



**MEDICE**  
THE HEALTH FAMILY

**MEDICE UK Ltd**

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17<sup>th</sup> December 2024

**Voluntary Notification Defective Medicine – Medikinet® XL ▼ 10mg capsules and Medikinet® XL ▼ 20mg capsules (methylphenidate hydrochloride)**

Dear Healthcare Professional,

MEDICE UK in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

**Summary**

- A small number of defects in the colouring of Medikinet® XL 10mg and 20mg capsules has been identified
- As a result of strong light exposure, the “mauve” colour of the capsules may appear as a “blue” colour in a limited number of batches (see figure 1)
- The defect in the identified batches does not have any effect to the medicinal product's efficacy and tolerability
- This Voluntary Notification is for information purposes only

**Background information for the safety concern**

Medikinet XL is indicated as part of a comprehensive treatment programme for attention-deficit/hyperactivity disorder (ADHD) in children aged 6 years of age and over and adults when remedial measures alone prove insufficient.

Medikinet XL capsules are supplied in a range of colours denoting the different product strength, from 5mg (white opaque colour) to 60mg (range of grey and mauve shades of colours) as described in the SPC and the Patient Information Leaflet.

The 10mg and 20mg Medikinet XL capsules utilise a light “mauve” colour that is a combination of Patent blue V (E131) and Erythrosine (E127). Erythrosine (E127-rose colour compound) is light sensitive which may cause it to become discoloured. The darker colour of Patent blue V is not impacted by light exposure. Light exposure of these capsules may cause them to appear blue because of Erythrosine (E127) discolouring, rather than a ‘mauve’ colour.

Light exposure has no impact on the active ingredient methylphenidate hydrochloride in Medikinet XL capsules which has been tested by assay parameters such as methylphenidate hydrochloride content, impurities and dispersion.



*Figure 1 – Example of blue coloured capsule (Middle, far right) in blister*

The presence of a 'blue' capsule in a blister pack may be noticed and may cause distress to the patient and/or their family. The medication must not be stopped unless directed by an appropriate clinician.

A limited number of batches have been affected. These were manufactured between April 1 and August 27, 2024. Please see below for details:

Item code	Item description	Batch
00060621	Medikinet XL 10 capsules 30 GB	2409404
00060621	Medikinet XL 10 capsules 30 GB	2409501
00060621	Medikinet XL 10 capsules 30 GB	2410202
00060621	Medikinet XL 10 capsules 30 GB	2410301
00060631	Medikinet XL 20 capsules 30 GB	2405206
00060631	Medikinet XL 20 capsules 30 GB	2405301
00060631	Medikinet XL 20 capsules 30 GB	2405703
00060631	Medikinet XL 20 capsules 30 GB	2405801
00060631	Medikinet XL 20 capsules 30 GB	2406602

Suitable actions have been undertaken to remove the risk of discolouration occurring in the future and Medice does not expect this to be repeated in future batch production. It is possible for capsules to be discoloured when in the presence of strong sunlight, which is why we recommend storing medicines in the original packaging.

### **Actions for the Healthcare Professional**

In the event of being notified of a defective capsule, please be reassured that the defect is cosmetic only and there is no impact to the efficacy of the active ingredient. The patient can continue to take the capsule as expected.

If the patient is not willing to take the colour affected capsule, please advise them that there is the option to open it up and sprinkle the contents onto soft food such as apple sauce, which should then be swallowed immediately, without chewing, to take the Medikinet XL dose. The capsule contents should not be crushed.

If the patient is dissatisfied with this option, and the pack is listed in the batches noted above, Medice UK will replace the pack free of charge if it is returned with all internal components (complete return of all blisters, remaining capsules and external packaging) to Movianto. Please notify the Movianto team of the return and the reason for it using the contact details below, providing photographic evidence of the defect and the total product packaging.

Email: [OrdertoCash.UK@movianto.com](mailto:OrdertoCash.UK@movianto.com)  
Include subject: Medikinet XL Colour

### **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 associated with new drugs and vaccines identified by the black triangle ▼
- 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

You can report via:

- The Yellow Card website
- The free Yellow Card app available from the Apple App Store or Google Play Store
- Some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

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

### Company Contact point

For further information please contact:

enquiries@medice.co.uk

We apologise for any inconvenience this may cause and will do our best to ensure future batches are not affected in a similar way.

Yours faithfully,



James Cox  
Country Manager  
Medice UK

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This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/> .  
Adverse events should also be reported to MEDICE UK on 020 4582 2845,  
pv-uk@medice.co.uk