



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Pharmacy/Wholesaler Level

Date: 14 August 2024

EL (24)A/37

Our Ref: MDR 195-05/24

Dear Healthcare Professional,

Dawa Limited

Trazodone Hydrochloride 50mg Capsules

PL 30684/0250

SNOMED Code: 35807611000001105

Batch No	Expiry Date	Pack Size	First Distributed
220191	Apr-26	84	01/12/2022
220192	Apr-26	84	28/11/2022
220193	Apr-26	84	03/11/2022
220212	Apr-26	84	28/11/2022
220340	Jun-26	84	10/10/2023
220382	Jul-26	84	11/12/2023
230259	May-27	84	26/02/2024

Trazodone Hydrochloride 100mg Capsules

PL 30684/0251

SNOMED Code: 35807111000001102

Batch No	Expiry Date	Pack Size	First Distributed
200284	Sep-24	84	23/03/2021
200285	Sep-24	56	03/08/2021
220194	Apr-26	56	03/11/2022
220213	May-26	56	03/01/2023
220214	May-26	56	26/01/2023
220215	May-26	56	17/01/2023
220237	May-26	56	09/10/2023
220300	Jun-26	56	09/11/2023
220341	Jun-26	56	13/10/2023
220383	Jul-26	56	03/11/2023
230260	May-27	56	30/01/2024

Trazodone Hydrochloride 50mg/5ml Oral Solution

PL 30684/0268

SNOMED Code: 41809411000001103

Batch No	Expiry Date	Pack Size	First Distributed
C31037	Sep-26	120ml	09/04/2024
C31038	Sep-26	120ml	30/01/2024

Active Pharmaceutical Ingredient: trazodone hydrochloride



Medicines & Healthcare products Regulatory Agency

Brief description of the problem

Dawa Limited has informed the MHRA of an error with the Patient Information Leaflets (PILs) that have been packed in the listed batches of Trazodone Hydrochloride 50mg and 100mg Capsules and Trazodone Hydrochloride 50mg/5ml Oral Solution.

The PIL does not contain the latest safety information relating to serotonergic products (trazodone) and the interaction with buprenorphine.

The missing information on the Trazodone Hydrochloride 50mg Capsules & Trazodone Hydrochloride 100mg Capsules PIL is as follows:

Check with your doctor or pharmacist before taking this medicine if you:

- are taking buprenorphine (a strong pain killer). The use of buprenorphine with Trazodone hydrochloride capsules can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Trazadone hydrochloride capsules").

Tell your doctor if you are taking any of the following medicines:

- Buprenorphine/opioids. These medicines may interact with Trazodone hydrochloride capsules and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

The missing information on the Trazodone Hydrochloride 50mg/5ml Oral Solution is as follows:

Talk to your doctor or pharmacist or nurse before taking Trazodone Oral Solution:-

- if you are taking buprenorphine (a strong pain killer). The use of buprenorphine with Trazodone Oral Solution can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Trazodone Oral Solution").

Tell your doctor if you are taking any of the following medicines:

- buprenorphine/opioids. These medicines may interact with Trazodone Oral Solution and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

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 following links:

- [Trazodone Hydrochloride 50mg Capsules](#)
- [Trazodone Hydrochloride 100mg Capsules](#)
- [Trazodone 50mg/5ml Oral Solution](#)

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.



Medicines & Healthcare products Regulatory Agency

The distributor, Drugsrus Limited, has confirmed that all future batches will contain the correct PIL. Upon request, Drugsrus Limited 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 in specific batches of Trazodone Hydrochloride 50mg and 100mg Capsules and Trazodone Hydrochloride 50mg/5ml Oral Solution indicated for anxiety and depression. 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 medical information enquiries please contact the distributor, Drugsrus Limited on 0208 423 3800, info@drugsrus.co.uk.

For stock control enquiries please contact the distributor, Drugsrus Limited on 0208 423 3800, info@drugsrus.co.uk.

Recipients of this Medicines Alert 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

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574
DMRC@mhra.gov.uk