IBSA Farmaceutici Italia Srl

Direct Healthcare Professional Communication

2nd September 2025

Sildenafil 50mg orodispersible film – New dosage form

Dear Pharmacist,

IBSA Farmaceutici Italia S.R.L. and Boots PLC (as OLS) in agreement with the MHRA would like to inform you of the following:

- Sildenafil 50mg orodispersible film uses a dosage form that is new to Pharmacy only market for the active ingredient
- There is no difference in the pharmacology of the orodispersible films compared with the standard film coated tablets
- The Marketing Authorisation (MA) for Sildenafil 50 mg orodispersible film was granted with Viagra Connect 50mg film coated tablets as the analogous product

This information is being communicated as it is a condition of the MA; it is intended to mitigate against any potential confusion and inform about this different formulation

Patients may have questions regarding this new dosage form so the below questions have been prepared to assist pharmacists with their responses and avoid potential confusion:

Q: Is there a difference in the efficacy of the orodispersible film compared to the tablets?
A: No, there is no difference

Q: Is there a difference in how quickly the orodispersible film works compared to the tablets?
A: No, there is no difference

Q: Are there any differences in how you take the orodispersible film compared to the tablets?
A: Both are taken orally. The tablets are taken with water. The orodispersible film can be taken with or without water.

Q: How do the ingredients differ between the two products?
A:

Viagra Connect 50mg film coated tablets	**Sildenafil 50mg Orodispersible Film**
Active: sildenafil citrate	**Active:** sildenafil citrate
Excipients: microcrystalline cellulose, calcium hydrogen phosphate (anhydrous), croscarmellose sodium, magnesium stearate, Hypromellose, titanium dioxide (E171), **lactose**, triacetin, indigo carmine aluminium lake (E132)	**Excipients:** Maltodextrin, Glycerol, Polysorbate 20, Propylene glycol monocaprylate, Polyvinyl acetate dispersion 30%, Lemon and Grapefruit flavours (Lemon essential oil, Citral, Linalool, Grapefruit essential oil, Orange essential oil, Nootkaton, Butylated hydroxyanisol E320, Ascorbic acid E300, Maltodextrin, Arabic gum E414), Sucralose, Titanium dioxide, Indigotine.

Further information can be found in the Summary of Product Characteristics (PL 21039/0071), revised March 2025.

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 or prolong an existing 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.

Company contact point
If you have any questions or require additional information, please contact IBSA (Marketing Authorisation Holder) on 01923 233 466 or email Boots (Own Label Supplier) at drugsafety@boots.co.uk.

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