

Feb 2025

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

MOVICOL range products: update to the product names and/or reconstituted solution shelf-life

Dear Healthcare Professional,

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

Summary

- During 2025, the MOVICOL range of products available in the UK will have updated product names and a uniform reconstituted solution shelf-life.
- The names of the MOVICOL range products are being changed to include the
 effective strength of active ingredients. They were previously named based on
 net sachet weights (i.e. active ingredients plus excipients). The actual amount of
 active ingredients in each product remains the same.
- There is no change in the formulation of the products, in terms of active ingredient composition.
- The reconstituted solution shelf-life of the products is being aligned to 6 hours.
- There are no concerns around the stability of the reconstituted solution however it is important that users are aware of the alignment and should be reminded to use and dispose of the product in accordance with the information presented in the patient information leaflet.

These updates are being performed to align all MOVICOL products across the UK market.

It is important to reassure all users that the strength, safety and efficacy of the MOVICOL range of products is exactly the same and has not changed.



The updated product names / reconstituted solution shelf-life of the MOVICOL range is as follows:

- MOVICOL 13.7g powder for oral solution (Reconstitution shelf-life: 6 hours)
- MOVICOL Chocolate 13.7g powder for oral solution (Reconstitution shelf-life: 6 hours)
- MOVICOL Plain 13.7g powder for oral solution (Reconstitution shelf-life: 6 hours)
- MOVICOL Paediatric Chocolate flavour 6.8g powder for oral solution* (Reconstitution shelf-life: 6 hours)
- MOVICOL Paediatric Plain 6.9g powder for oral solution (Reconstitution shelf-life: 6 hours)
- MOVICOL-Half 6.9g powder for oral solution (Reconstitution shelf-life: 6 hours)
- MOVICOL Liquid Orange flavour, 13.7g/25ml concentrate for oral solution (Reconstitution shelf-life: 6 hours)

MOVICOL Ready to Take, 13.7g/25ml, oral solution in sachet

(Reconstitution shelf-life: N/A)

*The strength of the MOVICOL Paediatric Chocolate flavour product differs by 0.1g because of the difference in the potassium chloride, not due to the difference in Macrogol 3350.

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 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.

Norgine also encourages healthcare professionals to report any suspected adverse reaction at medinfo@norgine.com.

Company contact point

If you have any questions or require additional information, please contact Norgine group of companies using the below listed details:

www.norgine.com

Norgine Pharmaceuticals Limited and/or

Norgine Limited

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Yours faithfully

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