome, that can manifest as mental status changes (e.g. agitation, hallucinations, coma), and other effects, such as fever, increase in heart rate, unstable blood pressure,

involuntary twitching, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea) (see section 2 'What you need to know before you take ').
- dependence and addiction (see section "How do I know if I am addicted?").

Advice for healthcare professionals
There is no risk to product quality because of this issue, therefore the affected batches are not being recalled. Healthcare professionals are advised to exercise caution when dispensing the products and where possible, provide an updated PIL. The updated PIL is available electronically and can be downloaded from the Somex Pharma Website. If it is not possible to provide an updated PIL, please advise patients of the missing information, discuss if this medicine is still suitable for them, and the need to seek medical advice if these signs or symptoms occur.

Strandhaven Limited t/a Somex Pharma has confirmed that all future batches will contain the correct PIL. Upon request, Strandhaven Limited t/a Somex Pharma will post hard copies of the updated PIL to wholesalers and pharmacies so that any remaining stock in the dispensary can be supplemented with the correct PIL information (see contact details below).

Advice for patients
No action is needed from patients. This issue is about missing information in the Patient information leaflets (PILs) in specific batches of Tramadol Hydrochloride 50mg film-coated tablets indicated for moderate to severe pain (pain reliever). The medication itself is not affected.

These products will have been prescribed and dispensed by qualified healthcare professional(s) responsible for your care. If you have concerns about a medicine you may be using, please contact your healthcare professional.

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 more information, medical information queries, contact: regulatory@somexpharma.com, tel: 020 8590 9399, choose option 3 or 4. For stock control queries, contact: accounts@somexpharma.com, tel: 020 8590 9399, choose option 2.

Recipients of this Medicines Notification 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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