



Macarthy's Laboratories Limited (trading as Martindale Pharma), is an entity of Ethypharm.

Line 1
Line 2
Line 3
Line 4
Line 5

10/10/2019

Product: Fentanyl 50 micrograms/ml Solution for Injection (10ml ampoules)

Non-UK marketing authorisation number on the label of the ampoules for batch 0112391R

Ethypharm, in agreement with the Medicines and Healthcare products Regulatory Agency, would like to inform you of the following:

Dear Healthcare Professional,

- There is currently no UK-labelled Fentanyl 50 micrograms/ml Solution for Injection (10ml ampoules) manufactured by Martindale Pharma available for distribution in the UK.
- In order to prevent a disruption of supply, one batch of product that was labelled for distribution in Saudi Arabia (batch 0112391R) will be released in the UK.
- While the ampoules have been labelled with non-UK labelling, this batch of product was manufactured in the UK, and the manufacturing process is identical to the registered manufacturing process of the UK product.
- In agreement with the MHRA and the Department of Health and Social Care (DHSC), Martindale Pharma has repackaged the ampoules into cartons with UK-approved labelling and patient information leaflet (PIL).

The differences between the ampoule labels for batch 0112391R and the UK approved ampoule labels are outlined as follows:

- The label of the ampoules for batch 0112391R contains the registration number of the product in Saudi Arabia (7-468-15), whereas the marketing authorisation number for the product in the UK is PL 00156/0038.
- The name of the company for this batch of product refers to the name that is registered in Saudi Arabia (Martindale Pharmaceuticals), whereas the name of the Marketing Authorisation Holder (MAH) in the UK is 'Martindale Pharma'.
- The batch number printed on the ampoules is 0112391, whereas the batch number printed on the outer carton is 0112391R. This has been undertaken by the MAH to highlight that this batch of product has been re-packaged into cartons with UK approved labelling and PIL.

Ethypharm UK Ltd

Unit 2, Glory Park,
Wooburn Green, High Wycombe,
Buckinghamshire, HP10 0DF

**Macarthy's Laboratories Ltd
t/a Martindale Pharma**

Bampton Road, Harold Hill,
Romford, Essex, RM3 8UG

Registered Office: Bampton Road, Harold Hill, Romford Essex, RM3 8UG

Ethypharm UK Ltd – Registered in England & Wales – Company number 08565401. VAT number GB701725270 www.ethypharm.co.uk
Macarthy's Laboratories Ltd t/a Martindale Pharma, Bampton Road, Harold Hill, Romford, Essex. RM3 8UG - Company number – 620024
VAT number GB701725270

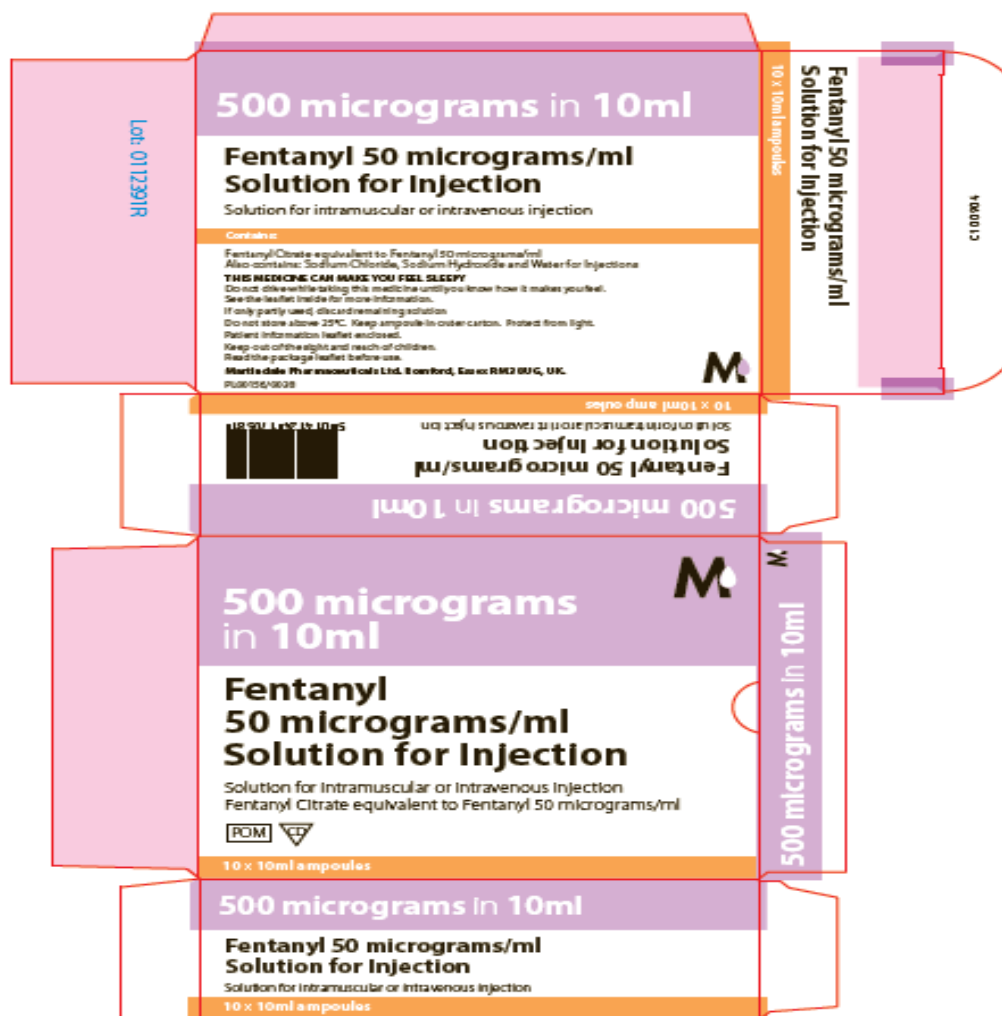
Ampoule label for batch 0112391R



UK approved ampoule label



Outer carton for batch 0112391R



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There are no other changes to the product except for the immediate labelling and outer packaging. The way the product is intended to be used remains unchanged.

It is anticipated that UK-labelled stock will be available for distribution in the UK circa November 2019.

The SmPC and PIL for the product can be accessed via the following links:

SmPC: <https://www.medicines.org.uk/emc/product/3387/smpc>

PIL: <https://www.medicines.org.uk/emc/product/3387/pil>

If you have any concerns about this product, please contact Martindale Pharma (an entity of Ethypharm) Medical Information at medinfo@ethypharm.com or Tel +44 (0)1277 266 600 for more information.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

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

Alternatively, prepaid Yellow Cards for reporting are available:

by writing to FREEPOST YELLOW CARD (no other address details necessary)

by emailing yellowcard@mhra.gov.uk

at the back of the British National Formulary (BNF)

by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789

by downloading and printing a form from the Yellow Card website (see link above)

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

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