



## Direct Healthcare Professional Communication (DHPC)

26<sup>th</sup> March 2026

### **Methylphenidate hydrochloride: Supply of Meflynate XL 10 mg, 20 mg, 40 mg & 60 mg modified-release hard capsules with blister strips printed with Spanish labelling**

Dear Healthcare professional,

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

#### **Summary**

- **Specified batches of Meflynate XL modified-release hard capsules are being supplied to the UK market in blister strips printed with Spanish labelling, referring to the product as it is registered in Spain: 'Rubifen Prolong 10 mg, 20 mg, 40 mg & 60 mg cápsulas duras de liberación modificada EFG'.**
- **The medicinal product packed within the Spanish blister strips is identical to the UK registered product 'Meflynate XL' and is provided packed in UK approved cartons and with the approved UK package leaflet.**
- **A letter to patients is provided with each pack for patient reassurance.**
- **Neither product efficacy nor patient safety is impacted.**

#### **Background**

Due to a shortage of Meflynate XL in the UK, Flynn Pharma Limited (MA Holder for these products in the UK), has been granted permission to supply the same product registered in Spain to the UK market.

The Spanish product 'Rubifen Prolong', is identical to the UK registered product 'Meflynate XL' and will be supplied to the UK market after repacking into UK approved cartons with the package leaflet as approved in the UK. As these products are supplied in child-resistant blisters, re-blistering or over-labelling is not possible, and therefore the blister strips packed within are printed with the Spanish labelling.

The only noticeable distinction for UK patients receiving these packs is the Spanish labelling printed on the blister strips, and hence a letter to patients is being provided with each pack to reassure patients that they have received the correct medicine as prescribed, and that the product within is as described on the UK carton and UK package leaflet provided. A copy of the letter to patients is appended to this DHPC letter.

The table below lists the batches Flynn Pharma Limited has received permission to place on the UK market with Spanish blister labelling:

<b>Product Name in the UK</b>	<b>Product Name in Spain (as included on Spanish blister label)</b>	<b>Batch Number embossed on blister strip</b>	<b>Batch Number printed on outer carton</b>	<b>Expiry Date (MM-YYYY)</b>
Meflynate XL 10 mg modified-release hard capsules	Rubifen Prolong 10 mg cápsulas duras de liberación modificada EFG	250196B	250196B - A	01-2028
Meflynate XL 20 mg modified-release hard capsules	Rubifen Prolong 20 mg cápsulas duras de liberación modificada EFG	250199D	250199D - A	01-2028
Meflynate XL 40 mg modified-release hard capsules	Rubifen Prolong 40 mg cápsulas duras de liberación modificada EFG	250426A	250426A - A	05-2028
Meflynate XL 60 mg modified-release hard capsules	Rubifen Prolong 60 mg cápsulas duras de liberación modificada EFG	250363A	250363A - A	04-2028

Images of the Spanish blister labelling packaged within these batches and the UK approved blister labelling are provided below:

	<b>Spanish Blister Label</b>	<b>UK Blister Label</b>
Meflynate XL 10 mg	<b>Rubifen Prolong® 10 mg cápsulas duras de liberación modificada EFG</b> metilfenidato hidrocloreuro Laboratorios Rubió, S.A.	<b>Meflynate XL 10 mg modified-release hard capsules</b> methylphenidate hydrochloride  Flynn Pharma Ltd
Meflynate XL 20 mg	<b>Rubifen Prolong® 20 mg cápsulas duras de liberación modificada EFG</b> metilfenidato hidrocloreuro Laboratorios Rubió, S.A.	<b>Meflynate XL 20 mg modified-release hard capsules</b> methylphenidate hydrochloride  Flynn Pharma Ltd
Meflynate XL 40 mg	<b>Rubifen Prolong® 40 mg cápsulas duras de liberación modificada EFG</b> metilfenidato hidrocloreuro Laboratorios Rubió, S.A.	<b>Meflynate XL 40 mg modified-release hard capsules</b> methylphenidate hydrochloride  Flynn Pharma Ltd
Meflynate XL 60 mg	<b>Rubifen Prolong® 60 mg cápsulas duras de liberación modificada EFG</b> metilfenidato hidrocloreuro Laboratorios Rubió, S.A.	<b>Meflynate XL 60 mg modified-release hard capsules</b> methylphenidate hydrochloride  Flynn Pharma Ltd

## **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 ▼

You can report via:

- the [Yellow Card website](#)
- the free Yellow Card app available from the Apple All 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.

Adverse events should also be reported to the Marketing Authorisation Holder, using the contact details provided below.

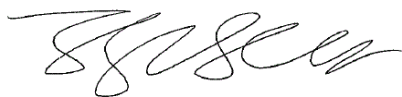
## **Company Contact Point**

Flynn Pharma Medical Information:

Phone: 01438 727822

Email: [medinfo@flynnpharma.com](mailto:medinfo@flynnpharma.com)

Yours faithfully,



Dr. James Leighton-Scott  
Chief Medical Officer  
FLYNN PHARMA LIMITED

## **Annexes**

Please find the following material attached to this letter:

- A copy of the letter to patients provided with each pack for the aforementioned batches Meflynate XL 10 mg, 20 mg and 40 mg modified-release hard capsules
- A copy of the letter to patients provided with each pack for the aforementioned batch of Meflynate XL 60 mg modified-release hard capsules

## MEFLYNATE XL: SUPPLY OF SPANISH BLISTERS TO UK MARKET

Dear Patient,

This pack of 'Meflynate XL modified-release hard capsules' contains blister strips printed with Spanish labelling. Although the text printed on the blister strips refers to the product as it is registered in Spain, we would like to reassure you that the medicine contained within is identical to that of the UK registered product and is as described on the UK carton and UK patient information leaflet this medicine is supplied with.

There is currently a shortage of Meflynate XL in the UK and we are supplying the same medicine from Spain to maintain availability to patients in the UK. The following batches of Meflynate XL are being supplied to the UK with Spanish blister labels:

Product Name in the UK	Product Name in Spain ( <i>as included on Spanish blister label</i> )	Batch Number embossed on blister strip	Batch Number printed on outer carton
Meflynate XL 10 mg modified-release hard capsules	Rubifen Prolong 10 mg cápsulas duras de liberación modificada EFG	250196B	250196B - A
Meflynate XL 20 mg modified-release hard capsules	Rubifen Prolong 20 mg cápsulas duras de liberación modificada EFG	250199D	250199D - A
Meflynate XL 40 mg modified-release hard capsules	Rubifen Prolong 40 mg cápsulas duras de liberación modificada EFG	250426A	250426A - A

Images of the Spanish blister labelling packaged within these batches and the UK approved blister labelling are provided below for your reassurance and reference:

	Spanish Blister Label	UK Blister Label
Meflynate XL 10 mg	<b>Rubifen Prolong® 10 mg cápsulas duras de liberación modificada EFG</b> metilfenidato hidrocloreuro Laboratorios Rubió, S.A.	<b>Meflynate XL 10 mg modified-release hard capsules</b> methylphenidate hydrochloride  Flynn Pharma Ltd
Meflynate XL 20 mg	<b>Rubifen Prolong® 20 mg cápsulas duras de liberación modificada EFG</b> metilfenidato hidrocloreuro Laboratorios Rubió, S.A.	<b>Meflynate XL 20 mg modified-release hard capsules</b> methylphenidate hydrochloride  Flynn Pharma Ltd
Meflynate XL 40 mg	<b>Rubifen Prolong® 40 mg cápsulas duras de liberación modificada EFG</b> metilfenidato hidrocloreuro Laboratorios Rubió, S.A.	<b>Meflynate XL 40 mg modified-release hard capsules</b> methylphenidate hydrochloride  Flynn Pharma Ltd

If you have any questions, please contact Flynn Pharma Medical Information:  
Phone: 01438 727822 Email: [medinfo@flynnpharma.com](mailto:medinfo@flynnpharma.com)

**Reporting of side effects.** If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple Store.

Yours faithfully,

FLYNN PHARMA LIMITED

*This letter has been agreed for dissemination by the Medicines and Healthcare products Regulatory Agency (MHRA).*



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There is currently a shortage of Meflynate XL in the UK and we are supplying the same medicine from Spain to maintain availability to patients in the UK. The following batch of Meflynate XL 60 mg is being supplied to the UK with Spanish blister labels:

<b>Product Name in the UK</b>	<b>Product Name in Spain (as included on Spanish blister label)</b>	<b>Batch Number embossed on blister strip</b>	<b>Batch Number printed on outer carton</b>
Meflynate XL 60 mg modified-release hard capsules	Rubifen Prolong 60 mg cápsulas duras de liberación modificada EFG	250363A	250363A - A

Images of the Spanish blister labelling packaged within these batches and the UK approved blister labelling are provided below for your reassurance and reference:

<b>Spanish Blister Label</b>	<b>UK Blister Label</b>
<b>Rubifen Prolong® 60 mg cápsulas duras de liberación modificada EFG</b> metilfenidato hidrocloreuro Laboratorios Rubió, S.A.	<b>Meflynate XL 60 mg modified-release hard capsules</b> methylphenidate hydrochloride Flynn Pharma Ltd

If you have any questions, please contact Flynn Pharma Medical Information:

Phone: 01438 727822

Email: [medinfo@flynnpharma.com](mailto:medinfo@flynnpharma.com)

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